ベトナム社会主義共和国
麻疹風疹混合ワクチン
製造技術移転プロジェクト
中間レビュー調査報告書

平成27年12月
（2015年）

独立行政法人国際協力機構
人間開発部

人 間
ＪＲ
15-115

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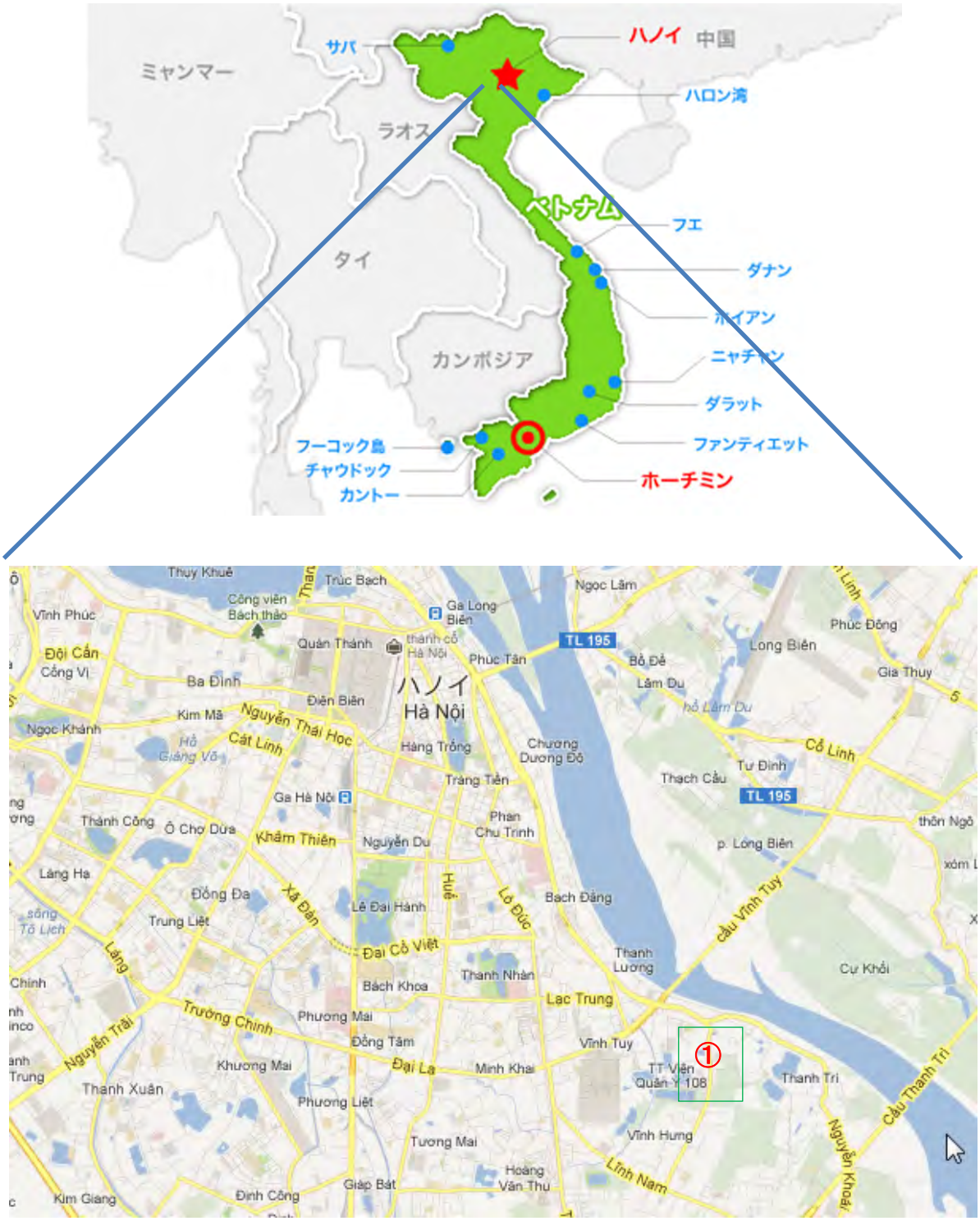

① POLYVAC 麻疹ワクチン製造施設プロジェクトサイト

住所：418 Vinh Hung, Hoang Mai, Hanoi

写　　真

POLYVAC 麻疹ワクチン製造棟見学

安全キャビネット（供与機材）での作業

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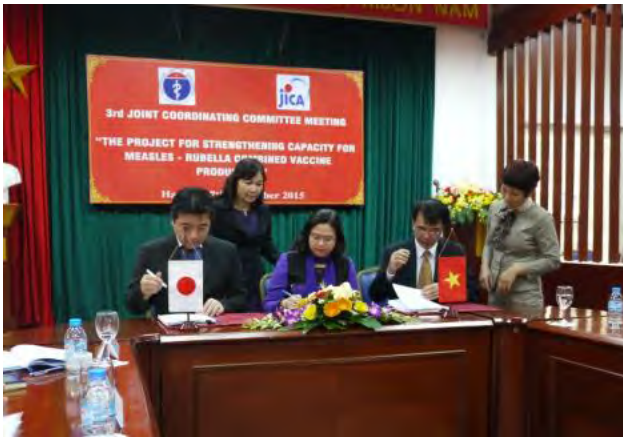


M/M 署名の様子

略　語　表

略　語	正　式　名	日　本　語
CRS	Congenital Rubella Syndrome	先天性風疹症候群
DCVMN	Developing Countries Vaccine Manufacturers Network	途上国ワクチン製造業者ネットワーク
EPI	Expanded Program on Immunization	拡大予防接種計画
GMP	Good Manufacturing Practice	医薬品適正製造基準
KDSV	Kitasato Daiichi Sankyo Vaccine Co., Ltd.	北里第一三共ワクチン株式会社
MFT	Media Fill Test	培地充填試験
M/M	Minutes of Meeting	協議議事録
MOH	Ministry of Health	保健省
MRワクチン	Measles-rubella Combined Vaccine	麻疹風疹混合ワクチン
NICVB	National Institute for Control of Vaccines and Biologicals	ワクチン生物製剤品質管理研究所
NRA	National Regulatory Authority	国家検定機関
OPV	Oral Polio Vaccine	経口ポリオワクチン
PDM	Project Design Matrix	プロジェクト・デザイン・マトリックス
POLYVAC	Center for Research and Production of Vaccines and Biologicals	ワクチン・生物製剤研究・製造センター
PQ	Performance Qualification	稼働時適格性検証
PST	Process Simulation Test	無菌性検証試験
PV	Process Validation	製造工程適格性検証
QA	Quality Assurance	品質保証
QC	Quality Control	品質管理
SOP	Standard Operating Procedure	標準操作手順書
SPF	Specific Pathogen Free	特定の病原体がいないこと
WHO	World Health Organization	世界保健機構

評価調査結果要約表

１．案件の概要	
国名：ベトナム社会主義共和国	案件名：麻疹風疹混合ワクチン製造技術移転プロジェクト
分野：保健・医療	援助形態：技術協力プロジェクト
所轄部署：人間開発部	協力金額：7 億 9,000 万円
協力期間： 2013 年 5 月～2018 年 3 月	先方関係機関：ワクチン・生物製剤研究・製造センター（POLYVAC）
	日本側協力機関：北里第一三共ワクチン株式会社（KDSV）
	他の関連協力：以下の 2 プロジェクト （1）無償資金協力「麻疹ワクチン製造施設建設計画」（2003-2005） （2）技術協力「麻疹ワクチン製造基盤技術移転プロジェクト」（2006-2010）

１－１　協力の背景と概要

ベトナム社会主義共和国（以下、「ベトナム」と記す）政府は、高い予防接種率の維持や、拡大予防接種計画（Expanded Program on Immunization：EPI）で使用されるワクチンの国内生産を進めてきた。2006 年 3 月から 2010 年 3 月までの「麻疹ワクチン製造基盤技術移転プロジェクト」を通じて、ワクチン・生物製剤研究・製造センター（Center for Research and Production of Vaccines and Biologicals：POLYVAC）は麻疹ワクチンの製造を開始できるようになった。

しかし、2010 年と 2011 年に風疹の流行がみられるようになり、先天性風疹症候群（Congenital Rubella Syndrome：CRS）など子どもの健康に対する脅威について、ベトナム国民の理解が深まっていった。これにより、風疹予防接種実施の重要性も高まり、麻疹風疹混合ワクチンの国内製造に必要な技術力を得ることが緊急の課題となった。

１－２　協力内容

（1）上位目標

・ベトナムにおける麻疹と風疹の罹患数が減少する。

（2）プロジェクト目標

・国際基準（WHO-cGMP）に準拠した麻疹風疹混合ワクチン（Measles-rubella Combined Vaccine：MR ワクチン）が、POLYVAC によって製造される。

（3）成果

1. POLYVAC が、MR ワクチン製造業者として適切な技術力を有する。
2. POLYVAC が WHO-cGMP に適合しつつ、MR ワクチンを適切に製造できる。

（4）中間レビュー時点までの投入

日本側

・短期専門家 29 名：プロジェクトマネジメント、品質保証（Quality Assurance：QA）/医薬品適正製造基準（Good Manufacturing Practice：GMP）/バリデーション、原液製造、製剤、品質管理（Quality Control：QC）、施設・機材バリデーション

・常勤プロジェクトスタッフ：秘書 1 名、通訳 4 名
・施設改修：風疹ワクチン原液製造、最新 WHO-cGMP への対応
・本邦研修：参加者 24 名。原液製造、製剤、培地調製、QC、QA、特定の病原体がいない（Specific Pathogen Free：SPF）ウサギ飼育。
・ローカルコスト負担：約 3,303 万円

ベトナム側
・カウンターパートの配置：POLYVAC スタッフ
・ローカルコスト負担：機材、材料の調達、施設・機材の維持管理など
・日本人専門家の執務スペース

２．評価調査団の概要

	担　当	氏　名	所　属
調査者	総括/団長	吉田　友哉	（JICA 人間開発部保健第三チーム　課長）
	協力企画	野村　明香	（JICA 人間開発部保健第三チーム　調査役）
	評価分析	竹　直樹	（株式会社かいはつマネジメント・コンサルティング）
調査期間	2015 年 11 月 16 日～2015 年 11 月 28 日		調査区分：中間レビュー

３．評価結果の概要

３－１　成果達成状況

３－１－１　成果 1

（1）指標 1-1：POLYVAC スタッフの技術レベル

本邦研修で指導を担当した日本人専門家によると、研修参加者のほとんどが最高レベルの「レベル 4」と評価された。また、中間レビュー調査団のインタビューによると、研修参加者全員が本邦研修で得た知識・技術を活用することができていると表明した。約 200 工程とされていた MR ワクチン製造工程は、詳細な検討の結果、325 工程となった。

（2）指標 1-2：機材、原材料、スペアパーツ、消耗品の利用・管理状況

POLYVAC は自らで作成した標準操作手順書（Standard Operating Procedures：SOP）に基づき機材、原材料、スペアパーツ、消耗品を適切に利用・管理していることが、中間レビュー調査団により観察された。

３－１－２　成果 2

（1）指標 2-1：GMP 関連書類の作成

POLYVAC は 19 種の GMP 関連文書と 532 種の SOP を作成した。POLYVAC によると、必要な文書については作成がほぼ終了している。

（2）指標 2-2：GMP 関連書類に沿った製造工程と品質管理の実施

中間レビュー調査団の観察を通じて、ワクチン製造工程と品質管理試験は GMP 関連書類に沿って行われていることを確認した。

（3）指標 2-3：バリデーションの実施

定期的なキャリブレーションとバリデーションが、POLYVAC によって行われていることを観察した。

（4）指標 2-4：稼働時適格性検証（Performance Qualification：PQ）、製造工程適格性検証（Process Validation：PV）の実施状況

風疹ワクチン原液製造に係る PQ と、その後の無菌性検証試験（Process Simulation Test：PST）及び PV については 2015 年 9 月に完了したが、2014 年 11～12 月に実施した PV が不適合となったことで全工程を見直した結果、当初計画から 10 カ月の遅れとなった。

MR ワクチン製剤については、PQ と培地充填試験（Media Fill Test：MFT）はそれぞれ 2015 年 8 月、9 月に完了した。PV については先述のとおり 2016 年 1 月中旬の完了予定である。風疹ワクチン原液製造 PV の遅れもあって、当初計画から 2 カ月の遅れとなった。

３－２　5 項目評価結果

（1）妥当性

本プロジェクトの妥当性は非常に高い。「ベトナム保健開発 5 カ年計画（2011-2015）」においても、EPI や感染症の流行防止などの予防医学の促進を優先項目としている。また、ベトナムは麻疹と風疹の流行にたびたび見舞われている。本プロジェクトは、EPI や 2014 年の麻疹大流行のような感染症流行への備えに関する保健省（Ministry of Health：MOH）の能力強化を、POLYVAC の MR ワクチン製造能力強化を通じて支援してきた。

（2）有効性

本プロジェクトの有効性は非常に高いが、プロジェクト目標達成の見込みは条件付きである。指標の現状を見る限り、成果 1 と 2 はほぼ達成というレベルである。本邦研修参加者のほとんどが最高レベルの「レベル 4」と評価されており、施設・機材は SOP に沿って適切に使用、維持管理されている。風疹ワクチン原液の PV に遅れがみられたが、プロジェクト全体の進捗に重大な影響を与えるものではなかった。プロジェクト目標の達成は、MR ワクチン製造の長期安定性試験と臨床試験の進捗にかかっている。

（3）効率性

本プロジェクトの効率性は非常に高い。本プロジェクトで供与された機材は、すべて SOP に沿って適切に使用、維持管理されている。また、本プロジェクトで本邦研修を受けたあと、離職した POLYVAC スタッフは 1 人もいない。POLYVAC スタッフにしても日本人専門家にしても、多くが前身のプロジェクトを経験していることも、本プロジェクトを通じた MR ワクチン製造技術の習得にプラスに作用している。長い年月を通じて構築された両者の緊密なコミュニケーションが、プロジェクト活動の効率的な進捗と成果達成度の現状に貢献している。

（4）インパクト

本プロジェクトの実施により、正のインパクトが既に現れている。本プロジェクトで習得した知識と技術を基に、POLYVAC のカウンターパートは社内のポリオワクチン（Oral Polio Vaccine：OPV）製造に係る GMP 書類整備、キャリブレーション、バリデーションの指導を行った。ワクチン生物製剤品質管理研究所（National Institute for Quality Control of Vaccine and Biologicals：NICVB）に対しても、キャリブレーション、バリデーションの技術力向上に貢献している。2014 年の麻疹大流行の際には、本プロジェクトはワクチン接種の重要性と日本の技術が入った POLYVAC 製造の麻疹ワクチンの安全性と効能に関する啓発を行った。また、国会議員を含め日本からの多くの来訪者受け入れも、本プロジェクトの評価を高めたと思われる。2015 年 11 月に本プロジェクトの日本人専門家 5 名が、保健省より「国民健康貢献賞（Memorabilia “For People’s Health”）」の表彰を受けたことも、正のインパクトと考えられる。

（5）持続性

POLYVAC が MR ワクチンを製造するための能力は持続し得るが、主に財務面で留意が必要である。

【政策面】保健省によると、EPI は現在策定中の保健開発 5 カ年計画（2016-2020）においても優先活動となっている。保健省は、ベトナム政府の麻疹ワクチンの 2 度目の接種を MR ワクチンに切り替える決定の通知を 2014 年に発した。POLYVAC にとって、このような決定はワクチンの市場を確保するうえで機会ととらえることができる。

【人材・技術面】POLYVAC はこれまでも、本邦研修の参加者を含め、優秀な技術、高い能力をもつスタッフに対し、手当・ボーナスの支給や昇進といった、国営企業として可能な限りの待遇改善策を行ってきた。また、本プロジェクトで習得した知識や技術を向上させるための機会も積極的に提供している。このような取り組みを継続することで、人材・技術面での持続性は確保可能である。

【財務面】POLYVAC の技術力を持続させるためのカギは、今後製造される MR ワクチンの収益性であるが、この点についてはまだ懸念が残る。麻疹ワクチンについては製造コストが販売価格を上回る状況が続いており、同様のことが MR ワクチンについても考えられる。対応としては、製造コストの削減とコストに見合った販売価格の設定の 2 つの側面から考えることができる。今後も引き続き、機材のキャリブレーションを POLYVAC スタッフが行うことや、ワクチン製造工程での凍結乾燥時間の短縮など、POLYVAC と日本人専門家双方でこのようなコスト削減策を検討していくことが必要である。ちなみに、これらの対応や提案は、ベトナム政府が必要な MR ワクチンをすべて POLYVAC から調達するという方針、すなわち MR ワクチンの市場が確保されていることが前提である。ワクチンの販売価格を製造コストに見合ったものに設定することも必要である。

【施設・機材面】施設・機材の操作、キャリブレーション、バリデーション、維持管理については、POLYVAC は既にメカニズムを構築していることから、今後も SOP に沿ってやっていくことが可能と思われる。

３－３　効果発現に貢献した要因

・前身の「麻疹ワクチン製造基盤技術移転プロジェクト」（2006-2010）の経験、知識、技術の効果的活用：POLYVAC、日本人専門家双方
・POLYVAC からの本邦研修参加者に離職がないこと。移転された知識・技術の喪失がないことを意味する。
・MR ワクチン製造技術習得に対する、POLYVAC 及び日本人専門家双方の献身的な努力

３－４　問題点及び問題を惹起した要因

・安価で良質な材料、スペアパーツ、消耗品調達の困難さ

３－５　提言

（1）対プロジェクト

・MR ワクチンの長期安定性試験と臨床試験を、計画どおり完了させること。
・MR ワクチン臨床試験の完了後、速やかに販売承認の申請を保健省に行うこと。
・高度施設・機材（例：凍結乾燥機）の維持管理については、今後も維持管理契約締結などの方策を続けていくこと。
・本プロジェクトで習得した知識・技術の保持・向上を続けること。
・POLYVAC スタッフの定着のための努力を続けること。
・MR ワクチンのコスト削減に向けた取り組みを続けること。

（2）対保健省

・POLYVAC より提出される MR ワクチンの販売承認申請を、「ファストトラック」で承認すること。
・コンベンショナル動物舎の建設と SPF ウサギ飼育の技術移転への投資について、当初の提案どおり実施すること。
・POLYVAC で製造される MR ワクチンのコストをカバーできるよう、適切な販売価格を設定すること。
・本プロジェクト後も POLYVAC で製造された MR ワクチンを用いて、95%以上の接種率を確保すること。
・ベトナム国内で製造されるワクチンを優先的に使用する政策を変更しないこと。

３－６　教訓

前身の「麻疹ワクチン製造基盤技術移転プロジェクト」やその前の無償資金協力「麻疹ワクチン製造施設建設計画」からの交流をベースに、POLYVAC と日本人専門家の間で非常に緊密なコミュニケーションがとられてきた。前身のプロジェクトより課題に組織横断的に対応することを目的として実施しているワーキンググループはその一例で、そのほかにも POLYVAC で実施されている週例会議の議事録共有が定期的に行われ、専門家側も必要に応じてコメントを行っている。これらを通じて、本邦研修の詳細な計画づくり、POLYVAC スタッフの技術レベルの評価など、着実な技術移転を可能にしてきた。専門家とカウンターパート間の緊密かつ建設的なコミュニケーションは、プロジェクトの目標達成のカギである。

第１章　中間レビュー調査

１－１　調査団派遣の経緯と目的

「麻疹ワクチン製造基盤技術移転プロジェクト」（以下、「フェーズ１」と記す）は、ベトナム社会主義共和国（以下、「ベトナム」と記す）のワクチン・生物製剤研究・製造センター（Center for Research and Production of Vaccines and Biologicals：POLYVAC）が、世界保健機構医薬品適正製造基準（World Health Organization-Good Manufacturing Practice：WHO-GMP）基準に準拠するベトナムGMP（VN-GMP）基準に合致した麻疹ワクチンを、ベトナムの麻疹対策に必要な分量を製造できる能力をもてるようにすることを目標として、2006年から2010年まで実施された。

また、フェーズ１に先立って、わが国は無償資金協力「麻疹ワクチン製造施設建設計画」（2003-2006）によりワクチン製造施設の整備を支援した。ワクチンの製造は、ワクチン株のウイルスの微妙な性状の違いにより、製造技術や製造方法（培養方法、温度管理など）が異なるため、それに合わせた施設及び機材を整備することが必須である。同無償資金協力では、学校法人北里研究所生物製剤研究所〔当時、現北里第一三共ワクチン株式会社（Kitasato Daiichi Sankyo Vaccine Co., Ltd：KDSV)〕とPOLYVACとの間で交わされた技術移転契約書に基づき、KDSVが開発したAIK-C株麻疹ワクチン製造に合致した施設及び機材が供与された。

これらの協力の結果、POLYVACはKDSVが独自に開発した麻疹ワクチン株（AIK-C株）を用いて、フェーズ1の実施期間中にVN-GMP基準に沿った麻疹ワクチンを生産する能力を獲得するに至った。同ワクチンは、ベトナム保健省による正式な承認を経て、国内需要を満たす量の製造、販売が実現され、ベトナムの拡大予防接種計画（Expanded Program on Immunization：EPI）事業に大きく貢献している。

その後、ベトナム政府は、昨今の風疹の大流行を踏まえ、WHOが2000年5月に策定した指針に基づき（その後2011年7月に改訂)、麻疹風疹混合ワクチン（Measles-rubella Combined Vaccine：MRワクチン）を近年中に導入するべく本プロジェクト「麻疹風疹混合ワクチン製造技術移転プロジェクトフェーズ2」（フェーズ2）をわが国に要請した。

本プロジェクトは、POLYVACが既に習得している麻疹ワクチン製造技術の基盤の上に、麻疹風疹混合ワクチンの製造技術を身に付けることによって、ベトナム政府がEPIの対象に加えることにしているMRワクチンを自国で製造し、EPIで使用されることをめざすものである。プロジェクトは、2013年5月より2018年3月までの約5年間の予定で実施されており、現在、複数名の短期専門家（チーフアドバイザー、業務調整、GMP査察、バリデーションなど）が派遣されている。

今回実施する中間レビュー調査では、本プロジェクトの目標達成度や成果などを分析するとともに、プロジェクトの残り期間の課題及び今後の方向性について確認し、（合同）評価報告書に取りまとめ、合意することを目的とする。

１－２　調査日程

Date	Day	Time	JICA		コンサルタント
			総括/団長	協力企画	評価分析
			吉田 友哉	野村 明香	竹　直樹
11/16	Mon	AM			成田（10:00）→
		PM			ハノイ（14:15）【VN311】 JICA ベトナム事務所打合せ
11/17	Tue	AM			9:30　専門家打合せ、ヒアリング、現場概況確認
		PM			14:00　POLYVAC 表敬訪問、評価方法の説明、C/P ヒアリング（所長、副所長）
11/18	Wed	AM			C/P ヒアリング（原液） 日本語教室見学
		PM			C/P ヒアリング（製剤）
11/19	Thu	AM			C/P ヒアリング（培地、技術） 書類整備状況、在庫管理状況確認（原液部）
		PM	成田（17:55）→ HCMC（22:35）【ANA831】		POLYVAC 週例会議参加
11/20	Fri	AM	別案件協議		C/P ヒアリング（QA） 書類審査（QA） C/P ヒアリング（QC）
		PM			POLYVAC 各部門現場確認 専門家へ不明点確認 専門家ヒアリング（臨床試験）
11/21	Sat	AM	資料整理		分析、評価 概要報告書作成
		PM	HCMC（12:35）→ ハノイ（14:40）【VN238】		
11/22	Sun	AM	資料整理	羽田（8:55）→ ハノイ（13:10）【ANA857】	概要報告書作成
		PM	コンサルタントとの打合せ		官団員との打合せ
11/23	Mon	AM	11:00 JICA ベトナム事務所打合せ		
		PM	14:00 POLYVAC 表敬訪問、協議、書類審査、現場確認など		
11/24	Tue	AM	9:30 POLYVAC との協議		
		PM	13:30 POLYVAC との協議		
11/25	Wed	AM	9:00 保健省表敬訪問（国際協力局、医薬品管理局、予防医療局合同）		
		PM	14:30 POLYVAC との協議		
11/26	Thu	AM	ミニッツ案修正のため待機、JCC 準備		
		PM	12:00 JICA ベトナム事務所打合せ		
11/27	Fri	AM	8:30 専門家 5 名表彰式、9:30 第 3 回 JCC、中間レビュー調査ミニッツ署名		
		PM	18:30 ベトナム政府関係者とのレセプションパーティー（ハノイ日航ホテル）		
11/28	Sat	AM			
		PM	ハノイ（14:25）→ 羽田（21:00）【ANA858】		ハノイ（1:25）→ 福岡（7:10）【VN356】

１－３　調査団の構成

担　当	氏　名	所　属	期　間
総括/団長	吉田　友哉	JICA人間開発部保健第三チーム　課長	11/22-11/28
協力企画	野村　明香	JICA人間開発部保健第三チーム　調査役	11/22-11/28
評価分析	竹　直樹	かいはつマネジメント・コンサルティング	11/16-11/28

１－４　主要面談者

（1）ワクチン・生物製剤研究・製造センター（POLYVAC）

Assoc. Prof. Dr. Nguyen Dang Hien	所長
Dr. Nguyen Thuy Huong	副所長
Mr. Nguyen Xuan Hoa	原液製造部　部長
Mr. Le Quoc Hung	製剤部　部長
Mr. Le Tuan Anh	培地調製部　部長
Mr. Nguyen Dang Anh	技術部　部長
Ms. Tran Thi Phuong	品質保証部　部長
Dr. Ngo Thu Huong	品質管理部　部長
Mr. Pham Thanh Truong	原液製造部　副部長
Mr. Nguyen Dang Quynh	製剤部　副部長

（2）保健省

Dr. Tran Thi Giang Huong	国際局　局長
Mr. Do Van Dong	医薬品管理局　副局長

（3）日本人専門家チーム

荒井　節夫	総括
李　富雄	副総括/ワクチン製造管理
馬場　建一	ワクチン品質管理
土田　安宏	組織管理（1）
田村　美貴	組織管理（2）/本邦研修事務管理
中山　哲夫	品質保証（臨床試験）
勝田　広樹	原液製造
小室　邦彦	最終製造（2）
池田　学	品質管理（病理）
武田　佳久	品質管理（生物）
小杉　俊雄	品質管理（動物）
石川　修三	エンジニアリング/業務調整

（4）JICAベトナム事務所

定本　ゆとり	所員
Ms. Dao Thi Khanh	プログラムオフィサー

第２章　プロジェクト評価の方法

２－１　プロジェクトの進捗確認

まず、プロジェクトの投入と進捗を確認した。

（1）投入の確認

プロジェクト・デザイン・マトリックス（Project Design Matrix：PDM）には、本プロジェクトを実施するのに必要な投入が、日本・ベトナム国側双方に分けて特定されている。この投入が計画どおりになされたかどうかを確認した。

（2）プロジェクトの進捗確認

日本・ベトナム国側双方の関係者から収集した情報を基に、本プロジェクトの成果を達成するための、諸活動の進捗を確認した。同様に、上位目標、プロジェクト目標、成果の達成度を評価した。

２－２　5 項目評価

次に、「妥当性」、「有効性」、「効率性」、「インパクト」、「持続性」の 5 項目から、プロジェクトを評価した。

（1）妥当性

プロジェクトの妥当性とは、プロジェクト目標がベトナム保健分野のニーズや優先課題からみて適切であること、開発課題や日本の協力プログラムに整合していることである。

妥当性の評価には、「非常に高い（highly relevant）」、「高い（relevant）」、「中程度（moderately relevant）」、「やや低い（relevant to some extent）」、「低い（not so relevant）」のスケールを用いた。

（2）有効性

プロジェクトの有効性とは、活動の進捗からみた成果とプロジェクト目標が達成される見通しのことである。

有効性の評価には、「非常に高い（highly effective）」、「高い（effective）」、「中程度（moderately effective）」、「やや低い（effective to some extent）」、「低い（not so effective）」のスケールを用いた。

（3）効率性

プロジェクトの効率性とは、投入が活動を通じてどの程度効率的に成果につながっているかである。投入量、投入の質とタイミングも評価される。

効率性の評価には、「非常に高い（highly efficient）」、「高い（efficient）」、「中程度（moderately efficient）」、「やや低い（efficient to some extent）」、「低い（not so efficient）」のスケールを用いた。

（4）インパクト

プロジェクトのインパクトとは、プロジェクト活動の進捗や外部環境からみて上位目標が達成できる見通しかどうかである。また、プロジェクト実施していることで予期しない正負のインパクトがあるかどうかも考察する。

インパクトの評価には、「正のインパクトが負のインパクトを上回っている（more positive impact expected）」、「正負同レベルのインパクトがみられる（both positive and negative impact expected equally）」、「インパクトなし（no impact expected）」、「負のインパクトが正のインパクトを上回っている（more negative impact expected）」のスケールを用いた。

（5）持続性

持続性とは、プロジェクトを通じて得られたものが終了後も持続する可能性のことである。これは、政策、人材、財務、設備・機材の側面から評価される。

持続性の評価には、「問題なく持続可能（expected without reservation）」、「持続可能、ただし条件付き（expected with some reservation）」、「持続性に難あり（not expected）」のスケールを用いた。

２－３　データの収集

この中間レビュー調査に必要な文書と情報・データは、関連ウェブサイトや本プロジェクト専門家から収集された。また、現地調査では、保健省やカウンターパートに対するインタビューを行い、プロジェクトの投入、活動の進捗、インパクト、持続性に関する意見を聴取した。

第３章　中間レビューの結果

３－１　投入実績

（1）日本側

1）専門家の派遣

本プロジェクトが開始された 2013 年 5 月から 2015 年 9 月末までに、計 29 名の短期専門家が、プロジェクトマネジメント、品質保証（Quality Assurance：QA）/医薬品適正製造基準（Good Manufacturing Practice：GMP）/バリデーション、原液製造、製剤、品質管理、施設・機材バリデーションの 6 分野に配置されてきた。

作業人日と現地渡航回数から判断すると、日本人専門家の配置はほぼ計画どおりである（表－１）。

表－１　専門家の配置（2013 年 5 月～2015 年 9 月）

年度	分野	現地従事人日			国内作業人日			現地渡航回数		
		計画	実績	達成率(%)	計画	実績	達成率(%)	計画	実績	達成率(%)
2013	プロジェクトマネジメント	414	403	97.3	174	176	101.1	23	24	104.3
	QA/GMP/バリデーション	163	163	100.0	158	158	100.0	13	13	100.0
	原液製造	35	39	111.4	9	6	66.7	3	2	66.7
	製剤	14	14	100.0	3	3	100.0	1	1	100.0
	品質管理	119	128	107.6	33	33	100.0	11	11	100.0
	施設・機材バリデーション	133	133	100.0	23	21	91.3	11	10	90.9
	合計	**878**	**880**	**100.2**	**400**	**397**	**99.3**	**62**	**61**	**98.4**
2014	プロジェクトマネジメント	362	315	87.0	118	118	100.0	21	21	100.0
	QA/GMP/バリデーション	114	99	86.8	82	79	96.3	10	9	90.0
	原液製造	56	72	128.6	12	15	125.0	4	5	125.0
	製剤	35	35	100.0	9	9	100.0	3	3	100.0
	品質管理	154	130	84.4	51	39	76.5	17	13	76.5
	施設・機材バリデーション	91	75	82.4	21	17	81.0	10	8	80.0
	合計	**812**	**726**	**89.4**	**293**	**277**	**94.5**	**65**	**59**	**90.8**
2015 (-9 月)	プロジェクトマネジメント	320	183	57.2	107	62	57.9	18	9	50.0
	QA/GMP/バリデーション	100	39	39.0	40	21	52.5	10	3	30.0
	原液製造	14	0	0.0	2	0	0.0	1	0	0.0
	製剤	42	7	16.7	8	2	25.0	4	1	25.0
	品質管理	84	70	83.3	18	13	72.2	9	6	66.7
	施設・機材バリデーション	21	64	304.8	3	11	366.7	1	5	500.0
	合計	**581**	**363**	**62.5**	**178**	**109**	**61.2**	**43**	**24**	**55.8**

2）常勤プロジェクトスタッフ

通訳 4 名と秘書 1 名が日本側により雇用されている。

3）施設改修

本プロジェクトは 2013 年と 2014 年に行われた、風疹ワクチン原液製造と WHO-cGMP と呼ばれる WHO の最新 GMP に適合させるための POLYVAC の施設改修を支援した。

4）本邦研修

2015 年 8 月末までに計 24 名の POLYVAC スタッフが、原液製造、製剤、品質保証、品質管理、SPF ウサギ飼育の技術移転に係る本邦研修に参加した（表－２）。また、2015 年 10～11 月には、製剤、培地調製、特定の病原体がいない（Specific Pathogen Free：SPF）ウ

サギ飼育、施設・機材バリデーションの分野に計 4 名のスタッフが本邦研修に参加している。

研修員数と研修日数から判断すると、本邦研修はほぼ計画どおりである。また、本プロジェクトにおいて、本邦研修後に離職したスタッフはいない。

表－２　本邦研修（2013 年 5 月～2015 年 8 月）

年度	分野	研修員数			研修日数		
		計画	実績	達成率（%）	計画	実績	達成率（%）
2013	原液製造	2	2	100.0	120	120	100.0
	製剤	2	2	100.0	60	56	93.3
	培地調製	1	1	100.0	30	28	93.3
	品質管理	6	6	100.0	360	340	94.4
	品質保証	2	2	100.0	60	56	93.3
	SPF ウサギ飼育	2	2	100.0	60	54	90.0
	合計	**15**	**15**	**100.0**	**690**	**654**	**94.8**
2014	原液製造	1	2	200.0	60	56	93.3
	製剤	1	1	100.0	30	27	90.0
	培地調製	1	1	100.0	30	27	90.0
	品質管理	3	3	100.0	150	139	92.7
	品質保証	2	2	100.0	60	52	86.7
	SPF ウサギ飼育	1	1	100.0	30	27	90.0
	合計	**9**	**10**	**111.1**	**360**	**328**	**91.1**
2015 (-8 月)	原液製造	1	1	100.0	30	28	93.3
	製剤	1	0	0.0	30	0	0.0
	品質管理	2	1	50.0	60	28	46.7
	品質保証	2	2	100.0	30	56	186.7
	SPF ウサギ飼育	1	0	0.0	30	0	0.0
	施設・機材バリデーション	2	0	0.0	30	0	0.0
	合計	**9**	**4**	**44.4**	**210**	**112**	**53.3**

5）機材・材料供与

本プロジェクトの開始以来、総額 5,932 万円の機材と材料が供与された。ここまで、すべての機材が問題なく稼働している。

6）ローカルコスト負担

本プロジェクトにおいて、2015 年 9 月末までに支出されたローカルコストは 3,303 万円で、ほぼ計画どおりである（表－３）。

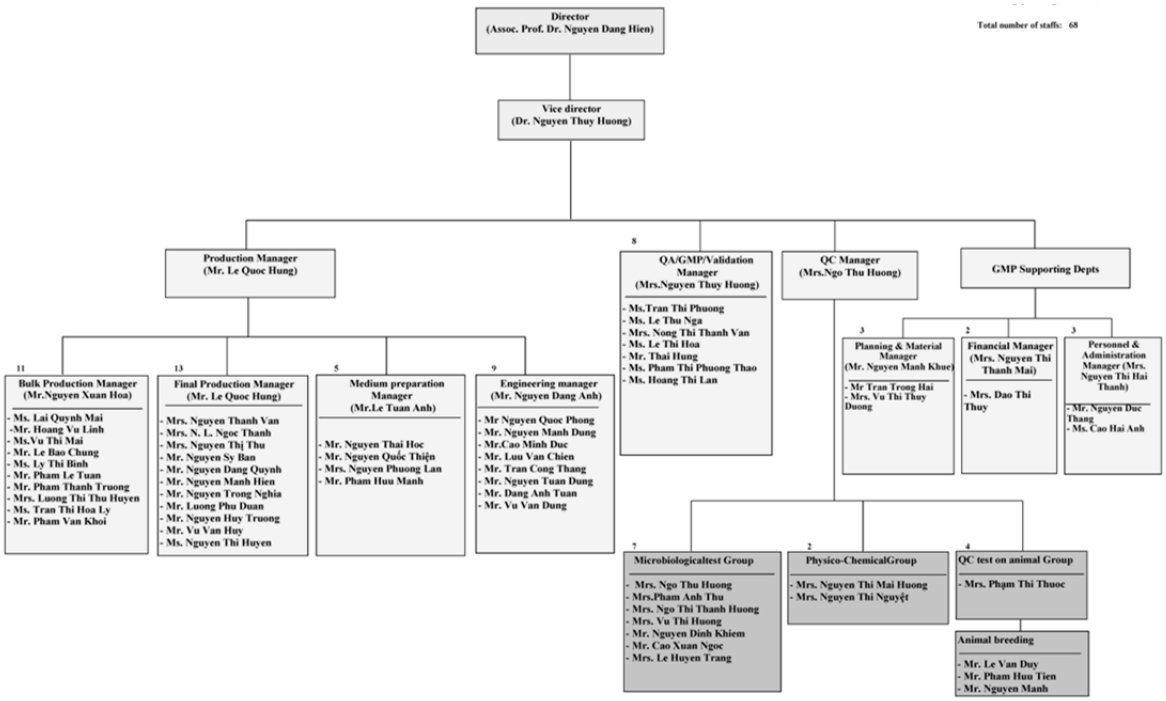
表－３　日本側ローカルコスト負担実績（単位：1,000 円）

年度	計画	実績	達成率 (%)
2013	17,920	17,490	97.6
2014/15	22,780	15,540	68.2
合計	**40,700**	**33,030**	81.2

(2) ベトナム側

1) カウンターパートの配置

当初の計画どおり、POLYVAC 所長、副所長と、品質保証、品質管理、原液製造、製剤、培地精製、施設・機材バリデーションの各部長とスタッフが、本プロジェクトのカウンターパートとして配置されている。MR ワクチン製造に係る POLYVAC の体制は図－１のとおりである。



図－１　MR ワクチン製造に係る POLYVAC 体制図

2) 機材・材料

2014 年と 2015 年にベトナム側が支出した機材・材料調達額は 89 億 386 万 2,000 ドン（4,808 万 1,000 円）である（表－４）。

表－４　ベトナム側機材・材料調達額

年	ドン	円換算額
2014	4,868,308,000	26,289,000
2015	4,035,554,000	21,792,000
合計	**8,903,862,000**	**48,081,000**

3) ローカルコスト負担

2015 年 8 月末までに、ベトナム側より 279 億 200 万ドン（1 億 4,399 万円）がローカルコストとして支出された（表－５）。これは、前項で述べた機材・材料調達にかかる金額を含む。保健省からの金額は、本プロジェクト開始時に提出されたプロジェクトドキュメントに基づいて計上されたカウンターファンドである。

表－５　ベトナム側ローカルコスト負担実績

年	金額（1,000 ドン）			円換算額（1,000 円）
	保健省	POLYVAC	合計	
2013	0	5,000,000	5,000,000	23,550
2014	6,200,000	9,500,000	15,700,000	80,541
2015 (-8 月)	2,202,000	5,000,000	7,202,000	39,899
合計	8,402,000	19,500,000	27,902,000	143,990

4）その他の投入

POLYVAC 事務棟内に、日本人専門家の事務所が確保されている。

３－２　成果１

本プロジェクトの成果 1 は、「POLYVAC が MR ワクチン製造業者として適切な技術力を有する」ことである。ワクチン製造のコスト削減に関する活動も、成果 1 のなかに位置づけられている。

（1）活動の進捗

成果 1 を達成するために、本プロジェクトでは本邦研修や専門家によるベトナムでの技術指導を通じて、風疹ワクチン原液製造（活動 1-1）、MR ワクチン製剤（活動 1-2）、品質管理（活動 1-3）に関する技術移転を行ってきた。これらの活動はほぼ計画どおりに進捗している。このうち風疹ワクチン原液製造については、製造工程適格性検証（Process Validation：PV）[1]を終えたことで完了した。MR ワクチン製剤については中間レビュー調査時点で PV の実施中であり、2016 年 1 月中旬に完了予定である。

MR ワクチンの製造コスト削減に関する情報収集と分析（活動 1-4）については、ベトナム国内で調達可能な原材料の検討や、MR ワクチン製剤の過程で行われる凍結乾燥プロセスの時間短縮といった取り組みが続けられている。

（2）指標の動向

成果 1 の達成度を測る指標は、（1）POLYVAC 職員が、MR ワクチン製造及び品質管理の各工程について十分な技術レベルを身に付ける（全体で約 200 工程）、（2）MR ワクチン製造のための機材類、原材料、スペアパーツ、消耗品が適切に利用・管理される、の 2 つである。

1）POLYVAC スタッフの技術レベル（指標 1-1）

本邦研修に参加した POLYVAC スタッフは、技術指導を担当した専門家によって 4 段階の評価を受ける[2]。本プロジェクトの資料によると、参加者のほとんどが最高レベルの「レ

[1] PV は、ワクチン製造工程・方法が初期の目的どおりに機能していることをシステマチックに検証する「バリデーション」の最終段階である。本プロジェクトにおいて、風疹ワクチン原液製造、MR ワクチン製剤とも、PV は 3 度実施される。

[2] 以下の 4 段階である。
レベル 1：基本的な教育を受け、実務知識を習得した。
レベル 2：人の指導があれば作業ができる、また若干の知識がある。
レベル 3：作業は 1 人でできる、また一応の知識はあるが他のスタッフを指導できるほどではない。
レベル 4：作業を主体的にできると同時に、他のスタッフを指導できる。

ベル 4」と評価された。また、中間レビュー調査団のインタビューによると、研修参加者全員が本邦研修で得た知識・技術を活用することができていると表明した。

ちなみに、指標 1 で約 200 工程とされていた MR ワクチン製造工程は、詳細な検討の結果、325 工程となった。

2）機材、原材料、スペアパーツ、消耗品の利用・管理状況（指標 1-2）

POLYVAC は自らで作成した標準操作手順書（Standard Operating Procedures：SOP）に基づき機材、原材料、スペアパーツ、消耗品を適切に利用・管理していることが、中間レビュー調査団により観察された。ベトナム国内におけるスペアパーツや消耗品の入手可能性についても、この数年で改善が進んでいる。

今後も、POLYVAC は製剤用機材などの維持管理や、スペアパーツ及び消耗品の調達について改良を続けていくことが望まれる。

３－３　成果 2

本プロジェクトの成果 2 は、「POLYVAC が WHO-cGMP に適合しつつ MR ワクチンを適切に製造できる」ことである。GMP に沿った各種文書を作成する、それらの文書に沿って作業を行い、その結果を記録するといったことが求められる。成果 2 は、成果 1 を通じて向上した POLYVAC の技術力を活用できるような環境づくりと位置づけられる。

（1）活動の進捗

1）バリデーションと WHO-cGMP に沿った品質保証の体制構築（活動 2-1、2-2）

POLYVAC 技術部は専門家の技術指導を通じて、施設・機材のキャリブレーション[3]とバリデーションを行うことができている。また、POLYVAC 品質保証部は、WHO-cGMP に沿ってキャリブレーションとバリデーションの文書と記録を管理できている。

2）GMP 関連文書と SOP の作成とその活用（活動 2-3、2-4）

POLYVAC では、19 種の GMP 関連文書と 532 種の SOP を作成した。これらはすべて、POLYVAC 品質保証部の承認を得ている。

3）稼働時適格性検証（Performance Qualification：PQ）[4]と PV の実施（活動 2-5）

風疹ワクチン原液製造の PQ と PV については、当初計画からの遅れはあったものの完了した。MR ワクチン製剤の PV は 3 度にわたり実施される。第 1 回 PV（PV-1）は、品質管理試験を含めて 2015 年 12 月に完了予定である。その後の第 2 回（PV-2）、第 3 回 PV（PV-3）については、2016 年 1 月中旬の完了をめざす。

4）MR ワクチンの臨床試験（活動 2-6）

本プロジェクトの前身「麻疹ワクチン製造基盤技術移転プロジェクト」（2006-2010）と

[3] 機材や装置に付属する計測機器の精度を判定すること。
[4] バリデーションの各段階のうち、PV の前に実施されるもの。

同様、POLYVAC は日本人専門家の指導の下、MR ワクチンの臨床試験に係るプロトコルの作成を進めている。この臨床試験のプロポーザルは 2014 年 12 月に提出されており、保健省で予備的な審査が進められている。

その後、必要な書類の提出をすべて行い、2016 年 3 月の臨床試験開始を POLYVAC はめざしている。指導を行っている日本人専門家によると、臨床試験の準備については前身のプロジェクトと比較するとスムーズに進んでいる。

（2）指標の動向

成果 2 の達成度を測る指標は、（1）WHO-cGMP に適合する GMP 関連書類が作成される、（2）作成された GMP 関連書類に従って製造工程が行われ、品質管理が行われる、（3）WHO-cGMP に適合したバリデーションが POLYVAC によって定期的に実施される、（4）PQ 及び PV が計画どおり実施される、の 4 つである。

1）GMP 関連書類の作成（指標 2-1）

先述のとおり、POLYVAC は 19 種の GMP 関連文書と 532 種の SOP を作成した。POLYVAC によると、必要な文書については作成がほぼ終了している。

2）GMP 関連書類に沿った製造工程と品質管理の実施（指標 2-2）

中間レビュー調査団の観察を通じて、ワクチン製造工程と品質管理試験は GMP 関連書類に沿って行われていることを確認した。

3）バリデーションの実施（指標 2-3）

定期的なキャリブレーションとバリデーションが、POLYVAC によって行われていることを観察した。

4）PQ、PV の実施状況（指標 2-4）

風疹ワクチン原液製造に係る PQ と、その後の無菌性検証試験（Process Simulation Test：PST）[5]及び PV については 2015 年 9 月に完了したが、2014 年 11～12 月に実施した PV が不適合となったことで全工程を見直した結果、当初計画から 10 カ月の遅れとなった。

MR ワクチン製剤については、PQ と培地充填試験（Media Fill Test：MFT）[6]はそれぞれ 2015 年 8 月、9 月に完了した。PV については先述のとおり 2016 年 1 月中旬の完了予定である。風疹ワクチン原液製造 PV の遅れもあって、当初計画から 2 カ月の遅れとなった。

ただし、活動の進捗を見る限り、これらの遅れはプロジェクト目標の達成に大きな影響を与えていない。

３－４　プロジェクト目標の達成状況

本プロジェクトの目標は、「WHO-cGMP に準拠した MR ワクチンが POLYVAC によって製造さ

[5] 無菌操作法で製造される医薬品の無菌性保証の適格性を、無菌培地などを用いて検証する PV の方法の 1 つ。
[6] 基本的に PST と同義で、製剤の PV について MFT と呼ばれる。

れる」ことで、具体的にはプロジェクト終了までに、ベトナム国家検定機関（National Regulatory Authority：NRA）[7]が発行する MR ワクチンの販売承認を得ることを指標としている。

本プロジェクトの全体スケジュールによると、POLYVAC による MR ワクチンの販売承認申請は、ワクチンの臨床試験後に行われることになっている。したがって、プロジェクト目標の達成見通しは、この臨床試験の進捗いかんということになる。

成果 1 と 2 の現状を考えると、本プロジェクトは MR ワクチンの販売承認に向けて着実に進んでいるといえる。

３－５　上位目標の達成状況

本プロジェクトの上位目標は、POLYVAC が製造する MR ワクチンが国内で使用されることを通じて、ベトナムにおける麻疹と風疹の罹患数が減少すること、ワクチンを接種した子どもの割合が 95%以上となることである。したがってこれらは、POLYVAC が NRA から MR ワクチンの販売認証を受けたあとに測ってこそ、意味をもつ。

参考までに、過去 5 年間の麻疹・風疹患者数と麻疹ワクチン接種率は、表－６のとおりである。

表－６　麻疹・風疹患者数と麻疹ワクチン接種率（2010～2014 年）

項目＼年	2010	2011	2012	2013	2014
麻疹患者数	2,809	750	578	1,123	15,033
風疹患者数	2,300	7,259	185	54	59
麻疹ワクチン接種率（1 回目、%）	98	96	96	98	97
麻疹ワクチン接種率（2 回目、%）	98	93	83	86	94

出所：WHO vaccine-preventable diseases: monitoring system[8]

３－６　プロジェクトの実施プロセス

ここでは、本プロジェクトを効果的・効率的に実施するうえでの工夫や、プロジェクトを取り巻く重要な出来事について述べる。

（1）2014 年の麻疹大流行への迅速な対応

2014 年初頭の麻疹大流行に際し、POLYVAC は保健省の要請に応じて 560 万ドーズの麻疹ワクチンを製造・供給した。このことにより流行は早期に沈静化し、POLYVAC 製造のワクチン品質と、前身の「麻疹ワクチン製造基盤技術移転プロジェクト」（2006-2010）を通じて強化された POLYVAC の技術力を示すこととなった。

[7] NRA は、WHO が検査機関に求める 6 つの機能を複数の組織で分担している。NRA を構成する組織と担当する機能は、保健省医薬品管理局（担当：製造・販売許認可と GMP 審査）、ワクチン生物製剤品質管理研究所（National Institute for Control of Vaccines and Biologicals：NICVB、担当はレファレンスラボへのアクセスとロットリリース）、科学研修局（臨床試験）、予防医療局（ポスト・マーケティングと呼ばれる発売後の副作用サーベイランス）である。

[8] http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria%5Bcountry%5D%5B%5D=VNM&commit=OK

（2）WHO、NRA を公式認証

2015 年 6 月、WHO はベトナムの NRA に対し、国内で製造・利用されるワクチンの安全性と効能を保証することができる検定機関であるとして認証した[9]。本プロジェクトの詳細計画策定調査報告書によると、NRA は 2009 年の時点で 6 つの機能のうち、製造・販売許認可、ロットリリース、レファレンスラボへのアクセスの 3 つについて合格していなかった[10]。しかし、2015 年 4 月に実施された外部評価の結果、NRA は WHO の評価基準すべてをクリアし、国際標準に達する検定機関であるとされた。

POLYVAC は、NRA のなかでロットリリースとレファレンスラボへのアクセスを担当する NICVB に対し、キャリブレーションやバリデーションの面で能力向上を支援した。

（3）POLYVAC で「5S+1M」実施

POLYVAC では、職場環境の改善を通じて、製造されるワクチンの品質改善を図る 5S 活動（整理、整頓、清掃、清潔、しつけ）を、前身のプロジェクトから実施している。より正確には、5S に維持管理（Maintenance）の M を加えた「5S+1M」である。POLYVAC のスタッフはすべてこの 5S+1M、GMP の 3 原則[11]、報告・連絡・相談（ほう・れん・そう）を記したカードを常に携行している。（図－２）

図－２　「5S＋1M、GMP3 原則、ほう・れん・そう」カード

（4）POLYVAC のワーキンググループと朝礼

POLYVAC では前身のプロジェクトより、(1) キャリブレーションとバリデーション、(2)

[9] 詳細は、以下を参照。http://www.wpro.who.int/vietnam/mediacentre/releases/2015/nra_vietnam_certification/en/

[10] JICA（2013）『ベトナム国　麻疹ワクチン製造基盤技術移転プロジェクトフェーズ 2　詳細計画策定調査報告書』、7～9 ページ

[11] 人為的な誤りを最小限とすること、製品の汚染・品質変化を防ぐこと、高い品質を保つ仕組みをつくること、の 3 原則。

ホルマリン燻蒸、(3) 環境汚染管理（防虫・防鼠)、(4) 環境モニタリング、(5) 調達、(6) リスクマネジメント、(7) 文書管理、(8) 臨床試験、の 8 つの課題に組織横断的に対応することを目的として、ワーキンググループを組織している。

このワーキンググループが、前身のプロジェクトと本プロジェクトの合間、すなわち「プロジェクトの空白期間」(2010 年 4 月～2013 年 4 月）においても開催されていたことは特筆に値する。POLYVAC スタッフはすべて、このワーキンググループが組織横断的なアプローチで問題解決を図る点で、有益であると考えている。

第４章　５項目評価結果

４－１　妥当性

ベトナムの政策の方向性、ベトナム保健分野におけるニーズ、日本の対ベトナム協力の方向性からみて、本プロジェクトの妥当性は非常に高い。

（1）ベトナムの政策との整合性

「ベトナム社会経済 5 カ年計画（2011-2015）」の目標の 1 つは、たとえば、感染症のリスクを軽減するため予防医療に関心を払うこと[12]など、健康状態を含めた国民生活の質改善を継続することである。

また、「ベトナム保健開発 5 カ年計画（2011-2015）」においても、EPI や感染症の流行防止などの予防医学の促進を優先項目としている[13]。

このように、本プロジェクトを取り巻く政策的な環境は、プロジェクト策定時と変わっていない。本プロジェクトは、EPI や 2014 年の麻疹大流行のような感染症流行への備えに関する保健省の能力強化を、POLYVAC の MR ワクチン製造能力強化を通じて支援してきた。

（2）ベトナム保健分野のニーズへの対応

12 ページの表－６からも分かるとおり、ベトナムは麻疹と風疹の流行にたびたび見舞われている。また、先天性風疹症候群（Congenital Rubella Syndrome：CRS）のリスクに関するベトナム国民の認識も深まっている。

このような状況及び WHO の勧告を受けて、ベトナム政府は 2014 年に麻疹ワクチンの 2 度目の接種を MR ワクチンに切り替えることを決定した。POLYVAC は 2006 年から 2010 年まで、前身の「麻疹ワクチン製造基盤技術移転プロジェクト」を通じて、麻疹ワクチンの製造をできるようになったことから、ベトナム政府は MR ワクチン製造の技術移転のための支援を日本政府に要請した。POLYVAC は自らの麻疹ワクチンの製造能力を基盤として、MR ワクチン製造能力の強化を効率的に行うことが期待されてきた。

麻疹・風疹への対応というベトナム保健分野のニーズは、本プロジェクト策定時と何ら変わるところはない。本プロジェクトは、このニーズに対応してきた。

（3）日本の対ベトナム協力の方向性との整合性

日本政府の「対ベトナム社会主義共和国　国別援助方針（2012 年 12 月）」においても、感染症対策を含めた保健分野への支援は「脆弱性への対応」という重点分野に位置づけられている[14]。本プロジェクトは「対ベトナム社会主義共和国　事業展開計画（2014 年 12 月）」のなかで、「保健医療プログラム」を構成する。

したがって、本プロジェクトは日本の対ベトナム協力の方向性と整合している。

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[12] http://www.chinhphu.vn/portal/page/portal/English/strategies/strategiesdetails?categoryId=30&articleId=10052505

[13] Ministry of Health (2010) *Five-Year Health Sector Development Plan 2011-2015*, pp37-38

[14] 外務省（2012 年）『対ベトナム社会主義共和国　国別援助方針』、2 ページ

４－２　有効性

本プロジェクトの有効性は非常に高いが、プロジェクト目標達成の見込みは条件付きである。

指標の現状を見る限り、成果 1 と 2 はほぼ達成というレベルである。本邦研修参加者のほとんどが最高レベルの「レベル 4」と評価されており、施設・機材は SOP に沿って適切に使用、維持管理されている。風疹ワクチン原液の PV に遅れがみられたが、プロジェクト全体の進捗に重大な影響を与えるものではなかった。

プロジェクト目標の達成は、MR ワクチン製造の長期安定性試験と臨床試験の進捗にかかっている。

４－３　効率性

本プロジェクトの効率性は、非常に高い。

本プロジェクトで供与された機材は、すべて SOP に沿って適切に使用、維持管理されている。また、本プロジェクトで本邦研修を受けたあと、離職した POLYVAC スタッフは 1 人もいない。これらのことが、本プロジェクトの効率的な実施を可能としている。

また、POLYVAC スタッフにしても日本人専門家にしても、多くが前身のプロジェクトを経験していることも、本プロジェクトを通じた MR ワクチン製造技術の習得にプラスに作用している。長い年月を通じて構築された両者の緊密なコミュニケーションが、プロジェクト活動の効率的な進捗と成果達成度の現状に貢献している。

４－４　インパクト

上位目標の達成見込みについてあれこれと言及するのは時期尚早であるが、本プロジェクトの実施により、正のインパクトが既に現れている。

本プロジェクトで習得した知識と技術を基に、POLYVAC のカウンターパートは社内のポリオワクチン（Oral Polio Vaccine: OPV）製造に係る GMP 書類整備、キャリブレーション、バリデーションの指導を行った。GMP、キャリブレーション、バリデーションに関しては、POLYVAC は今や他機関にとってのショーケースとなっている。

本プロジェクトによる広報活動がインパクトをもたらした例もみられる。2014 年の麻疹大流行の際には、ワクチン接種の重要性と日本の技術が入った POLYVAC 製造の麻疹ワクチンの安全性と効能に関する啓発を行った。また、国会議員を含め日本からの多くの来訪者受け入れも、本プロジェクトの評価を高めたと思われる。

2015 年 11 月、本プロジェクトの日本人専門家 5 名が、保健省より「国民健康貢献賞（Memorabilia “For People’s Health”）」の表彰を受けた。これも、正のインパクトと考えられる。

４－５　持続性

POLYVAC が MR ワクチンを製造するための能力は持続しうるが、主に財務面で留意が必要である。

（1）政策面

保健省によると、EPI は現在策定中の保健開発 5 カ年計画（2016-2020）においても優先活動となっている。また、同省予防医療局が実施している 2020 年までのマスタープランにお

いても同様で、ベトナムで製造されるワクチンを優先的に使用することとしている。したがって、政策面での持続性は確保されると考えられる。

妥当性の項でも述べたとおり、保健省は、ベトナム政府の麻疹ワクチンの2度目の接種をMRワクチンに切り替える決定の通知を2014年に発した。POLYVACにとって、このような決定はワクチンの市場を確保するうえで機会ととらえることができる。

（2）人材・技術面

POLYVACはこれまでも、本邦研修の参加者を含め、優秀な技術、高い能力をもつスタッフに対し、手当・ボーナスの支給や昇進といった、国営企業として可能な限りの待遇改善策を行ってきた。

POLYVACは本プロジェクトで習得した知識や技術を向上させるための機会も積極的に提供している。たとえば、保健省やWHOに加えて、途上国ワクチン製造業者ネットワーク（Developing Countries Vaccine Manufacturers Network：DCVMN）[15]のような組織が実施するセミナーや研修が定期的に行われており、POLYVACのスタッフも参加している。また、日本人専門家の指導を通じて得たGMPの最新情報を知ることができるウェブサイトも、POLYVACでは活用している。

このような取り組みを継続することで、人材・技術面での持続性は確保可能である。

（3）財務面

POLYVACの技術力を持続させるためのカギは、今後製造されるMRワクチンの収益性である。この点については、まだ懸念が残る。本プロジェクトの詳細計画策定調査報告書でも指摘されているとおり、麻疹ワクチンについては製造コストが販売価格を上回る状況が続いており[16]、同様のことがMRワクチンについても考えられる。将来、高度施設・機材の維持管理契約、老朽化した施設・機材の更新、生産力を拡大するための投資を考えると、収益性の確保は極めて重要である。

対応としては、製造コストの削減とコストに見合った販売価格の設定の2つの側面から考えることができる。コスト削減については、本プロジェクトでもさまざまな方策が行われてきた。例として、機材のキャリブレーションをPOLYVACスタッフが行うことや、ワクチン製造工程での凍結乾燥時間の短縮を挙げることができる。また、ワクチン材料費の抑制策として、SPFウサギの飼育をPOLYVAC敷地内で行うための技術移転とそれに必要なコンベンショナル動物舎建設の計画を保健省に提案している。今後も引き続き、POLYVACと日本人専門家双方でこのようなコスト削減策を検討していくことが必要である。ちなみに、これらの対応や提案は、ベトナム政府が必要なMRワクチンをすべてPOLYVACから調達するという方針、すなわちMRワクチンの市場が確保されていることが前提である。

ワクチンの販売価格を製造コストに見合ったものに設定することも必要である。中間レビュー調査時点でPOLYVACは保健省とワクチン価格について提案を行い、議論を続けている。

[15] 2000年に設立。アジア、中東、アフリカ、中南米の16カ国44社が加盟している。詳細は、ウェブサイト（http://www.dcvmn.org/）参照。

[16] JICA（2013）『ベトナム国　麻疹ワクチン製造基盤技術移転プロジェクトフェーズ2　詳細計画策定調査報告書』、11～12ページ

(4) 施設・機材面

施設・機材の操作、キャリブレーション、バリデーション、維持管理については、POLYVACは既にメカニズムを構築していることから、今後もSOPに沿ってやっていくことが可能と思われる。

高度施設・機材については、日本を含めたメーカーやその現地支店・代理店との維持管理契約を結んで対応していくことが求められる。既にPOLYVACでは、ボイラーやコンプレッサーといった施設・機材について維持管理契約を行っており、今後も適切な対応を続けていくことが求められる。昨今、ベトナム国内でのスペアパーツや消耗品の調達については改善がみられており、施設・機材の維持管理を取り巻く環境は以前よりもよくなっている。

ただ、POLYVACは老朽化した施設・機材の更新計画をまだ策定していない。将来の経営計画を考えていくうえで、施設・機材の要素を入れていく必要がある。

４－６　プロジェクトの貢献・阻害要因

(1) 貢献要因

・前身の「麻疹ワクチン製造基盤技術移転プロジェクト」(2006-2010)の経験、知識、技術の効果的活用：POLYVAC、日本人専門家双方
・POLYVACからの本邦研修参加者に離職がないこと。移転された知識・技術の喪失がないことを意味する。
・MRワクチン製造技術習得に対する、POLYVAC及び日本人専門家双方の献身的な努力

(2) 阻害要因

・安価で良質な材料、スペアパーツ、消耗品調達の困難さ

第５章　提言・教訓

５－１　提言

（1）プロジェクト（POLYVAC 及び日本人専門家）に対して

提言の内容としては、基本的にこれまでなされてきた取り組みの継続、これから計画されている重要な活動の着実な実施で、以下の 6 点である。

・MR ワクチンの長期安定性試験と臨床試験を、計画どおり完了させること。
・MR ワクチン臨床試験の完了後、速やかに販売承認の申請を保健省に行うこと。
・高度施設・機材（例：凍結乾燥機）の維持管理については、今後も維持管理契約締結などの方策を続けていくこと。
・本プロジェクトで習得した知識・技術の保持・向上を続けること。
・POLYVAC スタッフの定着のための努力を続けること。
・MR ワクチンのコスト削減に向けた取り組みを続けること。

（2）保健省に対して

POLYVAC による取り組みへの支援、上位目標達成のために保健省がやるべきことに関するもので、以下の 5 点である。

・POLYVAC より提出される MR ワクチンの販売承認申請を、「ファストトラック」で承認すること。
・コンベンショナル動物舎の建設と SPF ウサギ飼育の技術移転への投資について、当初の提案どおり実施すること。
・POLYVAC で製造される MR ワクチンのコストをカバーできるよう、適切な販売価格を設定すること。
・本プロジェクト後も POLYVAC で製造された MR ワクチンを用いて、95%以上の接種率を確保すること。
・ベトナム国内で製造されるワクチンを優先的に使用する政策を変更しないこと。

５－２　教訓

本プロジェクトでは、前身の「麻疹ワクチン製造基盤技術移転プロジェクト」やその前の無償資金協力「麻疹ワクチン製造施設建設計画」からの交流をベースに、POLYVAC と日本人専門家の間で非常に緊密なコミュニケーションがとられてきた。先述のワーキンググループはその一例で、そのほかにも POLYVAC で実施されている週例会議の議事録共有が定期的に行われ、専門家側も必要に応じてコメントを行っている。これらを通じて、本邦研修の詳細な計画づくり、POLYVAC スタッフの技術レベルの評価など、着実な技術移転を可能にしてきた。

専門家とカウンターパート間の緊密かつ建設的なコミュニケーションは、プロジェクトの目標達成のカギである。

第６章　PDM の改訂

本プロジェクトで達成可能な範囲をより正確に反映させるため、PDM の指標と外部条件について表－７のとおり改訂する。

表－７　PDM の改訂

	改訂前（Version 2）	改訂後（Version 3）
上位目標の指標 2	ベトナムにおける、麻疹風疹混合ワクチンを接種した子どもの割合が 95%以上となる。	ベトナムにおける、POLYVAC が製造した麻疹風疹混合ワクチンを接種した子どもの割合が 95%以上となる。
上位目標達成のための外部条件	・EPI 活動が保健セクターの国家優先プログラムとして継続される。 ・ベトナム国内で製造されたワクチンを利用するという政策が変わらない。 ・MR ワクチンの供給と EPI が変わりなく実施される。	左記に、以下 2 点を加える。 ・保健省が POLYVAC 製造の MR ワクチンを用いて 95%以上の接種率を確保する。 ・保健省が POLYVAC 製造の MR ワクチンの販売承認をファストトラックで承認する。
成果 1 の指標 1-1	POLYVAC 職員が、MR ワクチン製造及び品質管理の各工程について十分な技術レベルを身に付ける。（全体で、約 200 工程ある）…	POLYVAC 職員が、MR ワクチン製造及び品質管理の各工程について十分な技術レベルを身に付ける。（全体で、約 325 工程ある）…

付　属　資　料

１．協議議事録（M/M）

MINUTES OF MEETING
ON
THE MID-TERM REVIEW
OF THE JAPANESE TECHNICAL COOPERATION
FOR
THE PROJECT FORSTRENGTHENING CAPACITY FOR
MEASLES-RUBELLA COMBINED VACCINE PRODUCTION
IN THE SOCIALIST REPUBLIC OF VIET NAM

The Mid-term Review Mission (hereinafter referred to as "the MTR Mission") organized by the Japan International Cooperation Agency (hereinafter referred to as "JICA") visited the Socialist Republic of Viet Nam (hereinafter referred to as "Viet Nam") from November 16 to 27, 2015 to conduct the Joint Mid-term Review for the Project for Strengthening Capacity for Measles-Rubella Combined Vaccine Production (hereafter referred to as "the Project").

The MTR Mission had a series of meetings and interviews with relevant organizations concerning the first half of the Project activities to examine the achievement level of the outputs and purpose of the Project. The MTR Mission also discussed with the Center for Research and Production of Vaccines and Biologicals (hereinafter referred to as "POLYVAC") concerning the changes to be made to the design and operations of the second half of the Project.

As a result of the discussions, both the MTR Mission and the Vietnamese side (hereinafter referred to as "the both sides") reached common understanding and agreed upon the matters referred to in the documents attached hereto.

Hanoi, 27 November, 2015

Mr. Tomoya Yoshida
Team Leader,
Mid-term Review Mission,

Japan International Cooperation Agency
Japan

Asso. Prof, Dr. Nguyen Dang Hien
Director,
Center for Research and
Production of Vaccines and Biologicals
Ministry of Health
Socialist Republic of Viet Nam

Witness

Dr. Tran Thi Giang Huong
Director General,
International Cooperation Department
Ministry of Health

Socialist Republic of Viet Nam

ATTACHED DOCUMENT

1. Discussion Points

1-1 Revision of Project Design Matrix (PDM)

In order to better reflect the actual engagement of the Project, the following minor changes of indicators and important assumptions were made to the PDM during the MTR. Revised PDM was agreed by the both sides as PDM Ver.3 (Annex-1) as attached.

	Original PDM ver. 2	PDM ver. 3 (after MTR)
objectively indicators for Overall Goal	2. Coverage rate of children immunized with MR vaccine in Viet Nam is at or above 95%.	2. Coverage rate of children immunized MR vaccine in Viet Nam is at or above 95% with use of MR vaccine produced by POLYVAC.
Important Assumption for Overall Goal	-EPI activities are continued as national priority program in health sector. -Policy on utilization of vaccines produced in Viet Nam is not changed. -MR vaccine supply and EPI are conducted uneventfully.	-EPI activities are continued as national priority program in health sector. -Policy on utilization of vaccines produced in Viet Nam is not changed. -MR vaccine supply and EPI are conducted uneventfully. -MOH will achieve and maintain the percentage of coverage of MR vaccine at least 95% with use of MR vaccine produced by POLYVAC. -MOH willapprove the application of marketing license of MR vaccine produced by POLYVACon "fast-track" process.
Indicator for Output 1	**Indicator 1-1** Staff of POLYVAC has acquired sufficient technical level (i.e. level 4 *) for each process of MR vaccine production and quality control. (There are 200 processes approximately in total.) (*level 4: be able to work properly by himself/herself and can train other staff)	Staff of POLYVAC has acquired sufficient technical level (i.e. level 4 *) for each process of MR vaccine production and quality control. (There are 325 processes approximately in total.) (*level 4: be able to work properly by himself/herself and can train other staff)

2. Summary of the review

2-1 Conclusions

(1) The Project is still relevant, since it is in line with development policies of the government of Viet Nam, Japanese ODA policiesand needs of counterparts (C/Ps) and the target areas.

(2) The Project has progressed smoothly and achieved sufficient level of outputs as planned. Completion of PV of the rubella bulk production was delayed, but that did not show the serious damage to the overall progress of the Project.

(3) It is too early to mention the prospects to achieve the Overall Goal of the Project, but several positive impacts have already been realized. Quick response to measles outbreak in 2014 is one of the positive impacts of the Project.

(4) Technical capabilities of POLYVAC to produce MR vaccine can be sustained with

some reservation. Especially financial aspect and human resource aspect is of concern.

2-2 Recommendation

The Joint Review Team made the following recommendations based on the result of MTR.

(1) To the Project (POLYVAC and Japanese Experts)

- To complete long-term stability test and clinical trial of MR vaccine as scheduled
- To apply the marketing license promptly to MOH after completion of the clinical trial
- To continue making efforts to seek the best way of maintenance of sophisticated facilities and equipment such as those for freeze-drying vaccine
- To continue making current efforts to brush up and upgrade the knowledge learned from the Project
- To continue seeking measures for cost reduction of MR vaccine to ensure the profitability
- To continue making efforts to retain the staff members within POLYVAC

(2) To MOH

- To approve the application of marketing license of MR vaccine submitted by POLYVAC on"fast-track" process
- To invest in construction of conventional animal laboratory and technical transfer on breeding SPF rabbits in POLYVAC as originally planned
- To valorize the appropriate purchasing price of MR vaccine produced by POLYVACto cover the cost of production
- To achieve and maintain the percentage of coverage of MR vaccine at least 95%with use of MR vaccine produced by POLYVAC after the completion of the Project
- Not to change the policy to priorities vaccines produced in Viet Nam

Attached Document

Annex-1: PDM Ver.3

Annex-2: The Joint Mid-term Review Report

PDM (Project Design Matrix) (Version 3)

Project title: The Project for Strengthening Capacity for Measles-Rubella Combined Vaccine Production
Implementing Agency: Center for Research and Production of Vaccines and Biologicals (POLYVAC)
Project Duration: From the day of first dispatch of JICA Experts to March31, 2018
Target Area: The Socialist Republic of Viet Nam Target group: The staff of POLYVAC and People in the Socialist Republic of Viet Nam
Direct Beneficiaries: Children to receive MR vaccine immunization (annually around 1.5 million) Date: November 27, 2015

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumptions
Overall Goal Spread of measles and rubella in Viet Nam is decreased.	1. Number of case of children infected with measles and rubella in Viet Nam is decreased compared with the average between 2009 and 2012. (Measles: 2, 107 cases, Rubella: 3,710 cases)[1] 2. Coverage rate of children immunized MR vaccine in Viet Nam is at or above 95% with use of MR vaccine produced by POLYVAC.	1. Statistical data of the Ministry of Health 2. Statistical data of the Ministry of Health	・Public health activities in Viet Nam is strengthened.
Project Purpose Measles-Rubella combined vaccine (MR vaccine) conforming to international standard (WHO-cGMP) is produced by POLYVAC.	Marketing license of MR vaccine is issued by Viet Nam NRA.	Document on clearance issued by Viet Nam NRA	・EPI activities are continued as national priority program in health sector. ・Policy on utilization of vaccines produced in Viet Nam is not changed. ・MR vaccine supply and EPI are conducted uneventfully. -MOH will achieve and maintain the percentage of coverage of MR vaccine at least 95% with use of MR vaccine produced by POLYVAC. -MOH will approve the application of marketing license of MR vaccine produced by POLYVAC on "fast-track" process.
Outputs 1. POLYVAC has proper technical capabilities as a manufacturer of MR vaccine.	1-1 Staff of POLYVAC has acquired sufficient technical level (i.e. level 4 *) for each process of MR vaccine production and quality control. (There are 325 processes approximately in total.) (*level 4: be able to work properly by himself/herself and can train other staff) 1-2Equipment, apparatus, raw materials, spare parts and consumables for production of MR vaccine are properly utilized and maintained.	1-1Evaluation records on technical level of staff of POLYVAC 1-2 Appropriateness of inventory control and maintenance.	・GMP inspection is carried out at POLYVAC by Viet Nam NRA.
2. POLYVAC can produce MR vaccine properly complying with WHO-cGMP.	2-1 GMP documents complying with WHO-cGMP are prepared. 2-2 Production process and QC tests are executed complying with prepared GMP documents. 2-3Validations complying with WHO-cGMP are conducted periodically by POLYVAC. 2-4Performance Qualification (PQ) and Process Validation (PV) are executed as scheduled.	2-1 GMP documents 2-2 Records of production and QC tests 2-3 Records of validation activities 2-4Records of activities on PQ and PV	

[1] 2009-2011: Vaccine Preventable Diseases Monitoring (WHO), 2012: Measles-Rubella Bulletin (WHO/WPRO)

Activities	Inputs		
1. POLYVAC has proper technical capabilities as a manufacturer of MR vaccine. 1-1 Conduct technical transfer on production of rubella vaccine bulk through the processing of producing vaccine bulk from the seed virus. 1-2 Conduct technical transfer on final bulk composition, filling, freeze-dry through the process of producing MR vaccine. 1-3 Conduct technical transfer on quality control of the products. 1-4 Collect and examine information for lowering unit production cost of MR vaccine. 2. POLYVAC can produce MR vaccine properly complying with WHO-cGMP. 2-1Establish validation system for the production and quality control, and strengthen the validation skill of the staff. 2-2 Establish and implement quality assurance functions complying with WHO-cGMP standard. 2-3 Prepare and implement necessary SOPs for the process of production, storage, carrying in/out of the products, etc. 2-4 Conduct technical transfer on preparation of documents that need to meet WHO-cGMP standard and to be approved by NRA. 2-5 Conduct PQ/PV for vaccine production from seed virus. 2-6 Provide necessary advices on clinical trial on MR vaccine under management of Vietnamese side.	<Japan> ***1. JICA Experts*** (1) Chief Advisor/ Vaccine Production (2) Bulk Production (3) Histopathological Examination (4) Final Production (5) Quality Control (6) Management of Experimental Animals (7) Quality Assurance (8) GMP (9) Validation (10) Facility Management (including Third Country Experts) Other necessary fields. ***2. Full-time project staff*** (1)Secretary (2)Interpreter ***3. Training in Japan*** (1)Production management (2)Quality management ***4. Modification of facilities*** Modification of the facilities in the filling room on 1F and the disinfection room/changing room(IN) on 2F of the production building ***5. Provision of equipment and materials*** (1) Equipment for validation (2) Equipment for technical activities on vaccine production and quality assurance (3)Other equipment mutually agreed upon as necessary ***6. Local cost*** (1)Training textbooks and materials (2)Running expenses of the project office	<Viet Nam> ***1. Counterparts*** POLYVAC Staffs (1) Director (2) Deputy Director (3) QA Manager (4) Production Manager (5) QC Manager (6) Pathologists (7)Production Unit Staff (8)Quality Management Unit staff (9)Engineering Staff ***2. Equipment and materials*** (1)Stationary (2)Consumables for Vaccine Production and Quality Control (3) Working seed (4) Biological materials ***3. Local cost*** Maintenance for equipment ***4. Others*** Project office for Japanese Experts	• Most of trained staff keeps working at POLYVAC. **Pre-condition** Personnel distribution from C/P (Counterpart)

Note: GMP: Good Manufacturing Practice, NRA: National Regulatory Authority, SOPs: Standard Operating Procedures, PQ: Performance Qualification, PV: Process Validation

Socialist Republic of Viet Nam

Project for Strengthening Capacity for Measles-Rubella Combined Vaccine Production

MID-TERM REVIEW REPORT

27 November 2015

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ABBREVIATIONS AND ACRONYMS

DCVMN	Developing Countries Vaccine Manufacturers Network
EPI	Expanded Programme on Immunisation
GMP	Good Manufacturing Practice
JFY	Japanese Fiscal Year
JICA	Japan International Cooperation Agency
JPY	Japanese Yen
MCV	Measles Containing Vaccine
MCV1	First Dose of MCV
MCV2	Second Dose of MCV
MFT	Media Fill Test
MOH	Ministry of Health
NICVB	National Institute for Quality Control of Vaccine and Biologicals
MR Vaccine	Measles-Rubella Vaccine
NRA	National Regulatory Authority
OPV	Oral Polio Vaccine
PDM	Project Design Matrix
POLYVAC	Centre for Research and Production of Vaccines and Biologicals
PQ	Performance Qualification
PST	Process Simulation Test
PV	Process Validation
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SPF	Specific Pathogen Free
VND	Vietnamese Dong
WHO	World Health Organization

CHAPTER 1 OUTLINE OF MID-TERM REVIEW

1-1 Objectivesof the Mid-term Review

The objectives of the Mid-term Review are as follows:

- To review all the inputs, activities, outputs, and achievement of the plan based on the Project Design Matrix (PDM) and the project overall schedule ;
- To evaluate the achievement of the Project in light of five criteria, i.e. relevance, effectiveness, efficiency, impact and sustainability; and
- To prepare a Mid-term Review Report that will be attached to the Minutes of Meeting expected to be signed by Vietnamese and Japanese sides.

1-2 Members of the Mid-term Review Team

Name	Responsibility	Affiliation
Mr. Tomoya Yoshida	Team Leader	Director, Health Team 3 Human Development Dept. JICA HQs
Ms. Haruka Nomura	Cooperation Planning	Assistant Director, Health Team 3 Human Development Dept. JICA HQs
Mr. Naoki Take	Evaluation Analysis	Consultant, KMC Inc.

1-3 Schedule of the Mid-term Review

The Mid-term Review was carried out from 16 to 27 November 2015 (Appendix-01).

1-4 Persons Interviewed during the Mid-term Review

Persons interviewed during the Mid-term Review are listed in Appendix-02.

TY

CHAPTER 2 OUTLINE OF THE PROJECT

2-1 Background of the Project

Since 1981, the Government of Viet Nam has participated in the Expanded Programme on Immunisation (EPI) and continuously implemented national programmes for the inoculation of children against primarily the six major infectious diseases (measles, polio, diphtheria, pertussis, tetanus, and tuberculosis) as an effective means of lowering both infant and under-five mortality rates as well as of limiting the spread of infectious diseases. The EPI, which was initiated in 1974 by the World Health Organization (WHO), is considered one of the most effective means available for lowering mortality rates of children.

The Government of Viet Nam has not only placed a strong emphasis on maintaining high rates of immunization but has also implemented initiatives for the domestic production of the vaccines used for EPI, thereby to ensure a stable supply of the vaccines necessary for immunisation. As a part of these activities and in accordance with WHO recommendations, a second dose of immunisation against measles was started in 2006. In addition, the successful completion of the Project for Strengthening Capacity for Measles Vaccine Production undertaken during the period from March 2006 to March 2010 resulted in the start during 2009 of domestic production of measles vaccine in Viet Nam at the Centre for Research and Production of Vaccines and Biologicals (POLYVAC). At present, POLYVAC continues to production measles vaccine for use in EPI programmes in Viet Nam.

More recently, however, an increased incidence of rubella cases has been observed. This not only poses a threat to the health of children, but also has led to increased awareness of the previously underappreciated risk of congenital rubella syndrome in infants born to women who contract rubella during pregnancy and has increased understanding of the importance of implementing rubella immunisation programmes. This situation together with advice from WHO has led the Government of Viet Nam to initiate an inoculation campaign for measles-rubella (MR) vaccine through use of imported MR vaccines since 2014. For the routine vaccination, the Ministry of Health (MOH) decided to replace with a MR vaccine for the second inoculation. Therefore, acquiring the capability for domestic production of MR vaccine is now a matter of urgency for the Government of Viet Nam.

2-2 Summary of the Project

The Project is summarised in the Project Design Matrix (PDM) dated on 22 November 2013 (Appendix-03). Also as for the overall schedule of the Project, see Appendix-04.

CHAPTER 3 METHODOLOGY OF MID-TERM REVIEW

3-1 Review of Progress of the Project

The inputs and progress of project activities were reviewed.

(1) Review of Inputs

The PDM specifies the inputs necessary to implement the Project from both the Japanese and Vietnamese sides. This item was reviewed to ascertain whether or not inputs were allocated as planned.

(2) Review of Progress of Project Activities

Progress of activities to achieve the Outputs of the Project was assessed based upon the information collected from the Japanese experts and Vietnamese counterparts. Prospects of achieving the Outputs, Project Purpose and Overall Goal were also scrutinised with use of indicators to measure these current levels of achievement.

3-2 Review by Five Criteria

The Project was evaluated from the view of Five Criteria: relevance, effectiveness, efficiency, impact and sustainability.

(1) Relevance

Relevance of the project is the degree to which the Project Purpose remains pertinent, significant and worthwhile in relation to the priority needs and concerns in the Vietnamese health sector, the consistency of the Project with the Vietnamese development plan and alignment with Japan's assistance policy and JICA's country programme.

The following scale was used for evaluation of relevance: highly relevant, relevant, moderately relevant, relevant to some extent and not so relevant.

(2) Effectiveness

Effectiveness of the project is the prospects of achieving the Outputs and Project Purpose based on the progress of activities.

The effectiveness was assessed by the following scale: highly effective, effective, moderately effective, effective to some extent and not so effective.

(3) Efficiency

Efficiency of the project is to evaluate how efficiently the Inputs of the project produce the Outputs through the Activities. Quantity, quality and timing of the Inputs are also taken into consideration.

The efficiency was measured by the scale of highly efficient, efficient, moderately

efficient, efficient to some extent and not so efficient.

(4) Impact

Impact of the project is likelihood of achieving the Overall Goal based on the progress of activities and external circumstances around the project. Unintended impacts, both positive and negative, are also observed.

The impact was evaluated by the following scale: more positive impact expected, both positive and negative impact expected equally, no impact expected and more negative impact expected.

(5) Sustainability

Sustainability is the possibility that the fruits of the project will be prolonged after the completion. It is assessed from the aspects of policy, organisation, techniques and finance.

The scale of expected without reservation, expected with some reservation and not expected was used for evaluation of the sustainability.

3-3 Data Collection

The information necessary for the Mid-term Review was collected through sharing relevant documents possessed by the Japanese experts, searching relevant websites and interviews with Vietnamese stakeholders.

CHAPTER 4 RESULTS OF MID-TERM REVIEW

4-1 Inputs

(1) Japanese Side

1) Allocation of Japanese Experts

From May 2013 to September 2015, 29 short-term experts have been allocated for the categories of project management, quality assurance (QA)/Good Manufacturing Practice (GMP)/validation, bulk production, final production, quality control (QC) and facilities and equipment validation (Appendix-05).

In terms of man-days for the Project both in Viet Nam and Japan and number of trips to Viet Nam, Japanese experts have been allocated mostly as planned (Table-01).

Table-01: Allocation of Japanese Experts by Japanese Fiscal Year (JFY) and Category

JFY	Categories	Man-days in Viet Nam			Man-days in Japan			Trips to Viet Nam		
		Plan (A)	Actual (B)	% (B/A)	Plan (A)	Actual (B)	% (B/A)	Plan (A)	Actual (B)	% (B/A)
2013	Project Management	414	403	97.3%	174	176	101.1%	23	24	104.3%
	QA/GMP/Validation	163	163	100.0%	158	158	100.0%	13	13	100.0%
	Bulk Production	35	39	111.4%	9	6	66.7%	3	2	66.7%
	Final Production	14	14	100.0%	3	3	100.0%	1	1	100.0%
	Quality Control	119	128	107.6%	33	33	100.0%	11	11	100.0%
	Facilities/Equipment	133	133	100.0%	23	21	91.3%	11	10	90.9%
	TOTAL	**878**	**880**	**100.2%**	**400**	**397**	**99.3%**	**62**	**61**	**98.4%**
2014	Project Management	362	315	87.0%	118	118	100.0%	21	21	100.0%
	QA/GMP/Validation	114	99	86.8%	82	79	96.3%	10	9	90.0%
	Bulk Production	56	72	128.6%	12	15	125.0%	4	5	125.0%
	Final Production	35	35	100.0%	9	9	100.0%	3	3	100.0%
	Quality Control	154	130	84.4%	51	39	76.5%	17	13	76.5%
	Facilities/Equipment	91	75	82.4%	21	17	81.0%	10	8	80.0%
	TOTAL	**812**	**726**	**89.4%**	**293**	**277**	**94.5%**	**65**	**59**	**90.8%**
2015 (-Sep)	Project Management	320	183	57.2%	107	62	57.9%	18	9	50.0%
	QA/GMP/Validation	100	39	39.0%	40	21	52.5%	10	3	30.0%
	Bulk Production	14	0	0.0%	2	0	0.0%	1	0	0.0%
	Final Production	42	7	16.7%	8	2	25.0%	4	1	25.0%
	Quality Control	84	70	83.3%	18	13	72.2%	9	6	66.7%
	Facilities/Equipment	21	64	304.8%	3	11	366.7%	1	5	500.0%
	TOTAL	**581**	**363**	**62.5%**	**178**	**109**	**61.2%**	**43**	**24**	**55.8%**

2) Allocation of Full-time Project Staff

Four interpreters and one administrator have been hired by the Japanese side.

3) Modification of Facilities

The Project supported renovation and modification of facilities in POLYVAC in 2013 and 2014 to deal with the bulk production of rubella vaccine and to comply with the latest WHO-cGMP (Appendix-06).

4) Training in Japan

By the end of August 2015, 24 staff members working in POLYVAC have been trained in Japan in the categories of bulk production, final production, medium preparation, quality control, quality assurance and Specific Pathogen Free (SPF) rabbit breeding(Appendix-07).In addition, four staff members of final production, SPF rabbit

breeding and validation/calibration are trained in October and November 2015.

In terms of number of trainees and days of training, the training has been done mostly as planned (Table-02). It is noted that no participants left POLYVAC after the training in Japan.

Table-02: Training in Japan by Category

JFY	Categories	Number of Trainees			Number of Training Days		
		Plan (A)	Actual (B)	% (B/A)	Plan (A)	Actual (B)	% (B/A)
2013	Bulk Production	2	2	100.0%	120	120	100.0%
	Final Production	2	2	100.0%	60	56	93.3%
	Medium Preparation	1	1	100.0%	30	28	93.3%
	Quality Control	6	6	100.0%	360	340	94.4%
	Quality Assurance	2	2	100.0%	60	56	93.3%
	SPF Rabbit Breeding	2	2	100.0%	60	54	90.0%
	TOTAL	**15**	**15**	**100.0%**	**690**	**654**	**94.8%**
2014	Bulk Production	1	2	200.0%	60	56	93.3%
	Final Production	1	1	100.0%	30	27	90.0%
	Medium Preparation	1	1	100.0%	30	27	90.0%
	Quality Control	3	3	100.0%	150	139	92.7%
	Quality Assurance	2	2	100.0%	60	52	86.7%
	SPF Rabbit Breeding	1	1	100.0%	30	27	90.0%
	TOTAL	**9**	**10**	**111.1%**	**360**	**328**	**91.1%**
2015 (-Aug)	Bulk Production	1	1	100.0%	30	28	93.3%
	Final Production	1	0	0.0%	30	0	0.0%
	Quality Control	2	1	50.0%	60	28	46.7%
	Quality Assurance	2	2	100.0%	30	56	186.7%
	SPF Rabbit Breeding	1	0	0.0%	30	0	0.0%
	Validation/Calibration	2	0	0.0%	30	0	0.0%
	TOTAL	**9**	**4**	**44.4%**	**210**	**112**	**53.3%**

5) Provision of Equipment and Materials

Since the commencement of the Project, 59,320,000 Japanese Yen (JPY) has been spent for provision of equipment for vaccine production, quality control, pathology, calibration and validation (Appendix-08). All of them work properly.

6) Local Cost

In total, 33,030,000 JPY has been used for project implementation by the end of September 2015 mostly as planned (Table-03, Appendix-09).

Table-03: Summary of Local Cost by Japanese Side (Thousand JPY)

JFY	Plan (A)	Actual (B)	% (B/A)
2013	17,920	17,490	97.6%
2014/15	22,780	15,540	68.2%
TOTAL	**40,700**	**33,030**	81.2%

(2) Vietnamese Side

1) Assignment of Counterparts

As initially planned, Director, Deputy Director, managers and staff members of QA, QC,

bulk production, final production, medium preparation and engineering have been assigned from POLYVAC (Appendix-10).

2) Equipment and Materials

The Vietnamese side spent 8,903,862,000 Vietnamese Dong (VND: equivalent of 48,081,000 JPY) for provision of equipment and materials for the Project in 2014 and 2015 (Table-04, Appendix-11).

Table-04: Summary of Expense for Equipment and Materials by Vietnamese Side

Year	VND	JPY
2014	4,868,308,000	26,289,000
2015	4,035,554,000	21,792,000
TOTAL	**8,903,862,000**	**48,081,000**

3) Local Cost

By the end of August 2015, the Vietnamese side has allocated 27,902,000,000 VND (143,990,000 JPY) for the Project including maintenance of the equipment (Table-05, Appendix-12).

Table-05: Summary of Local Cost by Vietnamese Side

Year	Budget for the Project (Thousand VND)			JPY (,000)
	MOH	POLYVAC	TOTAL	
2013	0	5,000,000	5,000,000	23,550
2014	6,200,000	9,500,000	15,700,000	80,541
2015 (-Aug)	2,202,000	5,000,000	7,202,000	39,899
TOTAL	8,402,000	19,500,000	27,902,000	143,990

4) Other Inputs

POLYVAC has provided office space for the Japanese expert team in its premises.

4-2 Output 1

4-2-1 Outline of Output 1

Output 1 of the Project is to upgrade the technical capabilities of POLYVAC to produce MR vaccine. Cost reduction of MR vaccine is also examined in the Output.

4-2-2 Progress of Activities

The Project has provided opportunities to transfer technology of bulk production of rubella vaccine, final production of MR vaccine and quality control of the products through the training in Japan and the technical advices of the experts in Viet Nam. As illustrated in Appendices-05 and 07, these activities have been implemented mostly as scheduled. The technical transfer of bulk production of rubella vaccine was completed since the process validation (PV) was completed, while PV for the final production is

on-going and will be completed by Mid-January 2016.

As for the examination of the cost reduction of MR vaccine, the Project has tried to take consideration of materials procured locally and reduction of time for the process of freeze-drying of MR vaccine.

4-2-3 Current Status of Indicators

The two indicators are used to assess the level of achievement of Output 1: (1) Staff of POLYVAC has acquired sufficient technical level (i.e. Level 4) for each process of MR vaccine production and quality control; and (2) Equipment, apparatus, raw materials, spare parts and consumables for production of MR vaccine are properly utilised and maintained.

(1) Technical Level of POLYVAC

Appendix-13"Summary of Education and Training Activities" shows that most of participants in the training in Japan got "Level 4", i.e. capable of performing assigned works and providing training other staff members. According to them interviewed during the Mid-term Review, all can utilise their knowledge and techniques learned after the training.

After re-examination of the production process of MR vaccine by the Project, the total number of process was increased from 200 to 325.

(2) Status of Utilisation and Maintenance of Equipment, etc.

POLYVAC has properly utilised and maintained equipment, apparatus, spare parts and consumables in accordance with the standard operating procedures (SOPs) refined by the Project. Availability of spare parts and consumables has been also improved for the last few years.

It will bebetter if POLYVACcontinuesto elaborate the mechanism of maintenance of the equipment of the final production e.g. and procurement of spare parts and consumables further.

4-3 Output 2

4-3-1 Outline of Output 2

Output 2 of the Project is to develop the necessary documents complying with GMP, actually operate the mechanism based on the documents and record the results of operation. This mechanism is the environment that enables POLYVAC to utilise the capabilities upgraded by the Project.

4-2-2 Progress of Activities

(1) Establishment of Validation System and Quality Assurance in Line with WHO-cGMP

As described in Appendix-14, POLYVAC can operate the mechanism of calibration and validation of the facilities and equipment through the technical support of experts of the

Project. Its QA Department can also manage documents of calibration and validation complying with WHO-cGMP.

(2) Preparation and Implementation of GMP Documents and SOPs

As listed in Appendix-15, POLYVAC completed development of 19 GMP documents and 532 SOPs. According to the interview with QA Department, all of them were approved.

(3) Implementation of Performance Qualification (PQ) and PV

All process of PQ and PV was completed for the bulk production of Rubella vaccine in spite of the delay of schedule. As for the final production of MR vaccine, PV is conducted three times. PV-1 including QC tests will be completed in December 2015. PV-2, PV-3and their QC tests will be completed by Mid-January 2016.

(4) Clinical Trial of MR Vaccine

As done in the previous project on measles vaccine production in 2006-2010, POLYVAC is elaborating the protocol of clinical trial of MR vaccine with technical support from Japanese experts. The proposal of the trial was submitted in December 2014 and being preliminarily scrutinised by MOH.

Following the submission of all documents required to the Ministry, the clinical trial will be commenced in March 2016. According to the expert, POLYVAC is preparing the trial more smoothly than the previous project.

4-2-3 Current Status of Indicators

The four indicators are used to assess the level of achievement of Output 2: (1) GMP documents complying with WHO-cGMP are prepared; (2) Production process and QC tests are executed complying with prepared GMP documents; (3) Validations complying with WHO-cGMP are conducted periodically by POLYVAC; and (4) PQ and PV are executed as scheduled.

(1) Preparation of GMP Documents

As already described, 19 GMP documents and 532 SOPs were developed and approved by POLYVAC.

(2) Execution of Production Process and QC Tests

The Mid-term Review Team confirmed the execution of production process and QC tests based on the observation of facilities and documents.

(3) Implementation of Validation

Calibration and validation are being carried out regularly by POLYVAC, as indicated in Appendix-14.

(4) Performance of PQ and PV

PQ, Process Simulation Test (PST) and PV of the bulk of rubella vaccine were completed in September 2015, 10-month delay from the initial schedule due to the re-examination of whole process of the bulk production following failure of PV in November-December 2014.

As for the final production, PQ and Media Fill Test (MFT) were completed in August and September 2015 respectively, and PV will be done by Mid-January 2016. It was two-month delay due to the delay of the bulk production of rubella vaccine.

4-4 Project Purpose

The Project Purpose is that measles-rubella combined vaccine conforming to international standard is produced by POLYVAC, and its indicator is marketing license of MR vaccine is issued by Viet Nam National Regulatory Authority (NRA).

According to the overall schedule of the Project illustrated in Appendix-04, POLYVAC will apply the license following the long-term stability test and the clinical trial of MR vaccine. Prospects to achieve the Project Purpose depend on the progress of these activities.

It can be said for the moment that the Project is moving forward to getting the license steadily based on the current status of Output 1 and 2.

4-5 Overall Goal

The Overall Goal of the Project is to decrease the case of measles and rubella in Viet Nam and to reach the percentage of children immunised with MR vaccine at 95% or more as a result of utilisation of the vaccine produced by POLYVAC.Therefore, it can be measured after it gets the marketing license issued by Viet Nam NRA.

The number of reported cases of measles and rubella and the coverage of measles containing vaccine (MCV; MCV1 is first dose and MCV2 is second dose) for the last five years are summarised in Table-06.

Table-06: Reported Cases of Measles and Rubella and Coverage of MCV

Year / Item	2010	2011	2012	2013	2014
Cases of measles	2,809	750	578	1,123	15,033
Cases of rubella	2,300	7,259	185	54	59
% MCV1	98	96	96	98	97
% MCV2	98	93	83	86	94

Source: WHO vaccine-preventable diseases: monitoring system
(http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria%5Bcountry%5D%5B%5D=VNM&commit=OK)

4-6 Project Implementation Process

This section is used for summarising the measures to implement the Project effectively and efficiently and the major events around the Project.

(1) Quick Response of POLYVAC to Measles Outbreak in 2014

POLYVAC responded to the urgent request of MOH to deal with measles outbreak in early 2014 and provided 5.6 million doses of vaccines. That contributed to quick containment of measles and proved quality of the vaccines produced by POLYVAC and its technical capabilities strengthened by the previous project on measles vaccine production in 2006-2010.

(2) Viet Nam NRA Officially Certified by WHO

In June 2015, WHO officially certified Viet Nam NRA as a fully-equipped national regulatory system to ensure the safety and efficacy of vaccines produced and used in Viet Nam[1]. According to the information at the time of project formulation for MR vaccine, Viet Nam NRA could not meet the requirements of three functions out of six in 2009 i.e. marketing authorisation and licensing, lot release and laboratory access. But in April 2015, a team of independent experts evaluated that Viet Nam NRA has met all of the WHO criteria for functioning at international standards of excellence.

POLYVAC contributed to strengthening of technical capabilities of National Institute for Quality Controlof Vaccine and Biologicals (NICVB), which is in charge of lot release and laboratory access, from the aspects of calibration and validation.

(3) Practice of "5S+1M"

Figure-01: 5S+1M, GMP and Hou-Ren-Sou Card

[1] http://www.wpro.who.int/vietnam/mediacentre/releases/2015/nra_vietnam_certification/en/

POLYVAC is practicing 5S (Sort, Set, Shine, Standardise and Sustain) + 1M (Maintenance) to improve the working environment and process that result in the improvement of quality of vaccines. The staff members are always bringing a card illustrating 5S+1M as well as description of three principles of GMP (Figure-01).

(4) Working Groups and Morning Short Meeting

Since the previous project, POLYVAC has organised the working groups for eight different topics: (1) Calibration/Validation, (2) Formalin Fumigation, (3) Environmental Pollution Control, (4) Environmental Monitoring, (5) Procurement Control, (6) Risk Management, (7) Document Control and (8) Clinical Trial. All technical departments participate in and discuss specific topics (Appendix-16).

It is noted that the working groups were active even at the time of absence of JICA projects from April 2010 to April 2013. The staff members of POLYVAC recognise that they are very useful to seek solutions to the problems through the inter-departmental approach.

Chapter 5 MID-TERM REVIEW BYFIVE CRITERIA

5-1 Relevance

Implementation of the Project is highly relevant to Vietnamese policy direction, the needs of Vietnamese health sector and Japanese direction to Viet Nam.

(1) Alignment with Vietnamese Policy Direction

One of the objectives of *the Socio-economic Development Plan for 2011-2015 in Viet Nam* is to continue to improve quality of life of the people including their health status, e.g. "paying attention to preventive health to minimise people's risk of contracting infectious diseases"[2].

Five-Year Health Sector Development Plan 2011-2015 in Viet Nam also clearly prioritises the promotion of preventive medicine including EPI and containment of epidemics[3].

The Project has been supporting reinforcement of capacity of MOH on EPI and preparedness of epidemics such as measles outbreak in 2014 through strengthening capabilities of POLYVAC to produce MR vaccine.

Policy environment around the Project is unchanged from the time of the formulation.

(2) Addressing the Needs of Vietnamese Health Sector

Viet Nam often faces the epidemics of measles and rubella, and awareness of the risk of congenital rubella syndrome has been also raised in the country.

In response to these situations together with the advice from WHO, the Government of Viet Nam decided to replace the second inoculation of measles vaccine with MR in 2014. Therefore, it has become urgent needs to have capacity to produce quality MR vaccine in Viet Nam. Since POLYVAC could produce measles vaccines through the technical support from the JICA Project for Strengthening Capacity for Measles Vaccine Production in 2006-2010, the Government of Viet Nam requested the Government of Japan to support implementation of technology transfer to produce MR vaccine. POLYVAC has been expected to have capacities to do them efficiently based on the capacity of production of measles vaccine.

Such needs of Vietnamese health sector are still unchanged from the time of the formulation, and the Project has been addressing them.

(3) Alignment with Japan's direction to supportthe health sector in Viet Nam

Japan's Country Assistance Policy for Viet Nam prioritises strengthening of the Vietnamese health sector in the area of response to vulnerability, including infectious

[2] http://www.chinhphu.vn/portal/page/portal/English/strategies/strategiesdetails?categoryId=30&articleId=10052505
[3] Ministry of Health (2010) *Five-Year Health Sector Development Plan 2011-2015*, pp37-38

disease control[4]. The Project has been implemented within the health sector programme to contribute to strengthening capacity of infectious disease control in Viet Nam.

Therefore, the Project is clearly aligned with the Japan's assistance policy.

5-2 Effectiveness

The Project is highly effective, with some reservation.

Based on the current status of indicators, the Output 1 and 2 have almost achieved. Most of participants of training in Japan earned Level 4, and staff members of POLYVAC are operating and maintaining facilities and equipment in accordance with their own SOPs. Completion of PV of the rubella bulk production was delayed, but that did not show the serious damage to the overall progress of the Project.

The Project Purpose can be achieved if the long-term stability test and the clinical trial of MR vaccine move forward smoothly.

5-3 Efficiency

Implementation of the Project is highly efficient.

Close communication between Vietnamese counterparts and Japanese experts has contributed to effective and efficient progress of the project activities and current status of the Output 1 and 2. POLYVAC staff members can properly operate all facilities and equipment provided by the Project with use of SOPs, while nobody left POLYVAC after the participation in training in Japan.

It can be also said that the experiences of the JICA Project for Strengthening Capacity for Measles Vaccine Production in 2006-2010 by most of POLYVAC staff members also contributed to efficient intake of knowledge and techniques of MR vaccine production.

5-4 Impact

It is too early to mention the prospects to achieve the Overall Goal of the Project, but several positive impacts have already been realised.

With use of knowledge and techniques learned by the Project, POLYVAC counterparts actually instruct GMP, calibration and validation for the production of oral polio vaccine (OPV).POLYVAC also contributed to strengthening of technical capabilities of NICVB through the technical support of calibration and validation.The knowledge and techniques of POLYVAC on GMP and calibration/validation can now be a showcase to the other institutions.

It is also noted that five Japanese experts of the Project are awarded the memorabilia "For people's Health" by MOH.

[4]Ministry of Foreign Affairs, Government of Japan (2012) *Japan's Country Assistance Policy for Socialist Republic of Viet Nam*, p2

Activities of public relations of the Project facilitated the vaccinationcampaign of measles vaccines in 2014 through sensitisation of the Vietnamese on the importance of immunisation and safety and efficacy of measles vaccine manufactured by POLYVAC with Japanese technology.

The Project has also accepted various visitors from Japan including members of parliament. That has contributed to appreciation towards the Project.

5-5 Sustainability

Technical capabilities of POLYVAC to produce MR vaccine can be sustained with some reservation.

(1) Policy Aspect

EPI is prioritised in the next *Five-Year Health Sector Development Plan*.In 2014 the Government of Viet Nam decided to replace MCV2 with the MR vaccine and MOH issued the circular. That will be a great opportunity for POLYVAC to ensure a market.

(2) Human Resource/Technical Aspect

POLYVAC, a state enterprise in Viet Nam,has made efforts to retain the staff members including the participants in training in Japan, e.g. provision of allowances and promotion of the staff with outstanding expertise.

POLYVAC has actively used opportunities to brush up and upgrade the knowledge learned through the Project. Currently training and seminars are done by MOH, WHO and Developing Countries Vaccine Manufacturers Network (DCVMN) as an example. It also browses the websites that enable to know the update of GMP.

It can be expected for POLYVAC to continue these efforts.

(3) Financial Aspect

Profitability of MR vaccine is a key to sustainability of technical capabilities of POLYVAC. Currently it is a concern. Based on the situation of measles vaccine the cost is beyond the purchasing price of MOH (around 5,500 VND per dose), and the same thing can happen to MR vaccine. But it is important to ensure the profitability to proceed with maintenance contract,to replace the old facilities and equipment and to invest in expansion of the production capacity.

It is necessary for the Project (both POLYVAC and Japanese experts) to scrutinise the measures to contain the cost of production of MR vaccine, e.g. calibration of the equipment by POLYVAC staff, reduction of time to operate the freeze-drying machine for the vaccine production. The Project is proposing MOH to breed SPF rabbits in the premises of POLYVAC.Financial sustainability and stable production of vaccinesare based on the assumption that the Government of Viet Nam purchases all necessary vaccines from POLYVAC for EPI. The Government of Viet Nam should not change the policy to prioritise vaccines produced in Viet Nam.

It is also necessary to adjust the purchasing price of MR vaccine to the production cost. Currently POLYVAC is proposing the price of vaccines to discuss it with MOH.

(4) Facilities/Equipment Aspect

As for operation, calibration, validation and maintenance of facilities and equipment, POLYVAC has established the mechanism.It can be expected that the staff members can handle them in line with the SOPs in the future.

POLYVAC has signed maintenance contracts for some items of facilities and equipment even with Japanese manufacturers (e.g. boiler and compressor). It is also a good opportunity that availability of local agents to provide spare parts and consumables has been improved in Viet Nam. Therefore, it is necessary for POLYVAC to continue consideration of the best way of maintenance carefully.

Also, POLYVAC is required to incorporate a plan to replace obsolete facilities and equipment into its own business plan.

5-6 Facilitating and Impeding Factors of the Project

(1) Facilitating Factors

- Effective utilisation of the experiences, knowledge and techniques of the previous JICA Project for Strengthening Capacity for Measles Vaccine Production in 2006-2010, for both POLYVAC and Japanese experts
- All participants in training in Japan still retained in POLYVAC: no loss of knowledge and techniques the Project transferred
- Dedication to mastering the knowledge and techniques on the production of MR vaccine, of both POLYVAC and Japanese experts

(2) Impeding Factors

- Difficulty to procure cheaper and quality materials, spare parts and consumables

Chapter 6 RECOMMENDATIONS AND LESSONS LEARNED

(1) To the Project (POLYVAC and Japanese Experts)

- To complete long-term stability test and clinical trial of MR vaccine as scheduled
- To apply the marketing license promptly to MOH after completion of the clinical trial
- To continue making efforts to seek the best way of maintenance of sophisticated facilities and equipment such as those for freeze-drying vaccine
- To continue making current efforts to brush up and upgrade the knowledge learned from the Project
- To continue seeking measures for cost reduction of MR vaccine to ensure the profitability
- To continue making efforts to retain the staff members within POLYVAC

(2) To MOH

- To approvethe application of marketing licence of MR vaccine submitted by POLYVAC on"fast-track" process
- To invest in construction of conventional animal laboratoryand technical transfer on breeding SPF rabbits in POLYVAC as originally planned
- To valorise the appropriate purchasing price of MR vaccine produced by POLYVAC to cover the cost of production
- To achieve and maintain the percentage of coverage of MR vaccine at least 95% with use of vaccine produced by POLYVAC after the completion of the Project
- Not to change the policy to prioritise vaccines produced in Viet Nam

Chapter 7 MODIFICATION OF PROJECT DESIGN MATRIX

In order to better reflect the actual engagement of the Project, the following minor changes of indicators and important assumptions of the PDM are proposed in Table-07.

Table-07: Proposal of Modification of PDM

	Original PDM ver. 2	PDM ver. 3 (after MTR)
objectively indicators for Overall Goal	2. Coverage rate of children immunized with MR vaccine in Viet Nam is at or above 95%.	2. Coverage rate of children immunized MR vaccine in Viet Nam is at or above 95% **with use of MR vaccine produced by POLYVAC.**
Important Assumption for Overall Goal	-EPI activities are continued as national priority program in health sector. -Policy on utilization of vaccines produced in Viet Nam is not changed. -MR vaccine supply and EPI are conducted uneventfully.	-EPI activities are continued as national priority program in health sector. -Policy on utilization of vaccines produced in Viet Nam is not changed. -MR vaccine supply and EPI are conducted uneventfully. **-MOH will achieve and maintain the percentage of coverage of MR vaccine at least 95% with use of MR vaccine produced by POLYVAC.** **-MOH will approve the application of marketing license of MR vaccine produced by POLYVAC on "fast-track" process.**
Indicator for Output 1	**Indicator 1-1** Staff of POLYVAC has acquired sufficient technical level (i.e. level 4 *) for each process of MR vaccine production and quality control. (There are 200 processes approximately in total.) (*level 4: be able to work properly by himself/herself and can train other staff)	Staff of POLYVAC has acquired sufficient technical level (i.e. level 4 *) for each process of MR vaccine production and quality control. (There are **325** processes approximately in total.) (*level 4: be able to work properly by himself/herself and can train other staff)

Chapter 8 CONCLUSION

(1) The Project is still relevant, since it is in line with development policies of the government of Viet Nam, Japanese ODA policies and needs of counterparts and the target areas.
(2) The Project has progressed smoothly and achieved sufficient level of outputs as planned. Completion of PV of the rubella bulk production was delayed, but that did not show the serious damage to the overall progress of the Project.
(3) It is too early to mention the prospects to achieve the Overall Goal of the Project, but several positive impacts have already been realized. Quick response to measles outbreak in 2014 is one of the positive impacts of the Project.
(4) Technical capabilities of POLYVAC to produce MR vaccine can be sustained with some reservation. Especially financial aspect and human resource aspect is of concern.

Schedule of midterm review
The Project for Strengthening Capacity for Measles-Rubella Combined Vaccine Production

Date	Day	Time	JICA		Consultant
			Team Leader	Planning	Data Analysis
			YOSHIDA Tomoya	NOMURA Haruka	TAKE Naoki
11/16	Mon	AM		JICA HQ	Narita (10:00)→ Hanoi (14:15) 【VN311】 16:00 Meeting with JICA Vietnam Office
		PM			
11/17	Tue	AM			09:30 Meeting with Experts
		PM			14: 00 Meeting with Director of POLYVAC
11/18	Wed	AM			09:30 C/P hearing
		PM			14:00 C/P hearing
11/19	Thu	AM			09:30 C/P hearing 10:30 C/P hearing
		PM	Narita (17:55)→ HCMC(22:35) 【ANA831】		09:30 C/P hearing
11/20	Fri	AM	Cho Ray Hospital 201B Nguyen Chi Thanh, D5		09:30 C/P hearing
		PM			14:00 Report to experts
11/21	Sat	AM	TBC		Data Analysis
		PM	HCMC(12:35)→ Hanoi (14:40) 【VN238】		
11/22	Sun	AM	Prepare document	Haneda (08:55)→ Hanoi (13:10) 【ANA857】	Prepare report
		PM	Meeting with Consultant		Meeting with other members
11/23	Mon	AM	Meeting at JICA Viet Nam Office		
		PM	14:00 Courtersy call to POLYVAC Direcctor		
11/24	Tue	AM	Meeting with POLYVAC		
		PM	Meeting with POLYVAC		
11/25	Wed	AM	Meeting with Ministry of Health		
		PM	14:00 Meeting with POLYVAC on MM		
11/26	Thu	AM	09:30 Meeting with POLYVAC on MM		
		PM	12:00 Report of Nursing Education Project		Finalization of MM
11/27	Fri	AM	JCC at POLYVAC		
		PM	Diner party at NIKKO		
11/28	Sat	AM	Hanoi (14:25)→ Haneda (21:00) 【ANA858】		Hanoi (1:25)→ Fukuoka (7:10) 【VN356】
		PM			

List of Persons Interviewed during the Mid-term Review

(1) Centre for Research and Production of Vaccine and Biologicals (POLYVAC)

Name	Position
Assoc. Prof. Dr. Nguyen Dang Hien	Director
Dr. Nguyen Thuy Huong	Vice Director
Mr. Nguyen Xuan Hoa	Manager, Bulk Production Department
Mr. Pham Thanh Truong	Vice Manager, Bulk Production Department
Mr. Le Quoc Hung	Manager, Final Production Department
Mr. Nguyen Dang Quynh	Vice Manager, Final Production Department
Mr. Le Tuan Anh	Manager, Medium Preparation Department
Mr. Nguyen Dang Anh	Manager, Technical Department
Ms. Tran Thi Phuong	Manager, Quality Assurance Department
Dr. Ngo Thu Huong	Manager, Quality Control Department

(2) Ministry of Health, Socialist Republic of Viet Nam (MOH)

Name	Position

(3) Project Expert Team Led by Kitasato Daiichi Sankyo Vaccine Co., Ltd. (KDSV)

Name	Responsibility
Dr. Setsuo Arai	Chief Advisor
Dr. Tomio Lee	Deputy Chief Advisor/Vaccine Production Control
Mr. Yasuhiro Tsuchida	Organisational Management
Dr. Miki Tamura	Organisational Management Training Operations and Administration in Japan
Mr. Shuzo Ishikawa	Engineering/Project Coordination
Mr. Kenichi Baba	Vaccine Quality Control
Dr. Manabu Ikeda	Quality Control
Mr. Toshio Kosugi	Quality Control
Mr. Yoshihisa Takeda	Quality Control
Dr. Hiroki Katsuda	Bulk Production
Mr. KunihikoKomuro	Final Production
Prof. Tetsuo Nakayama	Quality Assurance (Clinical Trial)

(4) JICA Viet Nam Office

Name	Position
Ms. YutoriSadamoto	Representative
Ms. Dao Thi Khanh	Programme Officer

PDM (version2)

Project title: The Project for Strengthening Capacity for Measles-Rubella Combined Vaccine Production
Implementing Agency: Center for Research and Production of Vaccines and Biologicals (POLYVAC)
ProjectDuration:Fromthedayof firstdispatchofJICAExpertsto March31,2018
TargetArea:The Socialist Republic of Viet Nam
Target group:The staff ofPOLYVAC and People intheSocialist Republic of Viet Nam
Direct Beneficiaries: Children to receive MR vaccine immunization (annually around 1.5million)

Date:November22,2013

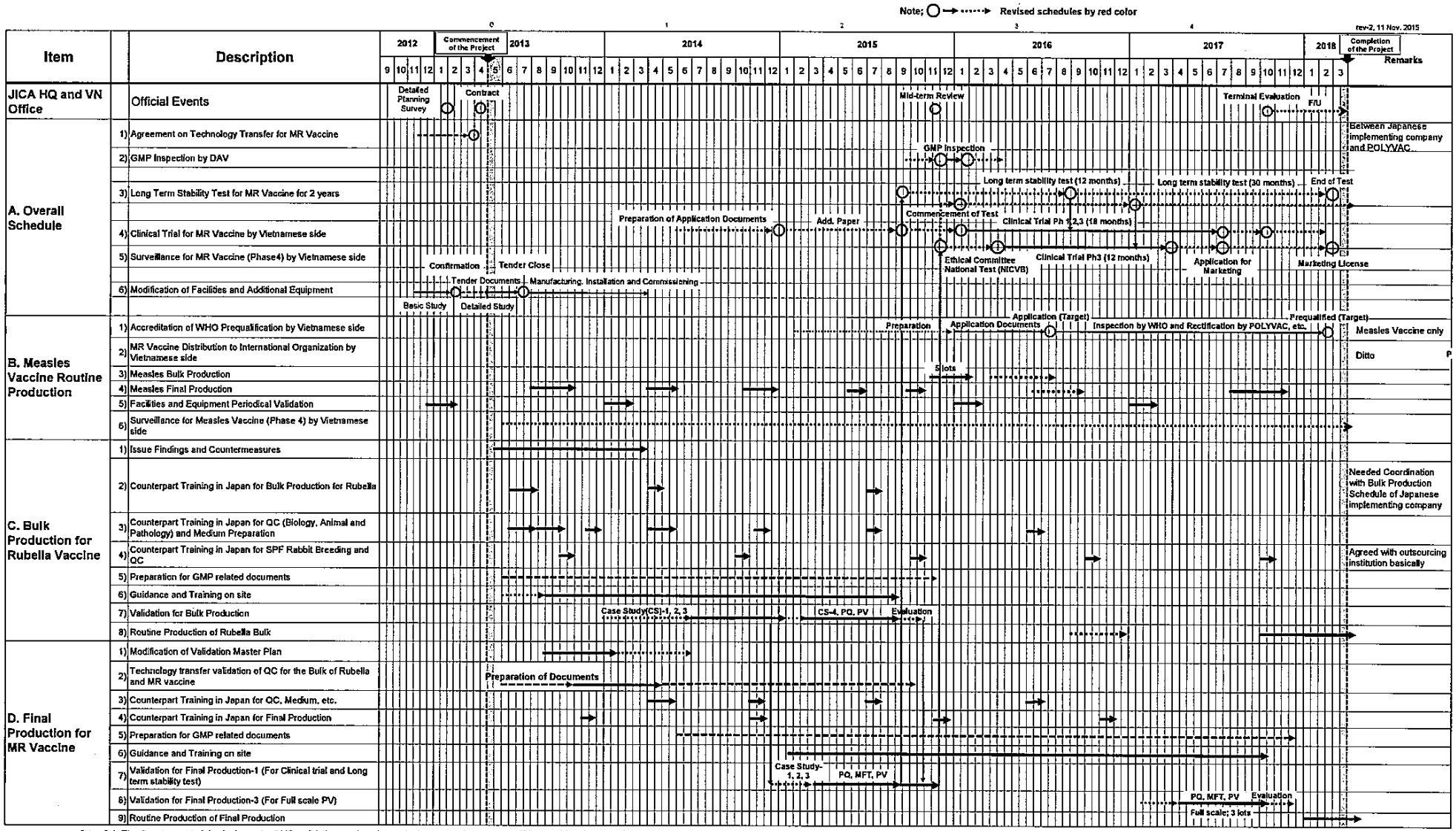
Descriptionof Project	Indicators	Obtainedfrom	Externalfactors
OverallGoal Spread of measles and rubella inViet Nam isdecreased.	1.Number of case of children infected with measles and rubella in Viet Nam is decreased compared with the average between 2009 and 2012. (Measles: 2, 107 cases, Rubella: 3,710cases)*[1] 2.Coverage rate of children immunized with MR vaccine in Viet Nam is at or above95%.	1. Statistical data ofthe Ministry ofHealth 2. Statistical data ofthe Ministry ofHealth	・Public healthactivitiesin Viet Namare strengthened.
ProjectPurpose Measles-Rubella combined vaccine (MR vaccine) conforming to internationalstandard (WHO-cGMP)is produced by POLYVAC.	Marketing license of MR vaccine is issued by Viet NamNRA.	Document on clearance issued by Viet NamNRA	・EPI activitiesarecontinued asnational priority program in healthsector. ・Policy on utilizationofvaccines producedin Viet Nam is not changed. ・MR vaccine supplyandEPI are conducted uneventfully.
Outputs 1. POLYVAC has propertechnical capabilities as a manufacturer of MRvaccine.	1-1 Staff of POLYVAC has acquired sufficient technical level (i.e. level 4 *) for each process of MR vaccine production and quality control. (There are 200 processes approximately in total.) (*level 4: be able to work properly by himself/herself and cantrain otherstaff) 1-2 Equipment, apparatus, raw materials, spare parts and consumables for production of MR vaccine are properly utilized andmaintained.	1-1 Evaluation records on technical level ofstaff ofPOLYVAC 1-2 Appropriateness of inventory control and maintenance.	・GMP inspectioniscarried out at POLYVAC by Viet NamNRA.
2. POLYVAC can produce MR vaccine properly complying with WHO-cGMP.	2-1 GMP documents complying with WHO-cGMP areprepared. 2-2 Production process and QC tests are executed complying with prepared GMP documents. 2-3 Validations complying with WHO-cGMP are conducted periodically byPOLYVAC. 2-4 Performance Qualification (PQ) and Process Validation (PV) are executed as scheduled.	2-1 GMPdocuments 2-2 Records of production and QC tests 2-3 Records of validation activities 2-4 Records of activities onPQ andPV	

*[1] 2009-2011: Vaccine Preventable Diseases Monitoring (WHO), 2012: Measles-Rubella Bulletin(WHO/WPRO)

Activities	Input		
1. POLYVAC has proper technical capabilities as a manufacturer of MR vaccine. 1-1 Conduct technical transfer on production of rubella vaccine bulk through the processing of producing vaccine bulk from the seedvirus. 1-2 Conduct technical transfer on final bulk composition, filling, freeze-dry through the process of producing MRvaccine. 1-3 Conduct technical transfer on quality control of theproducts. 1-4 Collect and examine Information for lowering unit production cost of MRvaccine. 2. POLYVAC can produce MR vaccine properly complying withWHO-cGMP. 2-1 Establish validation system for the production and quality control, and strengthen the validation skill of thestaff. 2-2 Establish and implement quality assurance functions complying with WHO-cGMPstandard. 2-3 Prepare andimplement necessary SOPs forthe process of production, storage, carrying in/out of the products, etc. 2-4 Conduct technical transfer on preparation of documents that need to meet WHO-cGMP standard and to be approved by NRA. 2-5 Conduct PQ/PV for vaccine production from seedvirus. 2-6 Provide necessary advices on clinical trial on MR vaccine under management of Vietnameseside.	<Japan> ***1. JICAExperts*** (1)Chief Advisor/ Vaccine Production (2) Bulk Production (3)HistopathologicalExamination (4) FinalProduction (5) Quality Control (6)Management of Experimental Animals (7) QualityAssurance (8) GMP (9) Validation (10) Facility Management (including Third CountryExperts) Other necessaryfields. ***2. Full-time projectstaff*** (1) Secretary (2) Interpreter ***3. Training inJapan*** (1) Productionmanagement (2) Qualitymanagement ***4. Modification of facilities*** Modification of the facilities in the filling room on 1F and the disinfection room/ changing room (IN) on 2F of the production building ***5. Provision of equipment and materials*** (1) Equipment forvalidation (2) Equipment fortechnical activities on vaccine production and quality assurance (3) Other equipmentmutually agreed upon asnecessary ***6. Localcost*** (1) Training textbooksand materials (2) Running expenses ofthe projectoffice	<Viet Nam> ***1. Counterparts*** POLYVACStaffs (1) Director (2) DeputyDirector (3) QA Manager (4)ProductionManager (5) QCManager (6) Pathologists (7)ProductionUnit Staff (8)Quality Management Unit staff (9) EngineeringStaff ***2. Equipment and materials*** (1) Stationary (2) Consumables for Vaccine Production and QualityControl (3) Workingseed (4) Biologicalmaterials ***3. Local cost*** Maintenancefor equipment ***4. Others*** Project office for JapaneseExperts	- Most of trainedstaff keeps working atPOLYVAC. **Pre-condition** Personnel distribution from C/P(Counterpart)

Note: GMP: Good Manufacturing Practice, NRA: National Regulatory Authority, SOPs: Standard Operating Procedures, PQ: Performance Qualification, PV: ProcessValidation

Overall Schedule (Revision-2)



【Note】 1. The Counterpart training in Japan for GMP, validation, engineering and other supporting systems will be considered separately.

Technical Cooperation Project for Strengthening Capacity for MR Combined Vaccine Production

Dispatch Record of Experts in FY2013 (第1年次 専門家派遣実績)

Legend: ——: Confirmed Schedule; ——: This application; ·····: Plan

Rev.: 9 Date: 28-Feb-14

No.	Category	Description	PIC	Class	Total days (Vietnam Plan / Actual / Balance; Japan Plan / Actual / Balance)	Total Trips (Plan / Actual / Balance)	Remarks
2	Management	総括 岡部正晴	Project Director	Masahiro Okabe	2	11 / 4 / -7	4 / 4 / 0	2 / 1 / -1	
		副総括 荒井節夫	Deputy PJ Director	Setsuo Arai	3	7 / 7 / 0	2 / 2 / 0	1 / 1 / 0	
		副総括 李 富雄	Deputy PJ Mger/ Production	Tomio Lee	3	133 / 141 / 8	28 / 31 / 5	8 / 8 / 2	
			Engineering, Project Coordination/Management	Shuzo Ishikawa	3	147 / 141 / -6	28 / 29 / 3	6 / 7 / 1	
			QC Mger	Kenichi Baba	3	70 / 64 / -6	48 / 40 / -8	4 / 3 / -1	Coordination on CPs
			Administration(1)	Yasuhiro Tsuchida	3	7 / 7 / 0	2 / 2 / 0	1 / 1 / 0	
			Administration(2)	Miki Tamura	3	39 / 39 / 0	6 / 6 / 0	3 / 3 / 0	
			GP training adml.	Miki Tamura	5	62 / 62 / 0			
3	QA/GMP/ Validation		GMP/Validation (1)	Shigemitsu Hirayama	3	50 / 50 / 0	85 / 85 / 0	4 / 4 / 0	Preparation of GMP Doc. in Japan
			Quality Assurance (1) /GMP/Validation (2)	Takanori Nakashima	3	85 / 85 / 0	65 / 65 / 0	6 / 6 / 0	Ditto
			Quality Assurance (2)	Tetsuo Nakayama	3	7 / 7 / 0	2 / 2 / 0	1 / 1 / 0	
		Antibody Test	Quality Assurance (3)		3	0 / 0 / 0	0 / 0 / 0	0 / 0 / 0	
		Total Adviser	WHO-GMP	Tsuguo Sasaki	3	21 / 21 / 0	6 / 8 / 0	2 / 2 / 0	
4	BP	Rubella	Bulk Production	Hiroki Katsuda	5	35 / 39 / 4	9 / 6 / -3	3 / 2 / -1	
5	FP	MR Vaccine	Final Production(1)	Shuichi Baba	3	14 / 14 / 0	3 / 3 / 0	1 / 1 / 0	-
6	QC	Pathology	Quality Control (1)	Manabu Ikeda	3	56 / 64 / 8	12 / 12 / 0	4 / 4 / 0	
		Biological	Quality Control (2)	Yoshihisa Takeda	3	21 / 21 / 0	6 / 6 / 0	2 / 2 / 0	
		Animal Test	Quality Control (3)	Toshio Kosugi	3	21 / 21 / 0	9 / 9 / 0	3 / 3 / 0	
		Animal Breeding	Quality Control (4)	Kuniji Ito	3	21 / 22 / 1	6 / 6 / 0	2 / 2 / 0	
7	MP	Rubella/MR Vaccine	Medium Preparation		3				
8	Facilities Validation / Engineering	Facilities/Equipment General	Facilities/Equipment Validation	Shuzo Ishikawa	3	28 / 35 / 7	3 / 3 / 0	1 / 1 / 0	
		HVAC(1)	Facilities Validation (1)	Yasushi Matsumoto	3	14 / 14 / 0	2 / 2 / 0	1 / 1 / 0	
		HVAC(2)	Facilities Validation (2)	Atsushi Shibata	4	7 / 7 / 0	2 / 2 / 0	1 / 1 / 0	
		Process Water	Equip Validation (1)	Hirohisa Kajioka	3	14 / 14 / 0	2 / 2 / 0	1 / 1 / 0	
		Autoclave	Equip Validation (2)	Kaoru Tomiyama	3	7 / 7 / 0	2 / 2 / 0	1 / 1 / 0	
		Vial Washing (Mechanical)	Equip Validation (3)	Haruo Hirose	3	7 / 7 / 0	2 / 2 / 0	1 / 1 / 0	
		Vial Washing (Electrical)	Equip Validation (4)	Kazuhiro Iwai	3	7 / 7 / 0	2 / 2 / 0	1 / 1 / 0	
		Filling Machine	Equip Validation (5)	Keisuke Suzuki	5	7 / 0 / -7	2 / 0 / -2	1 / 0 / -1	
		Freeze Dryer	Equip Validation (6)	Shigeru Iwami	3	14 / 14 / 0	2 / 2 / 0	1 / 1 / 0	
		Laminar/Clean bench/Safety cabinet	Equip Validation (7)	Yukihiro Motoki	3	14 / 14 / 0	2 / 2 / 0	1 / 1 / 0	
		Calibration	Equip Validation (8)	Kaname Hirose	3	14 / 14 / 0	2 / 2 / 0	1 / 1 / 0	
9		Summary				878 / 880 / 2	400 / 397 / -3	62 / 61 / -1	
						28.27 / 100.2%	20.00 / 99.3%		98.4%	Man-Month, %

Technical Cooperation Project for Strengthening Capacity for MR Combined Vaccine Production(Term 2)

Detailed Plan in FY2014 (2nd Year)

Dispatch Record of Experts in FY2014 (第2年次専門家派遣実績)

No.	Category	Description		PIC	Class	Apr 2014	May 2014	Jun 2014	Jul 2014	Aug 2014	Sep 2014	Oct 2014	Nov 2014	Dec 2014	Jan 2015	Feb 2015	Mar 2015	Total days Vietnam Plan	Vietnam Actual	Vietnam Balance	Total days Japan Plan	Japan Actual	Japan Balance	Total Trips Plan	Total Trips Actual	Total Trips Balance	Remarks
						1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W										
													New Year			TET										
	Dispatch of Experts	総括 荒井 節夫	PJ Manager	Setsuo Arai	2							7 (C/S–JC/12)						11	7	-4	7	7	0	1	1	0	
4	Management	副総括 李 富雄	Deputy PJ Mger/Production	Tomio Lee	3		18 (5/14–6/7)	7 (6/7–7/5)	11 (7/15–7/25)	2 (7/30–8/1) 10 (8/22–9/2) 6 (9/25–10/5)	7 (9/14–9/20)	14 (10/5–10/18)		8 (12/1–12/8) 16 (12/8–12/24)		8 (2/4–2/11)	21 (3/1–3/21)	126	128	2	19	27	8	6	9	3	
			QC Mger	Kenichi Baba	3						14 (9/7–9/20)							56	14	-42	30	21	-9	4	1	-3	Coordination on CPs
			Administration Mger	Yasuhiro Tsuchida	3							7 (10/5–JC/11)						7	7	0	2	2	0	1	1	0	
			Deputy Administration Mger	Miki Tamura	3	11 (4/20–4/30)					3 (9/28–10/1)	11 (10/1–JC/11)						36	25	-11	6	4	-2	3	2	-1	
			Administration for C/P Training	Miki Tamura	5																38	38	0				
5	QA/GMP/ Validation		GMP/Validation (1)	Shigemitsu Hirayama	3			11 (6/1–6/11)										22	11	-11	20	28	8	2	1	-1	Preparation of GMP Doc. in Japan
			Quality Assurance (1) /GMP/Validation (2)	Takanori Nakashima	3													28	0	-28	20	5	-15	2	0	-2	Ditto
			GMP/Validation (3)	Mika Mizuta	3			11 (6/5–6/18)			12 (9/8–9/19)			8 (12/1–12/8) 5 (12/8–12/12)			13 (3/2–3/14)	22	49	27	30	36	6	2	4	2	Ditto
			Quality Assurance (2)	Tetsuo Nakayama	3						6 (9/8–9/13)			5 (12/9–12/13)				14	11	-3	6	6	0	2	2	0	
		Antibody Test	Quality Assurance (3)	to be informed	3														0					0	0	0	
		Total Adviser	WHO-GMP	Tsuguo Sasaki	3			9 (6/22–7/5) 5							14 (1/18–1/31)			28	28	0	6	6	0	2	2	0	
6	BP	Rubella	Bulk Production	Hiroki Katsuda	4		12 (5/22–6/1) 3 (6/1–6/3)			14 (8/10–8/23)	14 (9/7–9/20)		15 (11/11–11/25)			14 (3/1–3/14)		58	72	16	12	15	3	4	5	1	
7	FP	MR Vaccine	Final Production(1)	Shuichi Baba	3			14 (6/1–6/14)						14 (12/14–12/27)				28	28	0	6	6	0	2	2	0	
			Final Production(2)	Kunihiko Komuro	3								7 (11/16–11/22)					7	7	0	3	3	0	1	1	0	
8	QC	Pathology	Quality Control (1)	Manabu Ikeda	3	7 (4/13–4/19)			14 (7/13–7/25)	14 (8/3–8/15)				1 (11/30) 20 (12/1–12/20)			14 (3/1–3/14)	70	70	0	15	15	0	5	5	0	
		Biological	Quality Control (2)	Yoshihisa Takeda	3	7 (4/20–4/28)	7 (5/11–5/17)				7 (9/14–9/20)							35	21	-14	15	9	-6	5	3	-2	
		Animal Test	Quality Control (3)	Toshio Kosugi	3	7 (4/13–4/19)	7 (5/18–5/24)					11 (10/12–10/22)						35	25	-10	15	9	-6	5	3	-2	
		Animal Breeding	Quality Control (4)	Kunji Ito	3		7 (5/13–5/19)			1 (8/31–9/1) 6 (9/1–9/6)								14	14	0	6	6	0	2	2	0	
9	MP	Rubella/MR Vaccine	Medium Preparation		3																						
	Management		Engineering/Project Coordination	Shuzo Ishikawa	3	21 (4/10–4/30)		9 (6/22–7/2) 12 (7/2–7/12)		14 (8/17–8/30)	14 (9/1–9/14)	11 (10/1–10/11) 6 (10/25–11/5) 5 (11/5–11/11)		11 (12/1–12/11)	17 (1/7–1/23)		14 (3/15–3/28)	126	134	8	18	21	3	6	7	1	
10	Facilities Validation / Engineering	Facilities/Equipment General	Facilities/Equipment Validation		3											13 (2/1–2/13)		21	13	-8	3	3	0	1	1	0	
		HVAC(1)	Facilities Validation (1)	Yasushi Matsumoto	3													7	0	-7	2	0	-2	1	0	-1	
		Process Water	Equip Validation (1)	Hirohisa Kajioka	3							6 (10/25–11/1) 1						7	7	0	2	2	0	1	1	0	
		Autoclave	Equip Validation (2)	Kaoru Tomiyama	3			2 (6/23–7/5) 5										7	7	0	2	2	0	1	1	0	
		Vial Washing (Mechanical)	Equip Validation (3)	to be informed	3													7	0	-7	2	0	-2	1	0	-1	
		Vial Washing (Electrical)	Equip Validation (4)	to be informed	3													7	0	-7	2	0	-2	1	0	-1	
		Filling Machine	Equip Validation (5)	Yoshihiko Kasuya	3			14 (5/1–5/14)										7	14	7	2	2	0	1	1	0	
		Freeze Dryer	Equip Validation (6)	Shigeru Iwami	3			14 (5/1–5/14)				6 (10/25–11/1) 1						14	21	7	2	4	2	1	2	1	
		Laminar/Clean bench/Safety cabinet	Equip Validation (7)	Yukihiro Motoki	3													7	0	-7	2	0	-2	1	0	-1	
		Calibration	Equip Validation (8)	Kaname Hirose	3												6 (3/23–3/28)	7	6	-1	2	2	0	1	1	0	
		Filling and Capping Machines	Equip Validation (9)	Yoshikazu Takahashi	5									1 (11/30–12/1) 6				0	7	7	0	2	2	0	1	1	
11			Summary															812	726	-86	293	277	-16	65	59	-6	
																		27.07	89.4%		14.65	94.5%			90.8%		Man-Month
12	Report						△ TT/P					△ FR/R		△ F/R													

Technical Cooperation Project for Strengthening Capacity for MR Combined Vaccine Production(Term 2)

Detailed Plan in FY2015 (3rd Year)

Dispatch Record of Experts until the end of September in FY2015 (第3年次9月末までの専門家派遣実績)

Legend: ——— ; Confirmed Schedule ——— ; This application ..... ; Plan

rev-16 Date: 05 October 2015

No.	Category	Description		PIC	Class	Apr 2015	May 2015	Jun 2015	Jul 2015	Aug 2015	Sep 2015	Oct 2015	Nov 2015	Dec 2015	Jan 2016	Feb 2016	Mar 2016	Total days Vietnam Plan	Vietnam Actual	Vietnam Balance	Total days Japan Plan	Japan Actual	Japan Balance	Total Trips Plan	Total Trips Actual	Total Trips Balance	Remarks
						1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W 4W	1W 2W 3W										
													JCC No.3 27 Nov.	New Year		TET (08 Feb.)										
1	Management	総括 荒井 耕夫	PJ Manager	Setsuo Arai	2								11/22 8 11/29					11	0	-11	11	4	-7	1	0	-1	
		副総括 李 富雄	Deputy PJ M'ger/Production	Tomio Lee	3	4/1 20 2	5/2 1 5/21	27 6/27	7/15 13 7/31	8/16 16 18	8/18		11/22 9 7 12/7		14	14		163	97	-66	22	13	-9	7	4	-3	
			QC M'ger	Kenichi Baba	3			6/21 10 4 7/4										14	14	0	12	8	-4	1	1	0	Coordination on CPs
			Administration M'ger	Yasuhiro Tauchida	3								11/22 8 11/29					7	0	-7	2	0	-2	1	0	-1	
			Administration	Miki Tamura	3	4/8 11 4/18							11/15 15 11/29			11		36	11	-25	6	2	-4	3	1	-2	
			Administration for C/P Training	Miki Tamura	5																43	26	-17				
2	QA/GMP/ Validation		GMP/Validation (1)	Shigemitsu Hirayama	3											14		11	0	-11	12	8	-4	1	0	-1	Preparation of GMP Doc. in Japan
			Quality Assurance (1) /GMP/Validation (2)	Mika Mizuta	3			6/29 2 9 7/8			9/8 14 9/19			14				33	25	-8	10	10	0	3	2	-1	Ditto
			Quality Assurance (2)	Tetsuo Nakayama	3								11/16 6 11/21		7			14	0	-14	6	0	-6	2	0	-2	
		Antibody Test	Quality Assurance (3)	to be informed	3								6		7			14	0	-14	6	0	-6	2	0	-2	
		Total Adviser	WHO-GMP	Tsuguo Sasaki	3					8/22 9 5 8/26					14			28	14	-14	6	3	-3	2	1	-1	
3	BP	Rubella vaccine bulk	Rubella Vaccine Bulk Production	Hiroki Katsuda	4													14	0	-14	2	0	-2	1	0	-1	
4	FP	MR Vaccine	Final Production(1)	Shuichi Baba	3							11/1	14 11/14					28	0	-28	4	0	-4	2	0	-2	
		MR Vaccine	Final Production(2)	Kuniaki Komuro	3				7/26 6 1 8/1					7				14	7	-7	4	2	-2	2	1	-1	
5	QC	Pathology	Quality Control (1)	Manabu Ikeda	3	4/12 14 4/25		6/21 10 4 7/4		8/5 21 8/25				14		7		70	49	-21	10	6	-4	5	3	-2	
		Biological	Quality Control (2)	Yoshihisa Takeda	3			6/24 3 4 7/4				10/4 7 10/10						21	7	-14	6	2	-4	3	1	-2	
		Animal Test	Quality Control (3)	Toshio Kosugi	3					8/5 7 8/15								21	7	-14	6	2	-4	3	1	-2	
		Animal Breeding	Quality Control (4)	Kunijl Ito	3		5/10 7 5/16											0	7	7	0	3	3	0	1	1	
6	MP	Facilities/Equipment General	Medium Preparation		3																					
7	Management /Engineering		Project Management and Engineering	Shuzo Ishikawa	3	4/8 18 4/25			7/2 14 7/16	8/16 16 13 8/15		11/1	29	11/29	21	15		126	61	-65	18	9	-9	6	3	-3	
8	Facilities and Equipment Validations	Facilities/Equipment General	Facilities/Equipment Validation		3		5/21 1 20 6/20											21	21	0	3	3	0	1	1	0	
		HVAC(1)	Facilities Validation (1)	Yasushi Matsumoto	3													7	0	-7	1	0	-1	1	0	-1	
		HVAC(2)	Facilities Validation (2)	Atsushi Shibata	4													0	0	0	0	0	0	0	0	0	
		Process Water	Equip Validation (1)	Hirohisa Kajioka	3													0	0	0	0	0	0	0	0	0	
		Autoclave	Equip Validation (2)	Kaoru Tomiyama	3													0	0	0	0	0	0	0	0	0	
		Vial Washing (Mechanical)	Equip Validation (3)	Hiroki Takahashi	5				7/2 12 7/16									7	12	5	2	2	0	1	1	0	
		Vial Washing (Electrical)	Equip Validation (4)	Atsushi Kobayashi	3				7/2 12 7/16									7	12	5	2	2	0	1	1	0	
		Filling Machine	Equip Validation (5)	Yoshihiko Kasuya	3													0	0	0	0	0	0	0	0	0	
		Freeze Dryer	Equip Validation (6)	Shigeru Iwami	3													0	0	0	0	0	0	0	0	0	
		Laminar/Clean bench/Safety cabinet	Equip Validation (7)	Yutchiro Motoki	3											7		0	0	0	0	0	0	0	0	0	
		Calibration	Equip Validation (8)	Kaname Hirose	3													0	0	0	0	0	0	0	0	0	
		Filling and Capping Machines	Equip Validation (9) Additional	Yoshikazu Takahashi	5				7/26 6 1 8/1									0	7	7	0	2	2	0	1	1	
		Vial Washing Machine (Total)	Equip Validation (10) Additional	Takeshi Yamaguchi	3				7/2 12 7/16									0	12	12	0	2	2	0	1	1	
9		Summary																567	363	-204	134	109	-25	43	24	-25	Original Contract in FY2015: 581days, 176trips. Revised Contract in FY2015: 567days, 134days, 49trips
																		22.33	64.4%		8.70	64.2%			49.0%	

Modification of Facilities in POLYVAC

JFY	Particulars	Thousand JPY
2013	Renovation for Bulk Production of Rubella Vaccine	19,400
2014	Renovation for complying with WHO-cGMP	28,900
2015	-	0
TOTAL		48,300

ベトナム国麻疹風疹混合ワクチン製造技術移転プロジェクト

本邦研修実績リスト（2013年6月～2015年8月）

Updated on 31/8/2015

No.	Full name	Position	Training Schedule	Days
1	Nguyen Xuan Hoa	Bulk Dept	23/06-21/08/2013	60
2	Pham Thanh Truong	Bulk Dept	23/06-21/08/2013	60
3	Ngo Thu Huong	QC Dept	23/06-21/08/2013	60
4	Pham Thi Thuoc	QC Dept	23/06-21/08/2013	60
5	Ngo Thu Huong	QC Dept	16/09-09/11/2013	55
6	Pham Thi Thuoc	QC Dept	16/09-09/11/2013	55
7	Cao Xuan Ngoc	QC Dept	16/09-09/11/2013	55
8	Ngo Thi Thanh Huong	QC Dept	16/09-09/11/2013	55
9	Pham Huu Tien	QC Dept (SPF rabbit)	14/10-09/11/2013	27
10	Le Van Duy	QC Dept (SPF rabbit)	14/10-09/11/2013	27
11	Nguyen Thuy Huong	QA Dept	17/11-14/12/2013	28
12	Tran Thi Phuong	QA Dept	17/11-14/12/2013	28
13	Le Quoc Hung	Final Production Dept	17/11-14/12/2013	28
14	Nguyen Dang Quynh	Final Production Dept	17/11-14/12/2013	28
15	Le Tuan Anh	Medium Preparation Dept	17/11-14/12/2013	28
16	Lai Quynh Mai	Bulk Dept	06/04-03/05/2014	28
17	Pham Van Khoi	Bulk Dept	06/04-03/05/2014	28
18	Nguyen Thi Nguyet	QC Dept	06/04-03/05/2014	56
19	Vu Thi Huong	QC Dept	06/04-03/05/2014	56
20	Pham Thi Phuong Thao	QA Dept	06/05-31/05/2014	26
21	Tran Thi Phuong	QA Dept	06/05-31/05/2014	26
22	Pham Huu Tien	QC Dept (SPF rabbit)	12/10-08/11/2014	27
23	Le Tuan Anh	Medium Dept	24/11-20/12/2014	27
24	Nguyen Huy Truong	Final Production Dept	24/11-20/12/2014	27
25	Nguyen Dinh Khiem	QC Dept	24/11-20/12/2014	27
26	Le Thu Nga	QA Dept	05/07-01/08/2015	28
27	Le Thi Hoa	QA Dept	05/07-01/08/2015	28
28	Vu Thi Mai	Bulk Dept	05/07-01/08/2015	28
29	Pham Anh Thu	QC Dept	05/07-01/08/2015	28
合計	延べ人数(人); 29		延日数(日);	1,094

EQUIPMENT LIST BY JICA IN FY2013

Lot	Component					
	No.	Equipment name	Quantity	Unit	Model	
					Reference	Designation
A	1	Compressor for compressed air supply system	2	sets	N/A	Kobelco FE200A-5 6A01P00202F2
Total			**2**	**sets**	**419,827,490 VND**	**1,955,976 JPY**
B	1	Calibration Kit	1	set	N/A	1885 Calibration system kit - Code: 58082010 5000 TOCe System Suitability Te - Code: 58091559
Total			**1**	**set**	**10,556 USD**	**1,037,170 JPY**
C	1	Particle counter	3	sets	HACH A2400	N/A
	2	Particle counter for Animal Lab	1	set	N/A	PMS Lasair III-310B
	3	Air sampler	3	sets	SATORIUS MD8	N/A
Total			**7**	**sets**	**71,820 USD**	**7,056,610 JPY**
D	1	Deep Freezer for BP	4	sets	PANASONIC MDF-U74V	N/A
	2	Deep Freezer for QC	1	set	PANASONIC MDF-U582	N/A
	3	Electronic Balance for Rabbit with Printer	2	sets	SHIMADZU BW12KH	N/A
	4	Rabbit breeding cage	3	sets	Local manufacturer	N/A
	5	Stirrer	1	set	IKA Eurostar 20 Digital	N/A
	6	Liquid nitrogen stocker	1	set	TAYLOR WHARTON LS-3000	N/A
	7	Refrigerator for wasted animals	1	set	YAMATO 231CD or PANASONIC NRBY602XS	N/A
	8	Silicon tube for MP	2	sets	COLE PARMER HV96420-36	N/A
Total			**15**	**sets**	**87,513 USD**	**8,598,511 JPY**
E	1	Pooling tank SUS 10L for BP	68	sets	Nitto Kinzoku SUS316L - 10L, 280x100x500mm (attached drawing)	N/A
	2	Gaskets for 70L Pooling tank	1	set	N/A	IKEMOTO Φ185mmx2, Φ34mmx6
	3	Sensors for Egg Incubator	1	set	N/A	Showa Furanki PPS-03
	4	Heat proof strings for Autoclave	1	set	Marufuji Karauchi-himo	N/A
	5	Roux bottle for QC	30	sets	Sanwa Rika	N/A
	6	Rotor for Cooled centrifuges	1	set	N/A	Kokusan RF-124T
	7	Dispenser 100mL	1	set	Toyo Riko JH-1x2	N/A
	8	Dispenser 10mL	1	set	Toyo Riko JA-1	N/A
Total			**104**	**sets**	**96,030 USD**	**9,813,690 JPY**

TH

Lot	Component					
	No.	Equipment name	Quantity	Unit	Model	
					Reference	Designation
F	1	Rubber stopper for Siphon	20	sets	N/A	N/A
	2	Silicon tube for Filling machine 8mmx10m	5	sets	N/A	N/A
	3	Clean shoes	60	sets	Goldwin PA9680P + PA5600	N/A
	4	Clean wear (Garment)	10	sets	Goldwin PP1940	N/A
	5	Finn pipette	1	set	Thermo Scientific 8 Nos. of piptes with Stepper	N/A
	6	Recorder for Freezer (Chino)	2	sets	Chino EH3D67-000	N/A
	7	Recorder for Freezer (Yokogawa)	1	set	Yokogawa μR20000(437112) HC-100	N/A
	8	Alcohol spray machine for hand washing	2	sets	AS ONE HDI - 2002	N/A
	9	Digital single-lens reflex camera (pathology)	1	set	N/A	OLYMPUS OM-D E-M5 with Accessories
	10	Compressor	1	set	AS ONE J1-16666	N/A
Total			**103**	**sets**	**22,465 USD**	**2,295,788 JPY**
G	1	Silicon tube with SUS adaptor-1	1	set	Advanta pure APSH-P1000 ID x 1405OD 1,600mm	N/A
	2	Silicon tube with SUS adaptor-2	1	set	Advanta pure APSH-P1000 ID x 1405OD 600mm	N/A
	3	Silicon tube with SUS adaptor-3	1	set	Advanta pure APSH- P500 ID x 875OD	N/A
	4	Silicon tube with SUS adaptor-4	1	set	Pure Gard FPD 100-HP	N/A
	5	Frame type working table set	1	set	N/A	N/A
	6	Fluorescent type task lamp	2	sets	N/A	N/A
	7	Collection tank 20L (pathology)	2	sets	N/A	N/A
	8	Digital timer	1	set	A&D AD-5713	N/A
	9	Cart for transportation	1	set	N/A	N/A
	10	Disinfectant Vat	6	sets	N/A	N/A
	11	Circulation pump for WFI production system	1	set	N/A	Alfa Laval LKH-25 (designated)
Total			**18**	**sets**	**16,506 USD**	**1,621,782 JPY**
H	1	Vacuum cleaner with HEPA filter for Clean room	1	set	Philips FC9228	N/A
	2	Automated plate preparation system	1	set	Labcompare Microbiology International Media fill / stack 220	N/A
	3	Pipette aid	4	sets	Corning	N/A
	4	Filtration and Sterilization system for drinking water for animal	2	sets	Local manufacturer	N/A
Total			**8**	**sets**	**38,926 USD**	**3,824,639 JPY**
Grand Total (A-H)			**258**	**sets**	**USD**	**36,204,166 JPY**

List of Equipment in the Contract (FY2013)

10-Sep-15
KDSV

No.	Name of Equipment	Model No.	Q'ty	Price
CE-1301	Autopsy Tool Set	Combination set	1 set	80,000
CE-1302	Surgical Set-BP	Ditto	1 set	620,000
CE-1303	Printing Thermometer	AP-800ES	1 set	100,000
CE-1304	Pooling Tank for Bulk	KDSV Special(10L)	12 sets	900,000
CE-1305	CO2 Incubator	MCO-19AIC-PE	1 set	630,000
CE-1306	Tissue Embedding System	Tissue-Tek TEC5	1 set	1,570,000
CE-1307	Automatic Tissue Processor	Tissue-Tek VIP 5 Jr	1 set	3,880,000
CE-1308	Paraffin Oven	PM-401-II	1 set	670,000
CE-1309	Microtome	HM430	1 set	1,020,000
CE-1310	Tissue Floating Water Bath	PS-110WH	1 set	130,000
CE-1311	Slide Warmer	PS-53	1 set	190,000
CE-1312	Camera System for the Microscope, BX-53	DP-73 etc.	1 set	1,210,000
CE-1313	Surgical Set-PT	Combination set	1 set	110,000
CE-1314	Rabbit Breeding Rack	NIH Standard w/Drawing	1 set	1,050,000
CE-1315	Clinical Thermometer	D717	1 set	180,000
CE-1316	Hair Clipper	Golden A5	1 set	60,000
CE-1317	Fixing Board	KDSV Special	1 set	200,000
CE-1318	Surgical Set-AL	Combination set	1 set	320,000
	Total		18 sets	**12,920,000**

(Not including Transportation Fee)

List of Equipment in the Contract (FY2014-FY2015)

10-Sep-15
KDSV

1. 1st Procurement in FY2014

No.	Name of Equipment	Model No.	Q'ty	Price
CE-1401	Cooled Centrifuge	H-60R	1 set	725,000
CE-1402	Hybrid Memory Recorder	AH4706-N0A-NNN	1 set	238,000
CE-1402	Metal-sheathed resistance thermometer sensor	NRHS1-0	6 sets	93,600
CE-1402	Inspection certificate with certificate for CE-1402	-	2 sets	14,400
	Sub Total		2 sets	**1,071,000**

2. 2nd Procurement in FY2014

No.	Name of Equipment	Model No.	Q'ty	Price
CE-1403	PH Meter	D-71S	1 set	153,900
CE-1403	Electrode for pH Meter	9625-10D	1 set	31,500
	Sub Total		1 set	**185,400**

3. 3rd Procurement in FY2014

No.	Name of Equipment	Model No.	Q'ty	Price
CE-1404	Mist Generator	ACV-500	1 set	343,000
	Sub Total		1 set	**343,000**

4. 1st Procurement in FY2015

No.	Name of Equipment	Model No.	Q'ty	Price
CE-1501	Formalin Fumigator	NABA T100G	1 set	605,000
CE-1502	Formalin Neutralizer	FOT2000	1 set	2,625,000
CE-1503	TOC Analyzer	GE USA	1 set	4,463,000
	Sub Total		3 sets	**7,693,000**

	Total (FY2014 and FY2015)	7 sets	**9,292,400**

(Not including Transportation Fee)

List of Local Costs provied by Japanese side (FY2013)

(FY2013; May 2013-March 2014)

rev-0, 30 Oct. 2015

Item （Sub topics）	FY2013 Cost (Th. Jyen)	Remarks
①Personnel Cost (General)	780,119	
②Personnel Cost (Special)	5,245,828	
③Car related Cost	0	
④Rental Fee	1,515,925	
⑤Maintenace Cost for Facilities/Equipment	27,594	
⑥Comsumables Cost	7,762,890	
⑦Traveling Cost	0	
⑧Communication / Transportation Costs	555,463	
⑨Documentation Cost	0	
⑩Utilites Cost	0	
⑪Miscellaneous Cost	1,606,149	
Tatal	17, 493, 968	
Total (Rounding off smaller than10 Th. Yen)	17, 490, 000	

List of Local Costs provied by Japanese side (FY2014 and FY2015)

(FY2014; April 2014-March 2015 and FY2015; April-September 2015)

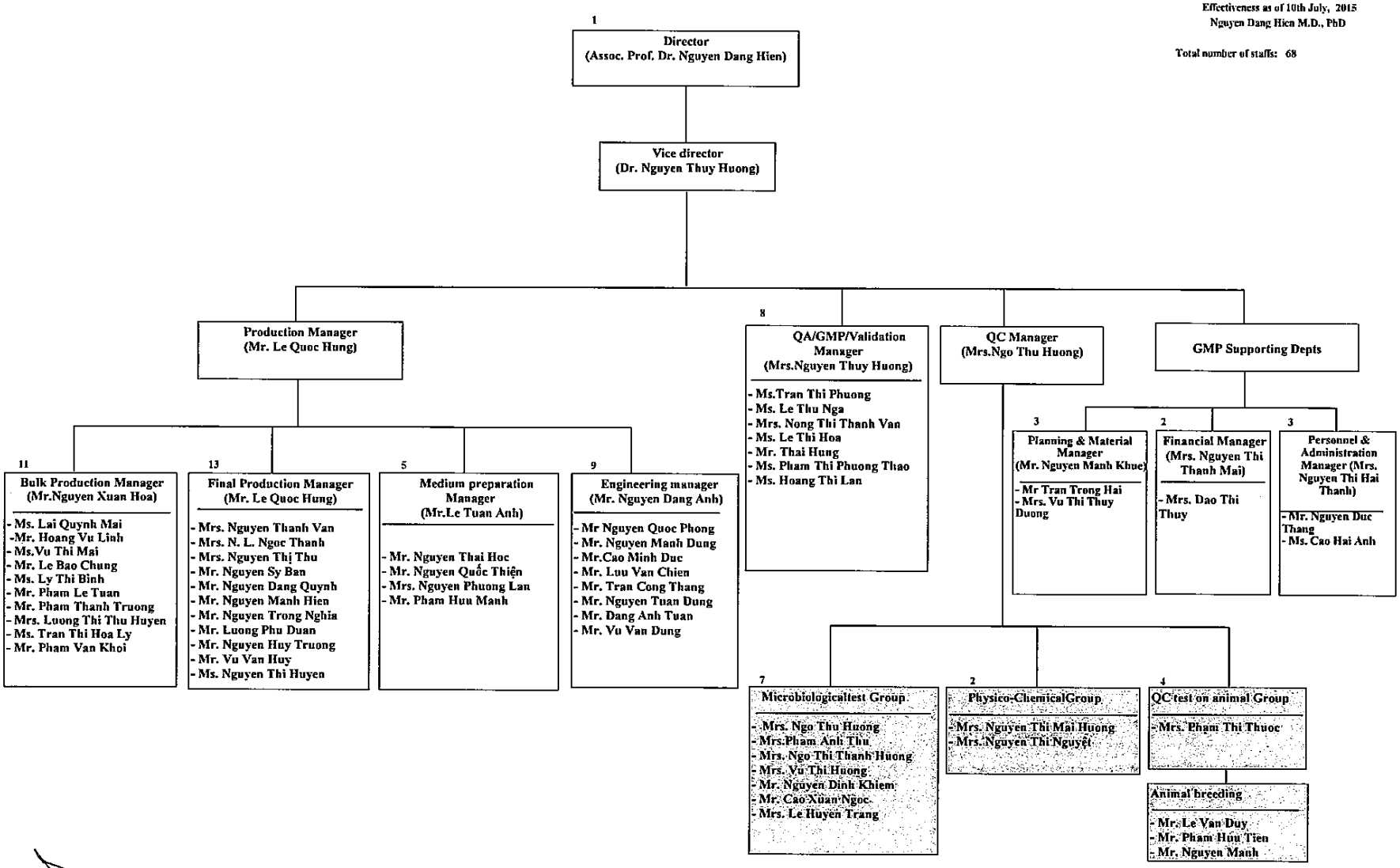
rev-0, 30 Oct. 2015

Item (Sub topics)	FY2014 Cost (Th. JYen)	FY2015 up to Sep. Cost (Th. JYen)	Remarks
①Personnel Cost (General)	0	200,391	
②Personnel Cost (Special)	6,524,418	2,843,220	
③Car related Cost	0	0	
④Rental Fee	1,945,030	741,130	
⑤Maintenace Cost for Facilities/Equipment	2,600	2,680	
⑥Comsumables Cost	1,441,652	1,577,310	
⑦Traveling Cost	0	0	
⑧Communication / Transportation Costs	151,031	83,404	
⑨Documentation Cost	0	0	
⑩Utilites Cost	0	0	
⑪Miscellaneous Cost	26,000	0	
Tatal	10,090,731	5,448,135	
Total (Rounding off smaller than10 Th. JYen)	10,090,000	5,450,000	15,540,000

Organization Chart for Measles-Rubella Combined Vaccine Production

Effectiveness as of 10th July, 2015
Nguyen Dang Hien M.D., PhD

Total number of staffs: 68



LIST OF MATERIALS, EQUIPMENTS AND CHEMICALS FOR MR PROJECT IN 2014
(Supplied by Vietnamese Side)

I Fuel

No.	Items	Quantity	Total Price (VND)	Year
1	Electricity for MVPF	710,000 KWh	1,065,000,000	2014
2	Diesel oil	75,000 L	1,632,696,000	2014
	Total		**2,697,696,000**	

II Equipment for Project Office

1	PC	5	85,995,000	2014
2	Printer	2	10,400,000	2014
3	Laptop	3	54,000,000	2014
	Total		**150,395,000**	

III Membranes, cartridges

1	0.45µm Membrane	1 box	10,120,000	2014
2	Gelatin Membrane	8 boxes	88,440,000	2014
3	0.1µm Membrane	1 box	4,604,000	2014
4	10" (0.65) Housing Cartridge	4 boxes	112,464,000	2014
5	4 inch Housing Cartridge	10 boxes	203,280,000	2014
6	10 inch Housing Cartridge	5 boxes	51,120,000	2014
7	Air filter for Autoclave	5 boxes	36,289,000	2014
8	Novaship Air filter	5 boxes	51,590,000	2014
9	Air filter for 70L tank	3 pcs	39,600,000	2014
10	Air filter for vial washing machine	1 pc	24,300,000	2014
11	Air filters for 70L tank, 200L tank, freeze-dryer	1 pc	31,900,000	2014
12	Air filter for buffer tank (use for WFI production)	1 pc	27,000,000	2014
13	Air filter for siphon	6 pcs	211,800,000	2014
14	WFI filter	1 pc	15,300,000	2014
15	Circle water filter of vial washing machine	1 pc	26,300,000	2014
16	Filter dryer for IT4	1 pc	3,400,000	2014

No.	Items	Quantity	Total Price (VND)	Year
17	Filter dryer for freeze dryer	1 pc	2,000,000	2014
18	Filter for washing machine	1 pc	12,000,000	2014
	Total		**951,507,000**	

III Chemicals, materials, tools for production and verification

	Chemicals for production			
1	Fetal bovine serum	5 tubes	90,150,000	2014
2	Bovine serum	8 tubes	14,000,000	2014
	Chemicals for verification			2014
3	Formaldehyde solution (Cica 1st class)	1 bottle	1,200,000	2014
4	Kit BSA	2 kit	63,480,000	2014
5	LAL Reagent Water (LRW) for TN BSA	2 bottles	6,216,000	2014
6	Aceton	1 bottle	1,066,000	2014
7	Glyxerin	1 bottle	572,000	2014
8	IgG FITC	1 bottle	4,118,000	2014
	Tools			
9	19 L glass bottle	27 bottles	147,015,000	2014
10	9 L glass bottle	20 bottles	54,725,000	2014
11	5 L glass bottle with screw cap	20 bottles	36,080,000	2014
12	1L glass bottle	60 hộp	13,320,000	2014
13	100 ml glass bottle	30 bottles	3,960,000	2014
14	500 ml glass bottle	30 bottles	4,770,000	2014
15	10 ml glass pipette	100 pcs	19,500,000	2014
16	25 ml glass pipette	50 pcs	10,500,000	2014
17	50 ml glass pipette	20 pcs	4,940,000	2014
18	100 ml glass tube	50 pcs	16,250,000	2014
19	20 ml glass tube	50 pcs	2,500,000	2014
20	Electrode for pH meter	2 pcs	22,000,000	2014
21	Electrode for conductivity meter	2 pcs	22,000,000	2014

No.	Items	Quantity	Total Price (VND)	Year
22	Funnel for water microorganism filter	2 pcs	7,268,000	2014
23	Base for membrane of water microorganism filter	1 pc	4,200,000	2014
24	Stopper (of water microorganism filter)	5 pcs	18,600,000	2014
25	Set Myco	1 pc	7,800,000	2014
26	40L tank	2 pcs	100,000,000	2014
	Total		**676,230,000**	

III Sensor

1	Sensor K class 2 for sterilize tunnel	9 ropes	80,730,000	2014
2	Sensor PT 100 for freeze -dryer	25 ropes	191,750,000	2014
3	Pressure sensor for freeze-dryer	2 pcs	120,000,000	2014
	Total		**392,480,000**	
	Grand Total(VND)		**4,868,308,000**	
	Grand Total(JYen)		**26,288,863**	JICA Exchange rate in Oct 2015; 0.0054

LIST OF MATERIALS, EQUIPMENTS AND CHEMICALS FOR MR PROJECT IN 2015
(Supplied by Vietnamese Side)

I Fuel

No.	Items	Quantity	Total Price	Year
1	Electricity for MVPF	395,000 KW	600,000,000	2015
2	Diesel oil	51,000 L	1,132,490,000	2015
	Total		**1,732,490,000**	

II Equipment for Project Office

1	PC	5	80,000,000	2015
2	Printer	2	14,670,000	2015
3	Photocopier	1	72,000,000	2015
	Total		**166,670,000**	

III Membranes, cartridges and chemicals

1	Gelatin membrane	2 boxes	22,040,000	2015
2	10" (0.65) Housing Cartridge	2 boxes	56,200,000	2015
3	4 inch Housing Cartridge	10 boxes	203,000,000	2015
4	Air filter for vial washing machine	1 pc	24,250,000	2015
5	Air filter for 70L tank, 200L tank, freeze-dryer	1 pc	31,850,000	2015
6	Air filter for buffer tank (use for WFI production)	1 pc	26,970,000	2015
7	Air filter for siphon	4 pcs	140,800,000	2015
8	WFI filter	1 pc	15,250,000	2015
9	Circle water filter of vial washing machine	1 pc	26,250,000	2015
10	Filter dryer for IT4	1 pc	3,380,000	2015
11	Filter dryer for freeze dryer	1 pc	1,960,000	2015
12	Filter for washing machine	1 pc	11,940,000	2015
13	Fetal bovine serum	25 tubes	450,500,000	2015
14	Kit BSA	5 kit	158,675,000	2015
15	LAL Reagent Water (LRW) for TN BSA	7 bottles	21,700,000	2015
16	SCD agar	2 bottles	13,454,000	2015

No.	Items	Quantity	Total Price	Year
	Aceton	1 bottle	1,050,000	2015
	Total		**1,209,269,000**	

III Sensor

1	Sensor K class 2 for sterilize tunnel	9 ropes	72,000,000	2015
2	Sensor PT 100 for freeze -dryer	25 ropes	174,500,000	2015
	Total		**246,500,000**	

IV Rubella working seed

1	Rubella working seed	50 tubes	680,625,000	2015
	Total		**680,625,000**	
	Grand Total(VND)		**4,035,554,000**	
	Grand Total(JYen)		**21,791,992**	JICA Exchange rate in Oct 2015; 0.0054

BUDGET ALLOCATION BY VIETNAMESE SIDE

Year	Budget (Th. VND)			Exchange Rate of JICA (Average)	Japanese Yen (Th. Yen)
	Project (MOH)	POLYVAC	Total		
2013		5,000,000	5,000,000	0.00471	¥23,550
2014	6,200,000	9,500,000	15,700,000	0.00513	¥80,541
2015 Up to 31st Aug.	2,202,000	5,000,000	7,202,000	0.00554	¥39,899
Total	8,402,000	19,500,000	27,902,000		¥143,990

Technical Cooperation Project for Strengthening Capacity for Measles-Rubella Combined Vaccine Production

SUMMARY OF EDUCATION AND TRAINING ACTIVITIES
TỔNG HỢP KẾT QUẢ ĐÀO TẠO
2013.05 ~ 2015.8.31

No.	Department	Name of process	Detail contents		Result				Sub Total	Remarks
					4	3	2	1		
1	Bulk Production Sản xuất bán thành phẩm	Basic lecture (Preparation) Lý thuyết cơ bản (chuẩn bị)	1-1	The similarity and difference between bulk production of measles vaccine and rubella vaccine. Điểm tương đồng và điểm khác biệt giữa sản xuất bán thành phẩm vắc xin sởi và bán thành phẩm vắc xin rubella.	4				4	
			1-2	The process of rubella vaccine bulk production. Các công đoạn sản xuất bán thành phẩm vắc xin rubella.	4				4	
2	Bulk Production Sản xuất bán thành phẩm	SPF rabbit kidney cell culture (Công đoạn lấy thận thỏ đến cắt nhỏ thận)	2-1	Fully understood the process Hiểu được đầy đủ quy trình	4				4	
			2-2	Preparation for tools Chuẩn bị dụng cụ	4				4	
			2-3	Extirpation of rabbit kidney Lấy thận	4				4	
			2-4	Splitting kidney into small parts Cắt nhỏ thận	4				4	
3	Bulk Production Sản xuất bán thành phẩm	Process of rabbit kidney extirpation/ rabbit kidney cell culture Công đoạn lấy thận thỏ / nuôi cấy tế bào thận thỏ	3-1	Fully understood the process Hiểu được đầy đủ quy trình	4				4	
			3-2	Preparation for tools Chuẩn bị dụng cụ	4				4	
			3-3	Transport splitted rabbit kidney Vận chuyển thận thỏ đã cắt nhỏ	4				4	
			3-4	Trypsinizing the splitted rabbit kidney cell Trypsin tế bào thận thỏ đã cắt nhỏ	4				4	
			3-5	Preparation of cell culturing solution, cell dispensing Pha dung dịch nuôi cấy tế bào, chia chai tế bào	4				4	
			3-6	Counting number of centrifugated cell Tính toán số tế bào ly tâm	2			2	4	
			3-7	Cell culture Nuôi cấy tế bào	2				2	
			3-8	Writing Standard Operating Procedure (SOP) Viết tài liệu quy trình (SOP)	2	1	1		4	
4	Bulk Production Sản xuất bán thành phẩm	Virus innoculation Công đoạn gây nhiễm vi rút	4-1	Fully understood the process Hiểu được đầy đủ quy trình	4				4	
			4-2	Preparation for tools, confirming operations of process Chuẩn bị dụng cụ, xác nhận các thao tác trong công đoạn	4				4	
			4-3	Observating cell culturing bottle Quan sát chai nuôi cấy tế bào	2			2	4	
			4-4	Preparation of culturing solution Pha dung dịch nuôi cấy	3			1	4	
			4-5	Writing Standard Operating Procedure (SOP) Viết tài liệu quy trình (SOP)	2		2		4	
5	Bulk Production Sản xuất bán thành phẩm	From washing virus to harvest Các công đoạn từ rửa tế bào đến gặt	5-1	Fully understood the process Hiểu được đầy đủ quy trình	4				4	
			5-2	Preparation for tools Chuẩn bị dụng cụ	4				4	
			5-3	Observating virus culturing bottle Quan sát chai nuôi cấy vi rút and evaluate CGI	1		2	1	4	
			5-4	Preparation of culturing solution, wash virus infected cell, dispensing, single harvest virus suspension appropriciately Pha dung dịch nuôi cấy, rửa tế bào gây nhiễm virus, chai chai, gặt hỗn dịch virus	4				4	
			5-5	Writing Standard Operating Procedure (SOP) Viết tài liệu quy trình (SOP)	2		2		4	
6	Bulk Production Sản xuất bán thành phẩm	Necessary PQ items in Rubella vaccine production	6-1	Understand rabbit disinfection efect validation, make and implement protocol Nắm được hạng mục thẩm định xác nhận hiệu quả khử trùng thỏ, lập	2				2	
			6-2	Understand sterilization validation for tools make and implement protocol Nắm được hạng mục thẩm định tiệt trùng dụng cụ, lập protocol và thực hiện theo protocol	3				3	
			6-3	Understand Enviroment monitoring validation after implement repairing works on production facility, make and implement protocol Nắm được hạng mục thẩm định giám sát môi trường khi cải tạo nhà xưởng, lập protocol và thực hiện theo protocol	3				3	
			6-4	Understand all processes, make and implement protocol for PQ in Rubella vaccine production Nắm được các công đoạn trong PQ sản xuất vắc xin rubella, lập protocol và thực hiện theo protocol	3				3	
			6-5	Understand cross-contamination preventing validation caused by using 2 different kinds of virus Nắm được hạng mục thẩm định chống nhiễm cheo do sử dụng 2 loại vi rút khác nhau	2				2	
7	Bulk Production Sản xuất bán thành phẩm	Implement PST, PV in rubella vaccine production	7-1	Understand PST, making and implementing protocol Nắm được quy trình PST, lập được protocol và thực hiện theo protocol	2				2	
			7-2	Understand all processes, make and implement protocol for PV in Rubella vaccine production Nắm được toàn bộ công đoạn PV trong sản xuất vắc xin rubella, lập được protocol và thực hiện theo protocol	2				2	
8	Final Production Sản xuất bán thành phẩm	Production of MR vaccine Công đoạn sản xuất vắc xin thành phẩm	8-1	Prepare final bulk of MR vaccine Có khả năng pha vắc xin MR bán thành phẩm cuối cùng	2	1			3	
			8-2	Process of washing, sterilising material Có khả năng thực hiện công đoạn rửa và tiệt trùng 1 cách hiệu quả	2	1			3	
			8-3	Process of filling of MR Có khả năng thực hiện công đoạn đóng ống vắc xin MR 1 cách thích hợp	2	1			3	
			8-4	Enviroment monitoring and bioburden management before sterilization Có khả năng thực hiện giám sát môi trường và quản lý bioburden 1 cách thí ch hợp		1			1	

No.	Department	Name of process		Detail contents	Result				Sub Total	Remarks
					4	3	2	1		
9	Medium production Sản xuất môi trường	Management and Maintainance of water production facility Quản lý duy trì hệ thống nước	9-1	Implement tasks relating to Management and Maintainance of water production facility Thực hiện được công việc quản lý duy trì nước dùng cho sản xuất	1				1	
			9-2	Implement tasks relating to all production process of water used for production Thực hiện công việc liên quan đến toàn bộ việc sản xuất nước dùng cho sản xuất		1			1	
			9-3	Implement tasks relating to take water used for production Thực hiện công việc liên quan đến toàn bộ việc sản xuất nước dùng cho sản xuất		1			1	
			9-4	Enviroment monitoring and bioburden management before sterilization Giám sát môi trường và quản lý Bioburden trước khi khử trùng		1			1	
10	A.lab Nhà chăn nuôi độngvật	Feeding and managing SPF rabbit Nuôi và quản lý sức khỏe	10-1	Capable of transporting imported SPF rabbit without contamination in rabbit. Nuôi và quản lý: Có thể vận chuyển thỏ SPF đã nhập về để không làm thỏ bị nhiễm bệnh.		2			2	
			10-2	Understood and capable of managing how to add feed and drinking water. Nắm được và có thể quản lý cách bổ sung thức ăn, nước uống.		2			2	
			10-3	Capable of handling rabbit easily, propitiously. Có thể sử dụng thỏ một cách dễ dàng, thuận lợi.		2			2	
			10-4	Understood how to distinguish gender and capable of distinguishing rabbit's gender. Nắm được cách thức phân biệt giới tính và phân biệt được giới tính của	2				2	
			10-5	Capable of weighing rabbit. Có thể cân trọng lượng thỏ	2				2	
			10-6	Capable of taking out rabbit from cage and fixing rabbit. Hỗ trợ thử nghiệm: Có thể lấy thỏ ra khỏi chuồng và cố định thỏ.		2			2	
			10-7	Capable of using hair clippers to shave hair on the shoulder area of rabbit. Có thể sử dụng tông đơ để cạo lông ở phần vai thỏ.		2			2	
11	A.lab, Pathology, QC Nhà chăn nuôi động vật, QC, BTP	Cutting hair, bleeding, disinfecting Cắt lông, lấy máu, khử trùng	11-1	Capable of preparing for tools, equipment, records and completion of testing condition before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, biên bản và hoàn thiện môi trường làm việc trước khi tiến hành thao tác một cách thích hợp.	2	1			3	
			11-2	Capable of fixing rabbit properly (note: avoid to hurt rabbit). Có thể tiến hành cố định thỏ một cách thích hợp (lưu ý tránh không làm thỏ bị tổn thương).	2	1			3	
			11-3	Capable of cutting neck and back hair appropriately (keep the blade of clipper parallely with skin surface, do not keep the blade vertically). Có thể cắt lông phần cổ và lưng một cách thích hợp (cho lưỡi dao của tông đơ song song với bề mặt da, không để lưỡi dao dựng đứng).	2	1			3	
			11-4	Capable of using band and fixing tools to fix rabbit on fixing table in upward position appropriately. Có thể sử dụng dây và dụng cụ cố định để cố định thỏ trên bàn cố định ở tư thế nằm ngửa một cách thích hợp.	2	1			3	
			11-5	Capable of using surgical scissors and tweezers to incise neck skin, then separate incised skin to expose carotid artery appropriately. Có thể dùng kéo ngoại khoa và pincette để rạch mở da vùng cổ, sau đó bóc tách vùng da đã rạch mở để bộc lộ động mạch cảnh một cách thích hợp.	2	1			3	
			11-6	Capable of using two forceps to block carotid artery, then using scissors to cut blocked carotid artery, remove one forceps and bleeding. Có thể dùng 2 panh kẹp chặn động mạch cảnh, sau đó dùng kéo cắt đoạn động mạch cảnh đã kẹp, tháo 1 panh kẹp ra và lấy máu	2	1			3	
			11-7	Capable of checking eyeball of rabbit changing colour after bleeding (from red to white) then rabbit stop breathing. Có thể kiểm tra thấy nhãn cầu thỏ đổi màu sau khi bị lấy máu (từ đỏ sang trắng) và thỏ ngừng hô hấp.	2	1			3	
			11-8	Capable of preparing disinfectant solution (benzalkonium chloride 0.1%). Có thể pha dung dịch khử trùng (benzalkonium chloride 0.1%).	2	1			3	
			11-9	Capable of putting rabbit into disinfectant solution, washing whole rabbit body carefully and soaking in disinfectant solution and capable of removing disinfectant chemical soaked into rabbit's skin and hair after disinfecting appropriately . Có thể cho thỏ vào dung dịch khử trùng, rửa kỹ toàn thân thỏ và ngâm khử trùng; đồng thời có thể loại bỏ hóa chất khử trùng đã ngấm vào lông và da thỏ sau khi khử trùng đầy đủ một cách thích hợp.	2	1			3	
			11-10	Capable of putting disinfected rabbit into sterilized transportation box and capable of giving out appropriate methods for transportation box (example: disinfection method, etc.) Có thể cho thỏ đã được khử trùng vào hộp vận chuyển đã tiệt trùng và có thể đưa ra các biện pháp thích hợp cho hộp vận chuyển (ví dụ: biện pháp khử trùng v.v.).	2	1			3	
12	Pathology Giải phẫu bệnh	Knowledge of rabbit disease necessary for rubella vaccine bulk production Kiến thức về bệnh ở thỏ cần thiết cho sản xuất bán thành phẩm vắc xin rubella	12-1	Capable of understanding the contents regulated by Biological Products Standard (for Freeze-dry Live Attenuated Rubella vaccine) Nắm được các hạng mục quy định trong Tiêu chuẩn thành phẩm sinh học (vắc xin Rubella sống đông khô giảm độc lực).		1			1	
			12-2	Capable of understanding diseases that can not be observed in material SPF rabbit (salmonellosis, tuberculosis, pseudotuberculosis, myxomatosis disease), which is regulated by Biological Products Standard (for Freeze-dry Live Attenuated Rubella vaccine) Nắm được về các bệnh không được phép gặp ở thỏ SPF - nguyên liệu sản xuất (bệnh Salmonella, bệnh lao, bệnh giả lao, bệnh Myxomatosis) được quy định trong Tiêu chuẩn thành phẩm sinh học (vắc xin Rubella sống đông khô giảm độc lực)		1			1	
			12-3	Capable of understanding the pathological lesions that affect Rubella vaccine bulk production. Nắm được những tổn thương gây hại cho sản xuất bán thành phẩm		1			1	
			12-4	Capable of understanding characteristic traits of SPF rabbit and monitoring diseases. Nắm được những đặc tính của thỏ SPF, nắm được các bệnh cần giám sát.		1			1	

No.	Department	Name of process	Detail contents		Result				Sub Total	Remarks
					4	3	2	1		
13	Pathology Giải phẫu bệnh	Pathological autopsy of rabbit necessary for rubella vaccine bulk production Giải phẫu bệnh lý thỏ cần thiết cho sản xuất bán thà nh phẩm vắc xin rubella	13-1	Capable of understanding autopsy process in Standard Operating Procedure of Rabbit acceptance test. Nắm được quy trình kiểm tra giải phẫu trong bản Quy trình chuẩn thao tác thử nghiệm tiếp nhận thỏ.		1			1	
			13-2	Capable of obtaining macroscopic findings of all organs appropriately. Có khả năng nắm được dấu hiệu bên ngoài của các cơ quan nội tạng trong toàn thân một cách phù hợp.		1			1	
			13-3	Capable of evaluating health condition and presence of infectious disease based on the pathological autopsy results. Có khả năng đánh giá tình trạng sức khỏe thỏ và xác định có bệnh truyền nhiễm hay không từ kết quả kiểm tra giải phẫu bệnh học.		1			1	
			13-4	Capable of evaluate possibility of using material (rabbit) in Rubella vaccine bulk production base on the pathological autopsy results. Có khả năng đánh giá khả năng sử dụng nguyên liệu (thỏ) vào sản xuất bán thành phẩm vắc xin Rubella từ kết quả kiểm tra giải phẫu bệnh học.		1			1	
			13-5	Capable of explaining about pathological autopsy results appropriately. Có khả năng giải thích một cách phù hợp về kết quả kiểm tra giải phẫu bệnh học.		1			1	
14	Pathology, QC, bulk production Giải phẫu bệnh, QC, BTP	Receiving rabbit (visual check rabbit kidney when splitinf into small part Thử nghiệm tiếp nhận thỏ (quan sát thận bằng mắt thường khi cắt nhỏ thận)	14-1	Understand size of normal kidney and evaluating the size of is abnormal Hiểu được độ lớn của thận bình thường và có thể đánh giá xem độ lớn có bất thường hay không		7			7	
			14-2	Evaluating perinephric fat tissue and evaluating the fat tissue is abnormal or not Có thể đánh giá được lượng mô mỡ bao quanh quả thận và đánh giá xem c ó phần mỡ bất thường hay không		7			7	
			14-3	Understand kidney shape, evaluate kidney is abnormal or not Có thể đánh giá hình dạng thận		3			3	
			14-4	Evaluate any abnormality of the kidney by visual check (such as: scar, cyst, abscess, neopaltic ruggedness) Có thể đánh giá xem thận có bất thường về ngoại quan không (sẹo, u nang, áp-xe, sựng tấy)		3			3	
			14-5	Evaluate capsule of kidney and desquamative state Có thể đánh giá tính chất của lớp màng và tình trạng bong tróc không bất thường		3			3	
			14-6	Understand structure of 3 layers on kidney slice surface and evaluate 3 layer are abnormal or not (hiểu 3 lớp trên bề mặt lát cắt thận và có thể đánh giá yếu tố cấu thành của 3 lớp đó không bất thường		3			3	
15	Pathology Giải phẫu bệnh	Receiving Rabbit (visual check and rabbit kidney autopsy) quan sát bằng mắt thường và khám nghiệm thận thỏ	15-1	Capable of checking rabbit code no. and evaluating is there any abnormality by visual check (state of hair, skin, mucous membrane, eye, nose, mouth, anus). Có thể kiểm tra mã số thỏ và đánh giá xem có bất thường ở ngoại quan kh ông (tình trạng lông, da, niêm mạc, mắt, mũi, miệng, hậu môn).		1			1	
			15-2	Capable of evaluating is there any abnormality on subcutaneuos tissue and typical lymph node or not. Có thể đánh giá xem có bất thường ở các mô dưới da và hạch bạch huyết ti êu biểu hay không.		1			1	
			15-3	Capable of evaluating is there any abnormality in abdominal cavity or not (imflammation, morbid liquid, ect.). Có thể đánh giá xem có bất thường trong khoang bụng không (chứng viêm nhiễm, dịch mang bệnh v.v.).		1			1	
			15-4	Capable of evaluating is there any abnormality in internal organs or not (spleen, omentum, mesentery, stomach, small intestine, large intestine, liver, gall-bladder, pancreas, adrenal gland). Có thể đánh giá xem có bất thường ở các cơ quan nội tạng (lá lách, màng lớn, màng treo ruột, dạ dày, ruột non, ruột già, gan, túi mật, tụy, tuyến thượng thận) hay không.		1			1	
			15-5	Capable of checking gender of rabbit. Có thể kiểm tra được giới tính của thỏ.		1			1	
			15-6	Capable of evaluating is there any abnormality in bladder and genital organs or not. Có thể đánh giá xem có bất thường ở bàng quang và cơ quan sinh dục khô		1			1	
			15-7	Capable of evaluating is there any abnormality of negative pressure inside thorax or not (mediastinum, epicardium, diaphragm, parietal pleura, pulmonary pleura). Có thể đánh giá xem có bất thường ở áp suất âm bên trong lồng ngực và c ác cơ quan nội tạng bên trong lồng ngực (trung thất, lá tạng ngoại tâm mạc, cơ hoành, màng phổi thành, màng phổi) hay không.		1			1	
			15-8	Capable of evaluating is there any abnormality in heart, large vessel system, pericardium or not (liquid accumulation, neoplastic disease). Có thể đánh giá xem có bất thường ở tim, hệ mạch lớn, màng ngoài tim (đ ọng dịch, chứng sựng phù) hay không.		1			1	
			15-9	Capable of evaluating is there any abnormality in trachea, lung or not. Có thể đánh giá xem có bất thường ở khí quản và phổi hay không.		1			1	
			15-10	Capable of extirpating abnormal organ appropriately. Có thể cắt lấy bộ phận có bất thường một cách thích hợp.		1			1	

No.	Department	Name of process	Detail contents		Result				Sub Total	Remarks
					4	3	2	1		
16	Pathology Giải phẫu bệnh	Prepare specimen for pathology test (Trimming of internal organs) Cắt lọc các cơ quan nội tạng	16-1	Acquired the anatomical structure of internal organs in animal bodies. Nắm được cấu tạo giải phẫu học về các cơ quan nội tạng trên toàn cơ thể đ ộng vật.		1			1	
			16-2	Capable of selecting appropriate surgical tools for extirpating the internal organs. Có thể lựa chọn các dụng cụ giải phẫu thích hợp cho việc lấy các cơ quan nội tạng.		1			1	
			16-3	Capable of preparing appropriate tools for tissue trimming. Có thể chuẩn bị các dụng cụ thích hợp cho việc cắt lọc các loại nội tạng.		1			1	
			16-4	Capable of selecting tissue parts appropriate for pathology test by optic microscope. Có thể lựa chọn phần nội tạng thích hợp cho việc kiểm tra mô học bằng kí nh hiển vi quang học.		1			1	
			16-5	Capable of considering the permeability of fixing solution (10% Formalin solution) to adjust the size (thickness). Có thể xem xét tính thẩm thấu của dung dịch cố định (dung dịch Formalin 10%) để điều chỉnh độ lớn (độ dày).		1			1	
			16-6	Capable of adjusting size appropriate to slide glass and embedding casset. Có thể điều chỉnh độ lớn phù hợp với lam kính và dụng cụ thẩm thấu		1			1	
			16-7	Capable of considering the operation of surface preparation by trimming a thin section to have a tissue part with smooth and fine surface. Có thể cân nhắc đến thao tác tạo bề mặt khi cắt lát mỏng để cắt được phần nội tạng có một mặt phẳng mịn.		1			1	
			16-8	Capable of making correct records of trimming process, and recording for specimen code distinction. Có thể thực hiện một cách chính xác việc ghi biên bản công đoạn cắt lọc, ghi biên bản để phân biệt mã số mẫu.		1			1	
17	Pathology Giải phẫu bệnh	Prepare specimen for pathology test (Trimming and extirpating diseased internal organs) Cắt lọc lấy cơ quan nội tạng có biểu hiện bệnh	17-1	Understood the normal structure of internal organs, capable of recognizing the affected area. Hiểu được cấu tạo bình thường (không có bệnh) của các bộ phận nội tạng, nắm được chính xác phần có biểu hiện bệnh.		1			1	
			17-2	Capable of recording exactly the gross findings of the affected area (by visual check) (taking photos, recording gross findings). Có thể ghi biên bản chính xác dấu hiệu đại thể phần có biểu hiện bệnh (quan sát bằng mắt thường) (chụp ảnh, ghi biên bản dấu hiệu quan sát).		1			1	
			17-3	Capable of selecting and trimming the appropriate part for tissue examination by optic microscope (observation of the affected area). Có thể lựa chọn và cắt lọc phần thích hợp cho việc kiểm tra mô bệnh học bằng kính hiển vi quang học (quan sát biểu hiện bệnh).		1			1	
			17-4	Capable of recording the specimen code, tissue information, identifying information, ect into information box of embedding cassette appropriately. Có thể ghi mã số mẫu, thông tin về nội tạng, thông tin phân biệt v.v. vào ô ghi thông tin về dụng cụ thẩm thấu parafin (embedding cassette) một cách thích hợp.		1			1	
			17-5	Capable of preserving and managing the remaining tissue appropriately after trimming. Sau thao tác cắt lọc, có thể bảo quản, quản lý phần nội tạng còn lại một cá ch thích hợp.		1			1	
18	Pathology Giải phẫu bệnh	Fixing tissue by Prepare specimen for pathology test (fix tiseue with formalin solution) Cố định nội tạng bằng formalin	18-1	Understood the purpose of tissue fixing operation and principle of tissue fixing. Nắm được mục đích của thao tác cố định nội tạng và nguyên lý cố định nội		1			1	
			18-2	Capable of preparing fixing solution (10% Formalin solution). Có thể pha dung dịch cố định (dung dịch Formallin 10%).		1			1	
			18-3	Capable of preparing an amount of fixing solution adequate for the size of the tissue. Có thể chuẩn bị lượng dung dịch cố định phù hợp với độ lớn của nội tạng.		1			1	
			18-4	Capable of accessing the fixing status of tissue (too much or not enough) Có thể đánh giá tình trạng cố định của nội tạng (quá mức hoặc chưa đủ).		1			1	
			18-5	Capable of handling bulk Formalin (poison, heavy poison) appropriately. Có thể quản lý bán thành phẩm Formalin (chất độc, chất độc mạnh) một cá ch thích hợp		1			1	
			18-6	Capable of discharging the used formalin solution appropriately. Có thể hủy dung dịch formalin sau khi sử dụng một cách thích hợp.		1			1	
19		Prepare specimen for pathology test (Embedding parafin into trimmed tissue) Cho parafin thẩm thấu vào nội tạng đã cắt lọc	19-1	Capable of managing and operating automatic tissue processor appropriately. Có thể quản lý và sử dụng máy thẩm thấu paraffin (máy xử lý mẫu tự động)		1			1	
			19-2	Understood the principle of embedding paraffin into tissue. Nắm được nguyên lý thẩm thấu parafin vào nội tạng.		1			1	
			19-3	Aquired the tissue processing, clarification processing, paraffin embedding process and capable to select time for tissue processing appropriately. Nắm được công đoạn xử lý mẫu nội tạng, công đoạn làm trong, công đoạn thẩm thấu parafin và có thể lựa chọn thời gian xử lý nội tạng một cách thích hợp.		1			1	
			19-4	Capable of preparing necessary solution (alcohol, xylene paraffin) for the process of paraffin embedding into fixed tissue. Có thể chuẩn bị và pha các loại hóa chất cần thiết (cồn, xilen, parafin) cho c ông đoạn thẩm thấu parafin vào nội tạng đã được cố định.		1			1	
			19-5	Capable of handling the chemicals (alcohol, xylene) used for paraffin embedding process appropriately. Có thể quản lý các loại hóa chất (cồn, xilen) dùng cho công đoạn thẩm thấu parafin một cách thích hợp.		1			1	
			19-6	Capable of discharging the used alcohol and xylene appropriately. Có thể hủy cồn và xilen đã sử dụng một cách thích hợp.		1			1	
20		Prepare specimen for pathology test (Embedding) Làm parafin block	20-1	Capable of managing and operating the tissue embedding system appropriately. Có thể quản lý và sử dụng máy tạo parafin block một cách thích hợp.		1			1	
			20-2	Capable of selecting the embedding dish proper to size of tissue. Có thể lựa chọn khay embedding phù hợp với độ lớn của nội tạng.		1			1	
			20-3	Capable of considering the section cutting and embedding the tissue appropriately. Có thể xem xét thao tác cắt lát và làm embedding nội tạng một cách thích		1			1	

No.	Department	Name of process		Detail contents	Result				Sub Total	Remarks
					4	3	2	1		
21		Prepare specimen for pathology test (Thin section) Tạo các lát cắt mỏng	21-1	Capable of managing and operating the Microtome machine safely and appropriately. Có thể quản lý và sử dụng máy Microtome một cách an toàn và thích hợp.		1			1	
			21-2	Capable of adusting the function of Microtome machine for cutting thin section of 3 to 5 μm thickness. Có thể điều chỉnh tính năng của máy Microtome để có thể cắt lát mỏng với độ dày từ 3 đến 5 μm.		1			1	
			21-3	Capable of performance the edge cutting of paraffin block to reveal the tissue surface to be observed. Có thể thực hiện thao tác cắt thô bề mặt cắt của parafin block để lộ bề mặt của mô cần quan sát.		1			1	
			21-4	Capable of cutting continuously thin section of 3 to 5 μm thickness without artifact (such as scratch damage due to microtome knife) Có thể cắt lát mỏng liên tục sao cho không có vết gợn (do vết xước của dao cắt) và độ dày của lát cắt từ 3 đến 5 μm.		1			1	
			21-5	Capable of repairing the wrinkle of the thin section with extension water bath appropriately. Capable of ensuring the water clean for extension. Có thể sửa nếp nhăn của lát cắt mỏng bằng bể kéo dãn lát cắt một cách thích hợp. Có thể đảm bảo vệ sinh nước dùng để kéo dãn.		1			1	
			21-6	Capable of extending the thin section with tissue floating water bath. Capable of controlling the water temperature and ensuring the clean of hot water. Có thể kéo dãn lát cắt mỏng bằng bể nước nóng. Có thể lưu ý quản lý nhiệt		1			1	
			21-7	Capable of inclusion of the slice into appropriate position on slide glass. Có thể gắn mảnh lát cắt vào vị trí thích hợp của lam kính .		1			1	
			21-8	Capable of completely dehydrating the vapor on the slide glass, using dryer and paraffin oven, and fixing the slice on the slide glass. Có thể hút hết hơi nước trên lam kính, sử dụng máy làm khô và máy kéo dãn parafin, thực hiện gắn hoàn toàn lát cắt vào lam kính.		1			1	
22		Staining Hematoxylin and Eosin Nhuộm Hematoxylin và Eosin	22-1	Fully obtained the knowledge of hematoxylin and eosin staining principle. Có kiến thức đầy đủ về nguyên lý nhuộm hematoxylin và eosin.		1			1	
			22-2	Capable of managing and preparing the chemicals necessary for staining operation (hematoxylin, eosin, alcohol, xylene, inclusion agent) appropriately. Có thể quản lý, chuẩn bị và pha các loại hóa chất cần thiết cho thao tác		1			1	
			22-3	Acquired knowledge and capable of operating the staining process (deparaffinization, hydrophilization, hematoxylin staining, coloring, eosin staining, separating eosin stain colour by ethanol, clarification by xylene). Nắm được và có thể thực hiện các công đoạn nhuộm (khử parafin, làm ưa nước, nhuộm hematoxylin, lên màu, nhuộm eosin, khử nước bằng ethanol, làm trong bằng xilen).		1			1	
			22-4	Capable of evaluating the clarification level by xylene of thin stained slice, using inclusion agent and cover glass to perform the inclusion operation appropriately. Có thể đánh giá mức độ làm trong bằng xilen của lát cắt mỏng đã nhuộm, dùng chất gắn lamen và lamen để thực hiện thao tác gắn lamen một cách thích hợp.		1			1	
			22-5	Capable of handling and discharging the used chemicals (alcohol, xylene, hematoxylin, eosin) appropriately. Có thể quản lý và hủy các hóa chất đã dùng (cồn, xilen, hematoxylin, eosin) một cách thích hợp.		1			1	
23	Pathology Giải phẫu bệnh	Method of using optical microscope Phương pháp sử dụng kính hiển vi quang học	23-1	Understood basic composition of optical microscope and capable of performing specimen observation appropriately. Nắm được cấu tạo cơ bản của kính hiển vi quang học và có thể tiến hành thao tác phù hợp để quan sát tiêu bản.		1			1	
			23-2	Capable of performing basic maintenance for optical microscope. Có thể tiến hành bảo dưỡng cơ bản cho kính hiển vi quang học.		1			1	
			23-3	Understood basic composition of digital camera system and capable of taking picture of tissues. Nắm được cấu tạo cơ bản của hệ thống máy ảnh kỹ thuật số và có thể chụp được ảnh các mô.		1			1	

No.	Department	Name of process		Detail contents	Result				Sub Total	Remarks
					4	3	2	1		
24	Pathology Giải phẫu bệnh	Method of checking pathological symptom Cách xem xét các dấu hiệu bệnh học	24-1	Capable of understanding normal histology of all organs. Nắm được cấu trúc giải phẫu của mô không có bất thường trong các cơ quan nội tạng toàn thân.		1			1	
			24-2	Having enough basic pathological knowledge in order to assess the histopathological changes. Có được kiến thức bệnh học cơ bản đủ để nắm bắt được những biến đổi bệnh học của các mô.		1			1	
			24-3	Capable of assessing the histopathological lesion. Có thể nắm bắt được chính xác khu vực tổn thương.		1			1	
			24-4	Capable of understanding character of the pathological lesion and capable of describing the histopathological findings. Nắm được tình trạng của tổn thương, có thể ghi chép được những dấu hiệu mô bệnh học.		1			1	
			24-5	Capable of understanding completely to pathological terminology in order to describe the histopathological findings. Hiểu được đầy đủ những thuật ngữ chuyên ngành bệnh học cần thiết để ghi chép được những dấu hiệu mô bệnh học.		1			1	
			24-6	Capable of making accurate histopathological diagnosis based on histopathological findings. Có thể đưa ra chẩn đoán mô bệnh học một cách chính xác từ các dấu hiệu mô bệnh học.		1			1	
25	Pathology Giải phẫu bệnh	Taking picture of histopathology tissue Chụp ảnh mô bệnh học	25-1	Capable of understanding digital microscope camera operation method and capable of taking the histological picture Nắm được cách thức thao tác máy ảnh kỹ thuật số của kính hiển vi, có thể chụp được ảnh mô.		1			1	
			25-2	Capable of taking consistent histological picture for histopathological findings. Có thể chụp ảnh mô phù hợp với dấu hiệu mô bệnh học.		1			1	
			25-3	Capable of taking appropriate tissue picture for explaining histopathological findings ① (chosing magnifications of microscope objective lens appropriately) Có thể chụp ảnh mô bệnh học phù hợp với giải thích của dấu hiệu mô bệnh học ① (lựa chọn vật kính ở các độ phóng đại một cách hợp lý).		1			1	
			25-4	Capable of taking appropriate tissue picture for explaining histopathological findings ② (chosing picture shooting range appropriately) Có thể chụp ảnh mô bệnh học phù hợp với giải thích của dấu hiệu mô bệnh học ② (vị trí chụp ảnh phù hợp).		1			1	
			25-5	Capable of giving appropriate description for tissue pictures taken. Có thể viết chú thích phù hợp cho ảnh mô đã chụp.		1			1	
26	Pathology Giải phẫu bệnh	Reporting result of pathology examination Làm báo cáo kết quả kiểm tra bệnh học	26-1	Capabale of using appropriate pathological terminology about macroscopic abnormality observed in organs to describe findings. Có thể sử dụng thuật ngữ chuyên ngành bệnh học phù hợp để ghi chép những dấu hiệu đại thể đối với những bất thường quan sát được bằng mắt thường trên nội tạng.		1			1	
			26-2	Capable of explaining about macroscopic abnormality using appropriate macroscopic picture. Có thể sử dụng hình ảnh thích hợp để giải thích về những bất thường quan sát được bằng mắt thường một cách phù hợp.		1			1	
			26-3	Capable of summarizing macroscopic diagnosis based on macroscopic findings that were described. Có thể tóm tắt được chẩn đoán giải phẫu (macroscopic diagnosis) dựa trên dấu hiệu đại thể đã ghi chép.		1			1	
			26-4	Capable of understranding histology of all organs and capable of describing histological findings. Nắm được mô học của các nội tạng toàn cơ thể, có thể ghi chép được những dấu hiệu mô học.		1			1	
			26-5	Capable of describing histopathological findings of histological abnormality (lesion) using appropriate pathological terminology. Có thể sử dụng thuật ngữ chuyên ngành bệnh học phù hợp để ghi chép những dấu hiệu mô bệnh học đối với những bất thường mô học (tổn		1			1	
			26-6	Capable of explaining histological abnormality (lesion) using appropritate histological picture. Có thể sử dụng hình ảnh mô học phù hợp để giải thích về những bất thường mô học (tổn thương).		1			1	
			26-7	Capable of summarizing histopathological diagnosis based on histopathological findings that were described. Có thể tóm tắt được chẩn đoán mô bệnh (histopathological diagnosis) dựa trên những dấu hiệu mô đã ghi chép.		1			1	
			26-8	Capable of summarizing pathological diagnosis based on macroscopic diagnosis and histopathological diagnosis. Có thể tóm tắt được chẩn đoán bệnh (pathological diagnosis) dựa trên chẩn đoán giải phẫu (macroscopic diagnosis) và chẩn đoán mô bệnh (histopathological diagnosis).		1			1	
			26-9	Capable of giving appropriate comments and advices to Bulk Department or Quality control Department based on pathological diagnosis. Từ chẩn đoán bệnh (pathological diagnosis), có thể đưa ra ý kiến, tư vấn phù hợp cho phòng bán thành phẩm hoặc phòng quản lý chất lượng.		1			1	
			26-10	Capable of explaining about pathological diagnosis from the pathological point of view. Có thể giải thích về chẩn đoán bệnh (pathological diagnosis) trên quan điểm bệnh học.		1			1	
			26-11	Capable of appropriately storing pathological examination reports and submitting according to other departments' requests. Có thể lưu trữ Báo cáo kiểm tra bệnh học một cách phù hợp, có thể nộp báo cáo cho các phòng ban khi được yêu cầu.		1			1	

No.	Department	Name of process		Detail contents	Result				Sub Total	Remarks
					4	3	2	1		
27	QC (Bio Group)	Test for haemadsorbing viruses Thử nghiệm vi rút hấp phụ hồng cầu	27-1	Capable of preparing for tools, equipment, chemicals and completing of testing condition before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thử nghiệm trước khi thực hiện thử nghiệm một cách thích hợp.	1				1	
			27-2	Capable of operating, checking the equipment to be used for the test appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.	1				1	
			27-3	Capable of understanding the contents of standard operating procedure of the test and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.	1				1	
			27-4	Capable of evaluating the status of normal rabbit kidney cell. Có thể đánh giá tình trạng của tế bào thận thỏ bình thường.	1				1	
			27-5	Capable of illustrating the status of cell culture with values and evaluating the cell culture status. Có thể thể hiện tình trạng nuôi tế bào bằng các trị số và đánh giá được tình trạng nuôi tế bào.	1				1	
			27-6	Capable of adjusting blood solution of Guinea pig appropriately. Có thể điều chỉnh dung dịch máu chuột lang một cách thích hợp	1				1	
			27-7	Capable of evaluating the haemadsorption test. Có thể đánh giá được thử nghiệm hấp phụ hồng cầu tế bào.	1				1	
			27-8	Capable of evaluating if any abnormality at cell culture completion. Có thể đánh giá xem khi kết thúc nuôi cấy tế bào có bất thường hay không.	1				1	
			27-9	Capable of implementing sanitation (cleaning, ect.,) appropriately after test completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v.) sau khi kết thúc thử nghiệm một cách thích hợp.	1				1	
			27-10	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.	1				1	
28	QC (Bio Group)	Inoculation of rabbit kidney cell culture Thử nghiệm gây nhiễm tế bào nuôi cấy thận thỏ	28-1	Capable of preparing for tools, equipment, chemicals and completing of testing condition before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thử nghiệm trước khi thực hiện thử nghiệm một cách thích hợp.	1				1	
			28-2	Capable of operating, checking the equipment to be used for the test appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.	1				1	
			28-3	Capable of understanding the contents of standard operating procedure of the test and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.	1				1	
			28-4	Capable of evaluating the status of normal RK13 cell. Có thể đánh giá tình trạng của tế bào thận thỏ bình thường.	1				1	
			28-5	Capable of performing the neutralization of sample containing rubella virus and adjusting sample appropriately. Có thể tiến hành thao tác trung hòa mẫu có chứa vi rút rubella và tiến hành điều chỉnh mẫu một cách thích hợp.	1				1	
			28-6	Capable of using, diluting and inoculating positive control appropriately. Có thể sử dụng, pha loãng và gây nhiễm chứng dương một cách thích hợp.		1			1	
			28-7	Capable of observating the cells and replacing cell culture solution appropriately. Có thể quan sát tế bào và thay dung dịch nuôi cấy một cách thích hợp.	1				1	
			28-8	Capable of thawing frozen cells and performing passage appropriately. Có thể làm tan tế bào bảo quản đông lạnh và tiến hành thao tác cấy chuyển một cách thích hợp.	1				1	
			28-9	Capable of adjusting chicken and guinea pig's blood appropriately. Có thể điều chỉnh dung dịch máu gà và chuột lang một cách thích hợp.	1				1	
			28-10	Capable of evaluating the haemadsorption test. Có thể đánh giá được thử nghiệm hấp phụ hồng cầu tế bào.	1				1	
			28-11	Capable of evaluating the cell transformation with positive control. Có thể đánh giá sự biến đổi của tế bào bằng chứng dương.	1				1	
			28-12	Capable of evaluating abnormality when completion of cell culture. Có thể đánh giá xem khi kết thúc nuôi cấy tế bào có bất thường hay không.	1				1	
			28-13	Capable of implementing sanitation (cleaning, ect.,) appropriately after test completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v.) sau khi kết thúc thử nghiệm một cách thích hợp.		1			1	
			28-14	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.		1			1	
			29-1	Capable of preparing for tools, equipment, chemicals and completion of testing condition before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thử nghiệm trước khi thực hiện thử nghiệm một cách thích hợp.	1				1	
			29-2	Capable of operating, checking the equipment to be used for the test appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.	1				1	
			29-3	Capable of understanding the contents of standard operating procedure of the test and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.	1				1	
			29-4	Capable of evaluating the status of normal Vero cell. Có thể đánh giá tình trạng tế bào Vero bình thường.	1				1	

No.	Department	Name of process		Detail contents	Result				Sub Total	Remarks
					4	3	2	1		
29	QC (Bio Group)	Inoculation of simian cell culture (VERO) Thử nghiệm gây nhiễm tế bào nuôi cấy khỉ (VERO)	29-5	Capable of neutralizing sample containing rubella virus and adjusting sample appropriately. Có thể thực hiện thao tác trung hòa mẫu có chứa vi rút rubella và điều chỉnh mẫu một cách thích hợp.	1				1	
			29-6	Capable of using positive control and performing dilution, inoculation appropriately. Có thể sử dụng chứng dương và tiến hành pha loãng, gây nhiễm một cách thích hợp.	1				1	
			29-7	Capable of observating cell and changing culture solution appropriately. Có thể quan sát tế bào và thay dung dịch nuôi cấy một cách thích hợp.	1				1	
			29-8	Capable of performing passage appropriately. Có thể tiến hành thao tác cấy chuyển một cách thích hợp	1				1	
			29-9	Capable of adjusting blood solution of chicken and guinea – pig appropriately.	1				1	
			29-10	Capbale of evaluating haemadsorption test. Có thể đánh giá được thử nghiệm hấp phụ hồng cầu của tế bào.	1				1	
			29-11	Capable of evaluating change of cell by positive control. Có thể đánh giá sự thay đổi của tế bào bằng chứng dương.	1				1	
			29-12	Capable of evaluating any abnormal cell upon completion of cell culture. Có thể đánh giá xem tế bào có bất thường hay không khi kết thúc nuôi cấy.	1				1	
			29-13	Capable of implementing sanitation (cleaning, ect.,) appropriately after test completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v.) sau khi kết thúc thử nghiệm một cách thích hợp.	1				1	
			29-14	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.	1				1	
30	QC (Bio Group)	Inoculation of FL cell culture Thử nghiệm gây nhiễm tế bào nuôi cấy FL	30-1	Capable of preparing for tools, equipment, chemicals and completion of testing condition before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thử nghiệm trước khi thực hiện thử nghiệm một cách thích hợp.	1				1	
			30-2	Capable of operating, checking the equipment to be used for the test appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.	1				1	
			30-3	Capable of understanding the contents of standard operating procedure of the test and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.	1				1	
			30-4	Capable of evaluating the status of normal FL cell. Có thể đánh giá tình trạng tế bào FL bình thường.	1				1	
			30-5	Capable of neutralizing sample containing rubella virus and adjusting sample appropriately. Có thể thực hiện thao tác trung hòa mẫu có chứa vi rút rubella và điều chỉnh mẫu một cách thích hợp.	1				1	
			30-6	Capable of using positive control and performing dilution, inoculation appropriately. Có thể sử dụng chứng dương và tiến hành pha loãng, gây nhiễm một cách thích hợp.	1				1	
			30-7	Capable of observating cell and changing culture solution appropriately. Có thể quan sát tế bào và thay dung dịch nuôi cấy một cách thích hợp.	1				1	
			30-8	Capable of performing passage appropriately. Có thể tiến hành thao tác cấy chuyển một cách thích hợp.	1				1	
			30-9	Capable of evaluating change of cell by positive control. Có thể đánh giá sự thay đổi của tế bào bằng chứng dương.		1			1	
			30-10	Capable of evaluating abnormal cell upon completion of cell culture. Có thể đánh giá xem tế bào có bất thường hay không khi kết thúc nuôi cấy.	1				1	
			30-11	Capable of implementing sanitation (cleaning, ect.,) appropriately after test completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v.) sau khi kết thúc thử nghiệm một cách thích hợp.	1				1	
			30-12	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.	1				1	
31	QC (Bio Group)	Encephalitozoon Cuniculi test Thử nghiệm Encephalitozoon Cuniculi	31-1	Capable of understanding of how to make a record and making record. Có thể hiểu cách ghi biên bản và ghi biên bản.	2				2	
			31-2	Capable of preparing sample and positive control, smearing sample and positive control. Có thể pha mẫu, pha chứng dương, phết mẫu và chứng dương.	2				2	
			31-3	Capable of preparing and adjusting Giemsa staining tests. Có thể chuẩn bị và điều chỉnh các thử nghiệm nhuộm Giêmsa.	2				2	
			31-4	Capable of conducting Giemsa staining compliantly to standard operating procedure. Có thể tiến hành nhuộm Giêmsa theo đúng tài liệu quy trình.	2				2	
			31-5	Capable of evaluating if sample containing Encephalitozoon Cuniculi or not. Có thể đánh giá xem trong mẫu có Encephalitozoon Cuniculi không.	2				2	
			31-6	Capable of preparing and adjusting chemical to be used for fluorescent antibody method. Có thể chuẩn bị và điều chỉnh các hóa chất dùng cho phương pháp kháng thể huỳnh quang.	2				2	
			31-7	Capable of conducting fluorescent antibody method compliantly to standard operating procedure. Có thể thực hiện phương pháp kháng thể huỳnh quang theo đúng tài liệu quy trình.	2				2	
			31-8	Capable of evaluating if there is any positive reaction to Encephalitozoon Cuniculi in the sample or not. Có thể đánh giá xem có phản ứng dương tính với Encephalitozoon Cuniculi có trong mẫu hay không.	2				2	

No.	Department	Name of process	Detail contents		Result				Sub Total	Remarks
					4	3	2	1		
32	QC (Bio Group)	Rubella virus potency test Thử nghiệm hiệu giá vi rút rubella	32-1	Capable of preparing for tools, equipment, chemicals and completing of testing conditon before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thử nghiệm trước khi thực hiện thử nghiệm một cách thích hợp.	1	1			2	
			32-2	Capable of operating, checking the equipment to be used for the test appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.	1	1			2	
			32-3	Capable of understanding the contents of standard operating procedure of the test and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.	1	1			2	
			32-4	Capable of evaluating the status of normal RK13 cell. Có thể đánh giá tình trạng tế bào RK13 bình thường.	1	1			2	
			32-5	Capable of diluting sample and conducting contamination appropriately. Có thể pha loãng mẫu và tiến hành thao tác gây nhiễm một cách thích hợp.	1	1			2	
			32-6	Capable of adding culturing solution and conducting culture appropriately. Có thể bổ sung dung dịch nuôi cấy và tiến hành nuôi cấy một cách thích	1	1			2	
			32-7	Capable of identifying and counting the plaque. Có thể phân biệt và đếm các đám plaque.	1	1			2	
			32-8	Capable of calculating the virus titration. Có thể tính toán được hiệu giá vi rút.	1	1			2	
			32-9	The test result of in house reference shall be within specified control range. Kết quả thử nghiệm của mẫu chuẩn nội bộ phải nằm trong phạm vi quản lý đã thiết lập.	1	1			2	
			32-10	Capable of implementing sanitation (cleaning, ect.,) appropriately after test completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v.) sau khi kết thúc thử nghiệm một cách thích hợp.	1	1			2	
			32-11	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm	1	1			2	
33	QC (Bio Group)	MR vaccine virus titration test Thử nghiệm hiệu giá vi rút vắc xin MR	33-1	Capable of preparing for tools, equipment, chemicals and completing of testing conditon before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thử nghiệm trước khi thực hiện thử nghiệm một cách thích hợp.	1	1			2	
			33-2	Capable of operating, checking the equipment to be used for the test appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.	1	1			2	
			33-3	Capable of evaluating the status of normal RK13 cell. Có thể đánh giá tình trạng tế bào RK13 bình thường.	1	1			2	
			33-4	Capable of evaluating the status of normal Vero cell. Có thể đánh giá tình trạng tế bào Vero bình thường.	1	1			2	
			33-5	Capable of thawing the frozen samples and diluting to inoculate RK13 and Vero cells appropriately. Có thể làm tan mẫu đã đông lạnh và thực hiện thao tác pha loãng để gây nhiễm vào tế bào RK13 và tế bào Vero một cách thích hợp.	1	1			2	
			33-6	Capable of adding cell culture solution and keeping cell culture in a proper temperature. Có thể bổ sung dung dịch nuôi cấy của các tế bào và nuôi cấy ở nhiệt độ nuôi cấy thích hợp.	1	1			2	
			33-7	Capable of using ABC kit to perform evaluation appropriately. Có thể sử dụng bộ kit ABC để thực hiện thao tác đánh giá một cách thích hợp.	1	1			2	
			33-8	Capable of identifying and counting the focus. Có thể phân biệt và đếm được focus.	1	1			2	
			33-9	Capable of calculating the titration. Có thể tính toán được hiệu giá.	1	1			2	
			33-10	The test result of in house referance shall be within specified control range. Kết quả thử nghiệm của mẫu chuẩn nội bộ phải nằm trong phạm vi quản lý đã thiết lập.	1	1			2	
			33-11	Capable of implementing sanitation (cleaning, ect.,) appropriately after test completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v.) sau khi kết thúc thử nghiệm một cách thích hợp	1	1			2	
			33-12	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.	1	1			2	
34	QC (Bio Group)	Cell bank for RK13 cell passage Ngân hàng nuôi cấy cấy chuyển tế bào RK 13	34-1	Capable of preparing for tools, equipment, chemicals and completing of testing condition before conducting the performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thao tác trước khi thực hiện thao tác một cách thích hợp.	1				1	
			34-2	Capable of operating, checking the equipment to be used for the performance appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thao tác đó một cách thích hợp và có thể quản lý các biên bản đó.	1				1	
			34-3	Capable of understanding the contents of standard operating procedure and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình thao tác và tiến hành thao tác theo quy trình.	1				1	
			34-4	Capable of thawing the frozen working seed and implementing cell culture appropriately. Có thể làm tan tế bào chủng working seed bảo quản đông lạnh và tiến hành nuôi cấy tế bào một cách thích hợp.	1				1	
			34-5	Capable of evaluating the status of normal RK13 cell. Có thể đánh giá tình trạng tế bào RK13 bình thường.	1				1	
			34-6	Capable of performing passage appropriately. Có thể thực hiện thao tác cấy chuyển một cách thích hợp.	1				1	
			34-7	Capable of counting cell quantity appropriately. Có thể đếm số lượng tế bào một cách thích hợp.	1				1	

No.	Department	Name of process		Detail contents	Result 4	3	2	1	Sub Total	Remarks
			34-8	Capable of diluting cell at concentration adequate for using purpose and dispensing into proper containers. Có thể pha loãng ra nồng độ tế bào phù hợp với mục đích sử dụng và chia vào các dụng cụ chứa thích hợp.	1				1	
			34-9	Capable of production and preservation of working seed. Có thể sản xuất và bảo quản tế bào working seed.	1				1	
			34-10	Capable of implementing sanitation (cleaning, ect.,) appropriately after performance completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v,) sau khi kết thúc thao tác một cá ch thích hợp.	1				1	
			34-11	Capable of making performance record appropriately and reporting the performance result. Có thể ghi biên bản thao tác một cách thích hợp và báo cáo kết quả thao tá	1				1	
35	QC (Bio Group)	Production of rubella immune serum antigen virus Sản xuất vi rút khá ng nguyên huyết thanh miễn dịch rubella	35-1	Capable of preparing for tools, equipment, chemicals and completing of testing condition before conducting the performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thao tá c trước khi thực hiện thao tác một cách thích hợp.	1	1			2	
			35-2	Capable of operating, checking the equipment to be used for the performance appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thao tác đó một cách thích hợp và có thể quản lý các biên bản đó.	1	1			2	
			35-3	Capable of understanding the procedure (or protocol) of performance and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình (hoặc bản đề cương hướng dẫn) thao tác và thực hiện thao tác theo quy trình.	1	1			2	
			35-4	Capable of thawing the frozen BHK cell and implementing cell culture appropriately. Có thể làm tan tế bào BHK bảo quản đông lạnh và tiến hành nuôi cấy tế bà o một cách thích hợp.		2			2	
			35-5	Capable of evaluating the status of normal BHK cell. Có thể đánh giá tình trạng tế bào BHK bình thường.		2			2	
			35-6	Capable of performing passage appropriately. Có thể tiến hành thao tác cấy chuyền một cách thích hợp.		2			2	
			35-7	Capable of counting cell appropriately. Có thể tiến hành đếm tế bào một cách thích hợp.		2			2	
			35-8	Capable of diluting cell liquid at concentration adequate for using purpose and dispensing liquid into proper containers. Có thể pha loãng ra nồng độ tế bào phù hợp với mục đích sử dụng và chia vào các dụng cụ chứa thích hợp.		2			2	
			35-9	Capable of thawing the frozen virus, calculating MOI and conducting virus inoculation at proper concentration. Có thể làm tan vi rút bảo quản đông lạnh, tính toán số MOI và tiến hành gây nhiễm vi rút với nồng độ thích hợp.		2			2	
			35-10	Capable of checking cell status and evaluating the transformation level of cell.		2			2	
			35-11	Capable of collecting the solution for virus culture and seed virus production.		2			2	
			35-12	Capable of implementing sannitation (cleaning, ect.,) appropriately after performance completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v,) sau khi kết thúc thao tác một cá ch thích hợp.		2			2	
			35-13	Capable of making performance record appropriately and reporting the performance result. Có thể ghi biên bản thao tác một cách thích hợp và báo cáo kết quả thao tá		2			2	
36	QC (Bio Group)	Pig immune serum production Sản xuất huyết thanh miễn dịch lợn							0	Not yet
37	QC (Bio Group)	Rabbit immune serum production Sản xuất huyết thanh miễn dịch thỏ							0	Not yet
38	QC (Bio Group)	Rabbit inoculation test Thử nghiệm tiêm thỏ	38-1	Acquired the purpose of inoculation test (extraneous virus could be found in rabbit (Rabbit pox, Herpes virus). Nắm được mục đích của thử nghiệm (vi rút ngoại lai có thể tìm thấy ở thỏ (Rabbit pox, Herpes virus).	2	1			3	
			38-2	Capable of preparing for tools, equipment, records and completing of testing condition before test performance. Có thể chuẩn bị dụng cụ, thiết bị, biên bản và hoàn thiện môi trường làm việc trước khi tiến hành thao tác một cách thích hợp	2	1			3	
			38-3	Capable of receiving animal, recognizing individual, acclimatizing and quarantining appropriately. Có thể tiến hành tiếp nhận động vật, phân biệt cá thể, cách ly kiểm dịch một cách thích hợp.		3			3	
			38-4	Capable of treating rabbit appropriately (example: fixing rabbit (avoid to hurt rabbit), etc.). Có thể sử dụng thỏ một cách thích hợp (ví dụ: cố định thỏ (tránh không làm thỏ tổn thương) v.v.).	2	1			3	
			38-5	Capable of using scale and confirm weight when weighing animal, capable of weighing before test performance (receiving date and the 5th day). Có thể tiến hành sử dụng cân và xác nhận cân khi cân trọng lượng động vật, có thể tiến hành cân trọng lượng trước khi thử nghiệm (ngày nhập và ngày thứ 5).	2	3			5	
			38-6	Capable of shaving hair on subcutaneous innoculation position of thigh part and inoculation position at the center of shoulder appropriately (keep the blade of clipper nearly parallel with skin surface). Có thể cạo lông ở vị trí tiêm dưới da ở phần đùi và vị trí tiêm ở phần giữa vai một cách thích hợp (để lưỡi dao của tông đơ gần như song song với bề mặt da).	2	1			3	

No.	Department	Name of process		Detail contents	Result				Sub Total	Remarks
					4	3	2	1		
			38-7	Capable of using sample appropriately and capable of preserving sample until inoculation appropriately. Có thể sử dụng mẫu một cách thích hợp và có thể bảo quản mẫu cho đến khi tiêm một cách thích hợp.	2	1			3	
			38-8	Capable of confirming no abnormality of animal and performance of subcutaneous inoculation on thigh position and at the center of shoulder. Có thể xác nhận thấy động vật không có bất thường và tiến hành tiêm dưới da vào phần đùi và tiêm vào phần giữa vai.	1	2			3	
			38-9	Capable of weighing rabbit after inoculation 7days/time, at the same time, capable of checking visually, checking behaviour, checking inoculation position. Có thể cân trọng lượng thỏ sau tiêm 7 ngày/lần, đồng thời có thể quan sát ngoại quan, quan sát hành vi, quan sát vị trí tiêm.	2	1			3	
			38-10	Capable of evaluating performance condition of test and distinguishing to evaluate appropriately. Có thể đánh giá điều kiện thành lập thử nghiệm và phân biệt để đánh giá một cách thích hợp.		3			3	
39	QC (Bio Group)	Marker test (Animal Test Operation) Thử nghiệm marker (thao tác trên động vật)	39-1	Acquired the purpose of the test (confirm rubella virus still remaining attenuation during rubella vaccine production processes and there is no denaturation of virus). Nắm được mục đích của thử nghiệm (xác nhận vi rút rubella vẫn duy trì tính giảm độc lực trong các công đoạn sản xuất vắc xin rubella và vi rút không bị biến đổi tính chất).	2	1			3	
			39-2	Capable of preparing for tools, equipment, records and completing of testing condition before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, biên bản và hoàn thiện môi trường làm việc trước khi tiến hành thao tác một cách thích hợp	2	1			3	
			39-3	Capable of receiving animal, recognizing individual, acclimatizing and quarantining appropriately. Có thể tiến hành tiếp nhận động vật, phân biệt cá thể, cách ly kiểm dịch một cách thích hợp.		3			3	
			39-4	Capable of treating guinea-pig appropriately (example: fixing (avoid to hurt guinea-pig), etc.). Có thể sử dụng chuột lang một cách thích hợp (ví dụ: cố định (tránh không l àm chuột lang tổn thương) v.v.).	2	1			3	
			39-5	Capable of using scale and confirm weight when weighing animal, capable of weighing before test performance (receiving date and the 3rd, 8th days). Có thể tiến hành sử dụng cân và xác nhận cân khi cân trọng lượng động vật, có thể tiến hành cân trọng lượng trước khi thử nghiệm (ngày nhập và ngày thứ 3, 8).	2	1			3	
			39-6	Capable of preparing solution diluting sample appropriately and capable of preserving sample until inoculation appropriately. Có thể pha dung dịch pha loãng mẫu một cách thích hợp và có thể bảo quản mẫu cho đến khi tiêm một cách thích hợp.	2	1			3	
			39-7	Capable of fixing guinea-pig, using ethanol soaked towel to clean chest and inject sterilized needle into rip slot to bleed from heart appropriately; and capable of removing needle from cylinder in order for blood to go into test tube slowly. Có thể cố định chuột lang, dùng khăn tẩm ethanol khử trùng lau sạch phần ngực rồi cắm kim tiêm đã tiệt trùng từ khe xương sườn để lấy máu từ tim một cách thích hợp; đồng thời có thể tháo kim tiêm ra khỏi ống tiêm (xylanh) để cho máu chảy từ từ sang ống nghiệm.		3			3	
			39-8	Capable of confirming no abnormality of animal after bleeding and performance of subcutaneous inoculation on hindleg of guinea-pig. Có thể xác nhận động vật không có bất thường sau khi lấy máu và có thể ti êm dưới da vào chi sau của chuột lang.	1	2			3	
			39-9	Capable of using centrifuge machine to separate serum from bleeded blood, and capable of managing and preserving appropriately. Có thể dùng máy ly tâm tách huyết thanh trong máu đã lấy, đồng thời có thể quản lý và bảo quản một cách thích hợp.	2	1			3	
			39-10	Capable of weighing guinea pig after injection every 7 days, at the same time, capable of checking and confirming clinical signs (swell at injection position, inactivity, abnormal movement, lots of hair shedding, skin lesion, diarrhoea, thin, abnormal breathing, rhinorrhea, weight lossing clearly, ect.). Có thể cân trọng lượng chuột lang sau tiêm 7 ngày/lần, đồng thời có thể quan sát và xác nhận các triệu chứng lâm sàng (sưng tấy tại vị trí tiêm, khô ng hoạt bát, đi lại bất thường, rụng lông quá nhiều, tổn thương ngoài da, tiê u chảy, nấy, hô hấp bất thường, sổ mũi, sụt cân rõ rệt v.v.)		3			3	
40	QC (Bio Group)	Marker test (HI test) Thử nghiệm marker (Thử nghiệm HI)	40-1	Capable of removing inhibitor in serum of test sample and HI positive/negative serum appropriately. Có thể tiến hành loại bỏ chất ức chế trong huyết thanh của mẫu kiểm tra và huyết thanh dương tính/âm tính HI một cách thích hợp.		2			2	
			40-2	Capable of diluting serum which had been removed inhibitor appropriately. Có thể tiến hành pha loãng các huyết thanh đã được loại bỏ chất ức chế một cách thích hợp.		2			2	
			40-3	Capable of dissolving and diluting 4 units antigen solution. Có thể tiến hành hòa tan và pha loãng dung dịch kháng nguyên 4 đơn vị.		2			2	
			40-4	Capable of preparing and adding 0.2% fixed solution of chicken erythrocyte appropriately. Có thể tiến hành pha và bổ sung dung dịch hồng cầu gà con cố định 0.2% một cách thích hợp.		2			2	
			40-5	Capable of dissolving and diluting 4 units antigen solution and capable of confirming unit (evaluating agglutination pattern). Có thể tiến hành hòa tan và pha loãng dung dịch kháng nguyên 4 đơn vị và có thể xác nhận đơn vị (đánh giá hình ảnh ngưng kết).		2			2	
			40-6	Capable of evaluating performance condition of test and distinguishing to evaluate appropriately. Có thể đánh giá điều kiện thành lập thử nghiệm và phân biệt để đánh giá một cách thích hợp.		2			2	

No.	Department	Name of process		Detail contents	Result				Sub Total	Remarks
					4	3	2	1		
41	QC (Phys-Chem Group	Test receiving vials (Test for soluble iron) Thử nghiệm chiết xuất sắt)	41-1	Capable of preparing for tools, equipment, chemicals before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất trước khi thực hiện thử nghiệm một cách thích hợp		1			1	
			41-2	Capable of operating, checking equipment using for test appropriately and capable of managing those records. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.		1			1	
			41-3	Capable of understanding content of standard operating procedures (SOP) for test and operating according to SOP. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.		1			1	
			41-4	Capable of doing necessary operations to create sample using for test appropriately. Có thể thao tác cần thiết để tạo mẫu thử sử dụng cho thử nghiệm một cách thích hợp.		1			1	
			41-5	Capable of preparing control solution appropriately. Có thể pha dung dịch đối chứng một cách thích hợp.		1			1	
			41-6	Capable of implementing cleaning up appropriately after test completion Sau khi kết thúc thử nghiệm, có thể thu dọn và vệ sinh một cách thích hợp.		1			1	
			41-7	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.		1			1	
42	QC (Phys-Chem Group	Test receiving vials (Test for light transmission) Thử nghiệm tính cản quang	42-1	Capable of preparing for tools, equipment, chemicals before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất trước khi thực hiện thử nghiệm một cách thích hợp.		1			1	
			42-2	Capable of operating, checking equipment using for test appropriately and capable of managing those records. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.		1			1	
			42-3	Capable of understanding content of standard operating procedures (SOP) for test and operating according to SOP. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.		1			1	
			42-4	Capable of doing necessary operations to create sample using for test appropriately. Có thể thao tác cần thiết để tạo mẫu thử sử dụng cho thử nghiệm một cách thích hợp.		1			1	
			42-5	Capable of operating spectrophotometer. Có thể thao tác với máy đo quang phổ.		1			1	
			42-6	Capable of implementing cleaning up appropriately after test completion. Sau khi kết thúc thử nghiệm có thể thu dọn và vệ sinh một cách thích hợp.		1			1	
			42-7	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.		1			1	
43	QC (Phys-Chem Group	Test receiving vials (Test for soluble alkali) Thử nghiệm chiết xuất kiềm	43-1	Capable of preparing for tools, equipment, chemicals before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất trước khi thực hiện thử nghiệm một cách thích hợp.		1			1	
			43-2	Capable of operating, checking equipment using for test appropriately and capable of managing those records. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.		1			1	
			43-3	Capable of understanding content of standard operating procedures (SOP) for test and operating according to SOP. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.		1			1	
			43-4	Capable of doing necessary operations to create sample using for test appropriately. Có thể thao tác cần thiết để tạo mẫu thử sử dụng cho thử nghiệm một cách thích hợp.		1			1	
			43-5	Capable of implementing titration test appropriately. Có thể thực hiện thử nghiệm chuẩn độ một cách thích hợp.		1			1	
			43-6	Capable of calculating according to test calculation. Có thể tính toán theo phép tính của thử nghiệm.		1			1	
			43-7	Capable of implementing cleaning up appropriately after test completion. Sau khi kết thúc thử nghiệm có thể thu dọn và vệ sinh một cách thích hợp.		1			1	
			43-8	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.		1			1	
			44-1	Capable of preparing for tools, equipment, chemicals and completion of testing condition before test performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thử nghiệm trước khi thực hiện thử nghiệm một cách thích hợp.	1	1			2	
			44-2	Capable of operating, checking the equipment to be used for the test appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thử nghiệm một cách thích hợp và có thể quản lý các biên bản đó.	1	1			2	
			44-3	Capable of understanding the contents of standard operating procedure of the test and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và thực hiện thao tác theo quy trình.	1	1			2	
			44-4	Capable of evaluating the status of normal Vero cell. Có thể đánh giá tình trạng tế bào Vero bình thường.	1	1			2	

No.	Department	Name of process	Detail contents		Result				Sub Total	Remarks
					4	3	2	1		
44	QC (Bio Group)	Measles immune antibody neutralization test Thử nghiệm trung hòa kháng thể miễn dịch sởi	44-5	Capable of diluting serum and performing sample preparation appropriately. Có thể pha loãng huyết thanh và thực hiện thao tác pha mẫu một cách thích hợp		2			2	
			44-6	Capable of diluting challenge virus to specified concentration. Có thể pha loãng vi rút thử thách ra nồng độ quy định.		2			2	
			44-7	Capable of performing serum neutralization appropriately. Có thể thực hiện thao tác trung hòa huyết thanh một cách thích hợp.		2			2	
			44-8	Capable of performing inoculation appropriately. Có thể thực hiện thao tác gây nhiễm một cách thích hợp.		2			2	
			44-9	Capable of adding culture solution and performing culture appropriately. Có thể bổ sung dung dịch nuôi cấy và tiến hành nuôi cấy một cách thích		2			2	
			44-10	Capable of confirming change of cell. Có thể xác nhận được sự biến đổi của tế bào.		2			2	
			44-11	Capable of calculating virus potency. Có thể tính toán được hiệu giá vi rút.	1	1			2	
			44-12	Capable of calculating neutralizing antibody titre. Có thể tính toán được hiệu giá kháng thể trung hòa.	1	1			2	
			44-13	Capable of implementing sanitation (cleaning, ect.,) appropriately after test completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v.) sau khi kết thúc thử nghiệm một cách thích hợp.	1	1			2	
			44-14	Capable of making test record appropriately and reporting the test result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thử nghiệm.	1	1			2	
45	QC (Bio Group)	Evaluation test of viable bacteria found in production water Thử nghiệm đánh giá khuẩn sống có trong nước sản xuất	45-1	Capable of preparing for tools, equipment, chemicals and completing of testing condition before conducting the performance appropriately. Có thể chuẩn bị dụng cụ, thiết bị, hóa chất và hoàn thiện môi trường thao tá c trước khi thực hiện thao tác một cách thích hợp.	1	1			2	
			45-2	Capable of operating, checking the equipment to be used for the test appropriately and capable of document control relatively. Có thể thao tác, kiểm tra các thiết bị dùng cho thao tác đó một cách thích hợp và có thể quản lý các biên bản đó.	1	1			2	
			45-3	Capable of understanding the contents of standard operating procedure of the test and conducting the performance accordingly. Có thể hiểu được nội dung của bản quy trình thao tác thử nghiệm và tiến hà nh thao tác theo quy trình.	1	1			2	
			45-4	Capable of diluting strain appropriately and performing growth promotion test for using medium. Có thể pha loãng chủng vi khuẩn một cách thích hợp và thực hiện thử nghiệm tính năng cho các môi trường sử dụng.	1	1			2	
			45-5	Capable of using sample appropriately and conducting sample filtering. Có thể sử dụng mẫu một cách thích hợp và tiến hành được thao tác lọc	1	1			2	
			45-6	Capable of conducting contamination after filtration into medium appropriately. Có thể gây nhiễm filter sau lọc vào môi trường một cách thích hợp.	1	1			2	
			45-7	Capable of obsevating and counting the colony in medium. Có thể quan sát và đếm các colony trên môi trường.	1	1			2	
			45-8	Capable of implementing sannitation (cleaning, ect.,) appropriately after test completion. Có thể tiến hành việc dọn dẹp (vệ sinh v.v.) sau khi kết thúc thử nghiệm một cách thích hợp.	1	1			2	
			45-9	Capable of making performance record appropriately and reporting the performance result. Có thể ghi biên bản thử nghiệm một cách thích hợp và báo cáo kết quả thao tác.	1	1			2	
Total					272	286	7	6	571	

Level 1: Completed basic training course and acquired practical knowledge.
Level 2: Capable of performing assigned work under the instruction of supervisors.
Level 3: Capable of performing his/her assigned work on his/her own but unable to provide training for other.
Level 4: Capable of performing his/her assigned work on his/her own actively and also provide training for other.

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POLYVAC

Summary Results of PQ, MFT/PST, PV - 2014

Data summarized from 10/2013~ 09/2014 Updated date: 15/08/2015

Dept.	Type	Protocol No.	Machine Name & PQ Items	Freq. (year)	PQ content	Summary of condition	Number of implementation (depent on type of validation)		Acceptance Criterria	Implementation Date	Result
							Periodical VAL	Prospective VAL			
BP	Re-PQ	M03-RePQ-02	Autoclave A3	2	Effect of sterilization	Loading pattern 2	1	-	BI:(-) Temp.&Time: ≧121℃,≧20min. Dev.temp.:±2℃, F0:≧12	23/04/2014	Passed
	Re-PQ	M03-RePQ-03	Autoclave A3	2	Effect of sterilization	Loading pattern 3	1	-		22/04/2014	Passed
	Re-PQ	M03-RePQ-04	Autoclave A3	2	Effect of sterilization	Loading pattern 4	1			17/04/2014	Passed
	Re-PQ	M03-RePQ-04	Autoclave A2	2	Effect of sterilization	Loading pattern 4	1	-		17/04/2014	Passed
	Re-PQ	M03-RePQ-06	Dry Oven A3	2	Effect of sterilization	Loading pattern 2	1	-	BI:(-) Temp.&Time: ≧190℃,≧30min. FH: ≥32	17/04/2014	Passed
	Re-PQ	M03-RePQ-07	Dry Oven A3	2	Effect of sterilization	Loading pattern 3	1	-		14/04/2014	Passed
	Re-PQ	M03-RePQ-17	Gowning validation	1	Confirmation of qualificated people	9 people	1	-	Microorganism (Contact Plate)	14/05/2014	Passed
	PQ	MR03-PQ-04	Incubation room 2 (with loading)	-	Temp. distribuition	Temp.: 30 deg.C	-	3	30 ±1 deg.C	08/04/2014	Passed
	PQ	MR03-PQ-07	Dryoven A2	-	Effect of sterilization	Loading 1	-	3	BI:(-), Temp.&Time: ≧190℃,≧30min.	17,18,21/04/2014	Passed
	PQ	MR03-PQ-08	Autoclave A2	-	Effect of sterilization	Loading 1	-	3	BI:(-) Temp.&Time: ≧121℃,≧20min. Dev.temp.:±2℃, F0:≧12	06,07,08/05/2014	Passed
	PQ	MR03-PQ-09	Autoclave A2	-	Effect of sterilization	Loading 5	-	3		28,29/04/2014 và 05/05/2014	Passed
	PQ	C03-PQ-20	Autoclave A2	-	Effect of sterilization	Loading 3	-	3		27,28,29/09/2014	Passed
	PQ	MR03-PQ-03	Fomaline fumigation (for egg disinfection & rabbit kidney taking room)	-	Effect of sanitation by formaline	Grade:B,C (Rabbit kidney cell taking room)	-	3	BI:≧3 log reduction, Residual formalin:≦ 0,1ppm	17/05/2014 18/07/2014 31/08/2014	Passed
	PQ	MR03-PQ-06	Enviroment monitoring (for egg disinfection & rabbit kidney taking room)	-	Confirmation of environmental condition	Grade:B,C (at static and dynamic)	-	static: 1 time Dynamic: 3 times	Microorganism:Airborn organism, settling plate, Contact plate; Airbon particle: ≦5μm, >5um	Static monitoring: 20/05/2014 Dynamic monitoring: 23/05/2014; 08/08/2014;14/11/2014	Passed
	PQ	MR03-PQ-16	Cross-contamination prevention	-	Effect of cross-contamination prevention	Grade A, C challenging by measles & rubella virus	-	3	Virus: ≧3 log reduction, Recover rate: 70%	02/08/2014 04/09/2014 25/10/2014	Passed
	PQ	MR03-PQ-12	SPF rabbit transferring into clean room	-	Qualification of SOP	(Rabbit) AL --> Production building (NC→D→C→A)	-	3	Microorganism (Contact Plate)	08/08/2014	Passed
	PQ	MR03-PQ-10	Virus inactivation by hot water	-	Effect of virus inactivation by heat	Temp.: 70 ±1 deg.C Time: 5; 10; 15 min	-	3	No observation of virus after inactivation	16/06/2014 (70±1 deg.C/ 5 min)	Passed
	PQ	MR03-PQ-19	Virus inactivation by NaClO	-		NaClO con.:0.12; 0.15; 0.24 Time: 1;2;3;4 (h)	-	3	No existence of virus after inactivation	05/08/2014 (0.12 % NaClO/ 1h)	Passed
	PQ	MR03-PQ-18	Determine the shaking time of bulk solution	-	Homogenous bulk solution	By manual	-	3	Lactose concentration: 5%	22/08/2014; 07/10/2014; 27/11/2014 (T=5 min)	Passed
	PQ	MR03-PQ-17	Tool washing	-	Effect of washing	By manual	-	3	TOC :≦1000ppb Conductivity: ≤2.1 μS/Cm at 25 deg.C Visible observation: no dusty and dry.	05/08/2014~ 25/08/2014	Passed
	PQ	Rb03-PQ-05	Confirmation of all process for Virus manufacturing	-	Confirmation of all process for Virus manufacturing	Same as normal production	-	1	Process control items Lot uniformity	08/08/2014 ~ 25/08/2014.	Passed
	PQ	MR03-OQ-01	Incubation 1 (without loading)		Temp. distribution	Temp.: 37 deg.C Without loading	-	3	37 ±1 deg.C	28~31/03/2014	Passed
	PQ		Incubation 2 (without loading)	-	Temp. distribution	Temp.: 30 deg.C Without loading	-	3	30 ±1 deg.C	28~31/03/2014	Passed
	PST	C03-PST-01	Process simulation test for bulk production.	-	Effect of aseptic manipulation and enviroment.	SCD agar	-	3	No contamination found for all lots	09/2014	Passed

Dept.	Type	Protocol No.	Machine Name & PQ Items	Freq. (year)	PQ content	Summary of condition	Number of implementation (depent on type of validation)		Acceptance Crirteria	Implementation Date	Result
							Periodical VAL	Prospective VAL			
	PQ	Rb03-PQ-05	Confirmation of all process for rubella bulk product manufacturing	-	Confirmation for all processes	Same as normal production	-	1	Meet all criteria for rubella vaccine	08/08/2014 ~ 25/08/2014.	Passed
FP	Re-PQ	M04-RePQ-33	Formaline fumigation (capping room)	1	Effect of sanitation by formaline	Grade:B,C (Rabbit kidney cell taking room)	1	-	BI:≧3 log reduction, Residual formalin:≦ 0.1ppm	17/03/2014	Passed
	Re-PQ	M04-RePQ-31	Tunnel Sterilizer		Effect of de-endotoxin (6000EU)	(Set Parameter) Hot zone temp.: 270℃ Belt Speed:137mm/min	1	-	Endotoxin: ≧3 log reduction Max Temp.:≧250℃,	21/03/2014	Passed
	Re-PQ	M04-RePQ-19	Gowning validation	1	Confirmation of qualificated people	7 people	1	-	Microorganism (Contact Plate)	13/03/2014	Passed
	MFT	M04-ReMFT	Process simulation test for final production.	6 months	Effect of aseptic manipulation and enviroment.	SCD agar	1	-	No contamination found for all lots	12/03/2014	Passed
QC	Re-PQ	M02-RePQ-61	Dry Oven	2	Effect of sterilization	Loading pattern 2	1	-	BI:(-) Temp.&Time: ≧190℃, ≧20min. Dev.temp.:±2℃,	19/03/2014	Passed
	Re-PQ	M02-RePQ-36	Gowning validation	1	Confirmation of qualificated people	6 people	1	-	Microorganism (Contact Plate)	27/02/2014	Passed
	Re-PQ	M02-RePQ-17	Autoclave D	2	Effect of sterilization	Loading pattern 2	1	-	BI:(-) Temp.&Time: ≧121℃, ≧20min. Dev.temp.:±2℃, F0;≧12	29/05/2014	Passed
	PQ	MR02-PQ-01	Establish the titer parameter range for in-house rubella refference	-	Validated titer parameter range	10 times of potency test for reference sample	-	1	Parameter range: Average ± 2SD	12/2013 ~ 04/2014 (Titer range: 3.9~4.2 lg PFU/0.5ml)	Passed
MP	Re-PQ	M05-RePQ-11	Gowning validation	1	Confirmation of qualificated people	6 people	1	-	Microorganism (Contact Plate)	13/01/2014	Passed
AL	PQ	M09-PQ-01	Autoclave	1	Effect of sterilization	Loading pattern 1	-	3	BI:(-) CI: color change	29/11/2013	Passed
	PQ	M09-PQ-02	Autoclave	1	Effect of sterilization	Loading pattern 2	-	3		06/12/2013	Passed
	PQ	M09-PQ-04	Autoclave	1	Effect of sterilization	Loading pattern 3	-	3		20/12/2013	Passed
	PQ	M09-PQ-03	Formaline fumigation	1	Effect of sanitation by formaline	Grade D	-	1	BI:≧3 log reduction, Residual formalin:≦ 0.1ppm	13/12/2013	Passed

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Summary result table of Calibration for HVAC - 2014

Data summarized from 10/2013~ 09/2014 Updated date: 15/08/2015

No.	Name of Equipment	Place	Method	Criteria	Implementation date	Pass/ Fail	Freq. (year)
1	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-2	Final dept.	Temprature (Thermohygro recorder- TRU-72U)	± 0.81℃	06/03/2014	**Passed**	1
2	TED-P-101-2 SENSOR AND RP-1 RECORDER - FREEZER RM-2						
3	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-1						
4	TED-P-101-2 SENSOR AND RP-1 RECORDER - FREEZER RM-1						
5	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - COLD RM-4						
6	TED-P-101-2 SENSOR AND RP1 REORDER - COLD RM-4						
7	TED-P-101-2 SENSOR AND RP-1-2 INDICATOR - COLD RM-3						
8	TED-P-101-2 SENSOR AND RP-1 RECORDER- COLD RM-3						
9	THE-P-102 SENSOR AND TI-P-102 INDICATOR- FILLING RM				Not done (expire date: 18/03/2015)		2
10	THE-P-103 SENSOR AND TI-P-103 INDICATOR- CLEAN RM5						
11	THE-P-101 SENSOR AND TI-P-101 INDICATOR- CAPING RM1						
12	THE-P-104 SENSOR AND TI-P-104 INDICATOR- VIAL WASHING RM1						
13	THE-P-104 SENSOR AND HI-P-104 INDICATOR- VIAL WASHING RM1						
14	THE-P-105 SENSOR AND TI-P-105 WASHING RM3						
15	THE-P-102 SENSOR AND HI-P-102 INDICATOR- FILLING RM		Humidity (Thermohygro recorder- TRU-72U)	± 5.0%	Not done (expire date: 18/03/2015)		2
16	THE-P-103 SENSOR AND HI-P-103 INDICATOR- CLEAN RM5						
17	THE-P-101 SENSOR AND HI-P-101 INDICATOR- CAPING RM1						
18	THE-P-105 SENSOR AND HI-P-105 WASHINH RM3						
19	PdIA-P-101 CAPPING RM - CORRIDOR 7		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different Pressure ± 2.0Pa	06/03/2014	**Passed**	1
20	PdIA-P-102 FILLING RM-CAPPING RM						
21	PdIA-P-103 CLEAN RM5-CORRIDOR7						
22	PdIA-P-104 IN9-2 - CORRIDOR7						
23	PdIA-P-105 FILLING RM - VIAL WASHING RM						
24	PdIA-P-106 ANTE RM6 - CORRIDOR7						
25	PdIA-P-107 VIAL WASHING RM - CORRIDOR7						
26	TED-P-103-2 SENSOR AND RP-2-2 INDICATOR - COLD RM-2	Bulk and medium depts.	Temprature (Thermohygro recorder- TRU-72U)	± 0.81℃	21/03/2014	**Passed**	1
27	TED-P-103-2 SENSOR AND RP-2 RECORDER - COLD RM-2						
28	TED-P-103-4 SENSOR AND TIC-P103-2 INDICATOR - COLD RM-2						
29	TED-P-104-1 SENSOR AND RP-2-3 INDICATOR - INCUBATION RM-1						
30	TED-P-104-1 SENSOR AND RP-2 RECORDER - INCUBATION RM-1						
31	TED-P-104-2 SENSOR AND TIC-P104-1 INDICATOR - INCUBATION RM-1						
32	TED-P-103-1 SENSOR AND RP-2 RECORDER - INCUBATION RM-2						
33	TED-P-103-1 SENSOR AND RP-2-1 INDICATOR - INCUBATION RM-2						
34	TED-P-103-3 SENSOR AND TIC P103-1 INDICATOR - INCUBATION RM-2						
35	TED-P-105-1 SENSOR AND RP-2-4 INDICATOR - COLD RM-1				27/02/2014	**Passed**	
36	TED-P-105-1 SENSOR AND RP-2- µ2000 RECORDER - COLD RM-1						
37	THE-P-201 SENSOR AND TI-P-201 THAWING RM				Not done (expire date: 27/12/2014)		2
38	THE-P-202 SENSOR AND TI-P-202 CLEAN RM3						
39	THE-P-203 SENSOR AND TI-P-203 CLEAN RM4						
40	THE-P-206 SENSOR AND TI-P-206 DISINFECTION RM1						
41	THE-P-204 SENSOR AND TI-P-204 DISINFECTION RM2						
42	THE-P-205 SENSOR AND TI-P-205 WASHING RM1						
43	THE-P-207 SENSOR AND TI-P-207 MEDIA PREPARATION RM1.						
44	THE-P-209 SENSOR AND TI-P-209 CLEAN RM1.						
45	THE-P-210 SENSOR AND TI-P-210 CLEAN RM2.						
46	THE-P-208 SENSOR AND TI-P-208 CUTTING RM						
47	THE-P-211 SENSOR AND TI-P-211 STERILEFILTRATION RM2						
48	THE-P-212 SENSOR AND TI-P-212 OBSERVATION RM2						
49	THE-P-201 SENSOR AND HI-P-201 THAWING RM		Humidity (Thermohygro recorder- TRU-72U)	± 5.0%	Not done (expire date: 27/12/2014)		2
50	THE-P-202 SENSOR AND HI-P-202 CLEAN RM3						
51	THE-P-203 SENSOR AND HI-P-203 CLEAN RM4						
52	THE-P-206 SENSOR AND HI-P-206 DISINFECTION RM1						
53	THE-P-204 SENSOR AND HI-P-204 DISINFECTION RM2						
54	THE-P-205 SENSOR AND HI-P-205 WASHING RM1						
55	THE-P-207 SENSOR AND HI-P-207 MEDIA PREPARATION RM1						
56	THE-P-209 SENSOR AND HI-P-209 MEDIA PREPARATION RM1						
57	THE-P-210 SENSOR AND HI-P-210 CLEAN RM2						
58	THE-P-208 SENSOR AND HI-P-208 CUTTING RM						
59	THE-P-211 SENSOR AND HI-P-211 STERILEFILTRATION RM2						
60	THE-P-212 SENSOR AND HI-P-212 OBSERVATION RM2						

No.	Name of Equipment	Place	Method	Criteria	Implementation date	Pass/ Fail	Freq. (year)
61	PdIA-P-201 THAWING RM - CORRIDOR5	Bulk and medium depts.	Pressure (Difference pressure gauge KAL84 HALSTRUP)	± 2.0Pa	27/02/2014	**Passed**	1
62	PdIA-P-202 CLEAN RM3 - CORRIDOR5						
63	PdIA-P-203 CLEAN RM4 - CORRIDOR5						
64	PdIA-P-204 ANTE RM4 - CORRIDOR5						
65	PdIA-P-205 DISINFECTION RM2 - CORRIDOR5						
66	PdIA-P-206 WASHING RM1 - CORRIDOR5						
67	PdIA-P-207 DISINFECTION RM1 - CORRIDOR5						
68	PdIA-P-208 MEDIA PREPERATION RM - CORRIDOR5						
69	PdIA-P-209 CLEAN RM1 - CORRIDOR6						
70	PdIA-P-210 CLEAN RM2 - CORRIDOR6						
71	PdIA-P-211 CUTTING RM - CORRIDOR6						
72	PdIA-P-212 STRELLEFILTRATION RM - CORRIDOR6						
73	PdIA-P-213 ANTE RM1 - CORRIDOR6						
74	PdIA-P-214 CENTRIFUGATION & OBSERVATION RM1 - CORRIDOR6						
75	PdIG-P-203 PR11 - DISINFECTION RM2						
76	PdIG-P-204 PR7 - ANTE RM4						
77	PdIG-P-205 PR6 - CORRIDOR3						
78	THE-P-215 SENSOR AND TI-P-215 CLEAN RM6	QC	Temprature (Thermohygro recorder- TRU-72U)	± 0.81℃	Not done (expire date: 11/01/2015)		2
79	THE-P-216 SENSOR AND TI-P-216 CLEAN RM7						
80	THE-P-213 SENSOR AND TI-P-213 CLEAN RM8						
81	THE-P-214 SENSOR AND TI-P-214 PREPERATION RM						
82	TED-P-107-2 SENSOR AND TIC P107-1 INDICATOR - INCUBATION RM-3				12/02/2014	**Passed**	1
83	TED-P-107-2 SENSOR AND RP-3 - µ2000 RECORDER INCUBATION RM-3						
84	TED-P-107-2 SENSOR AND RP-3-2-INDICATOR - INCUBATION RM-3						
85	TED-P-107-1 SENSOR AND RP-3-2-INDICATOR - COLD RM-5						
86	TED-P-107-1 SENSOR AND RP-3- µ2000 RECORDER COLD RM-5						
87	THE-P-215 SENSOR AND HI-P-215 CLEAN RM6		Humidity (Thermohygro recorder- TRU-72U)	± 5.0%	Not done (expire date:11/01/2015)		2
88	THE-P-216 SENSOR AND HI-P-216 CLEAN RM7						
89	THE-P-213 SENSOR AND HI-P-213 CLEAN RM8						
90	THE-P-214 SENSOR AND HI-P-214 PREPERATION RM						
91	PdIA-P-215 PREPARATION RM - CORRIDOR10		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different Pressure ± 2.0Pa	13/02/2014	**Passed**	1
92	PdIA-P-216 CLEAN RM8 - CORRIDOR10						
93	PdIA-P-217 IN12 - CHANGING RM12						
94	PdIA-P-218 CLEAN RM6 - CORRIDOR10						
95	PdIA-P-219 CLEAN RM7 - CORRIDOR10						
96	PdIG-P-201 OUT 11-2 - PERFORMANCE TEST RM						
97	PdIG-P-202 IN11-2 - CHANGING RM11						
98	Rabbit Test	Animal lab	Temprature (Thermohygro recorder- TRU-72U)	Tempratur e ± 0.81℃	Not done (expire date:16/01/2015)		2
99	Guinea Pig Test						
100	Quaratine Rm1						
101	Mice Test Rm 1						
102	Mice Test Rm 2						
103	Quaratine Rm 2						
104	Rabbit Test		Humidity (Thermohygro recorder- TRU-72U)	Humidity ± 5.0%	Not done (expire date:16/01/2015)		2
105	Guinea Pig Test						
106	Quaratine Rm1						
107	Mice Test Rm 1						
108	Mice Test Rm 2						
109	Quaratine Rm 2						
110	PdIA_A-101 DIRTY CORRIDOR1 - CORRIDOR1A		Pressure (Difference pressure gauge	Different Pressure	22/02/2014	**Passed**	1
111	PdIA_A-102 ANTE RM - CORRIDOR1A						
112	PdIA_A-103 DIRTY CORRIDOR2 - CORRIDOR1A						

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Summary result table of Maintenance validation for HVAC - 2014

Data summarized from 10/2013~ 09/2014 Updated date: 15/08/2015

Frequency of maintenance validation: once per year.

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
1	Ante room 6	101-01	Final Dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	03/03/2014	Passed
2		101-02					Passed
3		101-03					Passed
4	Clean room 5	101-04					Passed
5		101-05					Passed
6	Filling room	101-06					Passed
7		101-07					Passed
8		101-08					Passed
9		101-09					Passed
10		101-10					Passed
11		101-11					Passed
12		101-12					Passed
13		101-13					Passed
14		101-14					Passed
15		101-15					Passed
16	Al 9-1	101-16					Passed
17	Al 9-2	101-17					Passed
18	In 9-2	101-18					Passed
19	Al	101-19					Passed
20	Capping room	102-01					Passed
21		102-02					Passed
22	In 9-1	102-03					Passed
23	Pr 14	102-04					Passed
24	Washing rm 3	102-05					Passed
25		102-06					Passed
26		102-07					Passed
27		102-08					Passed
28		102-09					Passed
29		102-10					Passed
30	Vial&Sterili rm	102-11					Passed
31		102-12					Passed
32		102-13					Passed
33		102-14					Passed
34		102-15					Passed
35	In Out 10	102-16					Passed
36	Pr 16	102-17					Passed
37	Disinfection rm 3	102-18					Passed
38	Pr 15	102-19					Passed
39	Corridor 4	201-01					Passed
40		201-02					Passed
41		201-03					Passed
42	Pr 8	201-04					Passed

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
43	Freezing rm	201-05	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	24/03/2014	Passed
44	Thawing	201-06					Passed
45	Refrigerator rm 2	201-07					Passed
46		201-08					Passed
47	Storage 4	201-09					Passed
48	In 5	201-10					Passed
49	Refrigerator rm 2	201-11					Passed
50	Corridor 3	202-01					Passed
51		202-02					Passed
52	Clean rm 4	202-03					Passed
53		202-04					Passed
54		202-05					Passed
55		202-06					Passed
56	Clean rm 3	202-07					Passed
57		202-08					Passed
58		202-09					Passed
59		202-10					Passed
60	Ante rm 4	202-11	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	25/03/2014	Passed
61		202-12					Passed
62	Disinfection rm 2	202-13					Passed
63		202-14					Passed
64	Storage 3	202-15					Passed
65	Pr 6	202-16					Passed
66	Al 6	202-17					Passed
67	In 6	202-18					Passed
68	Ante rm 3	202-19					Passed
69		202-20					Passed
70	Pr 7	202-21					Passed
71	Pr 11	202-22					Passed
72	Corridor 2	203-01				28/03/2014	Passed
73		203-02					Passed
74		203-03					Passed
75		203-04					Passed
76	Centri&Observa	203-05					Passed
77		203-06					Passed
78	Storage 2	203-07					Passed
79	Refrigerator rm 1	203-08					Passed
80		203-09					Passed
81		203-10					Passed
82	Pr 5	203-11					Passed
83	In 4-2	203-12					Passed
84	Centri&Observa	203-13					Passed
85	Clean rm 1	204-01					Passed
86		204-02					Passed
87		204-03					Passed
88		204-04					Passed

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
89	Clean rm 2	204-05	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	24/02/2014	Passed
90		204-06					Passed
91		204-07					Passed
92		204-08					Passed
93	Ante rm 1	204-09					Passed
94		204-10					Passed
95		204-11					Passed
96		204-12					Passed
97	Corridor 1	204-13					Passed
98		204-14					Passed
99	Storage 1	204-15					Passed
100	Sterile Filtration	204-16					Passed
101		204-17					Passed
102	Cutting rm	204-18					Passed
103		204-19					Passed
104	Al 4	204-20					Passed
105	In 4-1	204-21					Passed
106	Pr 13	204-22					Passed
107	Ante rm 2	204-23					Passed
108	Pr 14	204-24					Passed
109	Pr 3	204-25					Passed
110	Pr2	204-26					Passed
111	Disinfection rm 1	261-01				27/03/2014	Passed
112	In 3-1	261-02					Passed
113	Media Preparation	262-01				24/02/2014	Passed
114		262-02					Passed
115	Pr 12	262-03					Passed
116	In 3-2	262-04					Passed
117	Check weight	262-05					Passed
118	Storage 6	212-01					Passed
119	Storage 5	212-02					Passed
120	Laundry rm	212-03					Passed
121		212-04					Passed
122	Washing rm 1	212-05	Bulk dept.	Leak test & Ventilation frequency measurement			Passed
123		212-06					Passed
124		212-07					Passed
125		212-08					Passed
126		212-09					Passed
127		212-10					Passed
128		212-11					Passed
129		212-12					Passed
130	In Out 7	212-13					Passed
131	Washing rm 2	212-14					Passed
132		212-15					Passed
133		212-16					Passed
134		212-17					Passed
135	Pr 9	212-18					Passed
136	Storage 7	212-19					Passed
137	Pr 1	212-20					Passed
138	Pr 10	212-21					Passed

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
139	Observation Area	208-01	QC	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	12/02/2014	Passed
140		208-02					Passed
141	Refrigerator rm 3	208-03					Passed
142		208-04					Passed
143	Clean rm 7	208-05					Passed
144		208-06					Passed
145	Incubation rm 2	208-07					Passed
146	Clean rm 6	208-08					Passed
147		208-09					Passed
148	Pr 19	208-10					Passed
149	Al 11-1	208-11					Passed
150	In 11-1	208-12					Passed
151	Clean rm 8	209-01					Passed
152		209-02					Passed
153		209-03					Passed
154	Preparation rm	209-04					Passed
155		209-05					Passed
156	Al 12-2	209-06					Passed
157	Al 12-1	209-07					Passed
158	In 12	209-08					Passed
159	Preformance test	211-01					Passed
160		211-02					Passed
161	AL 11-2	211-03					Passed
162	In 11-2	211-04					Passed
163	Dirty corridor 1	101-01	Nhà động vật			22/02/2014	Passed
164	Quarantine rm 1	101-02					Passed
165	Material out 1	101-03					Passed
166	Inocubation rm 1	101-04					Passed
167	Rabbits test rm	101-05					Passed
168	Inocubation rm 2	101-06					Passed
169	Guinea Pigs test rm	101-07					Passed
170	Clean Corridor 1	101-08					Passed
171	Ante rm	101-09					Passed
172	Ante rm	102-01					Passed
173	Clean orridor 2	102-02					Passed
174	AutoPsy rm 2	102-03					Passed
175	Quarantine rm 2	102-04					Passed
176	Mice Test rm 1	102-05					Passed
177	Inocubation rm3	102-06					Passed
178	Mice Test rm 2	102-07					Passed
179	Inoculation rm 4	102-08					Passed
180	Dirty corridor 2	102-09					Passed

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Summary Result Table of Calibration for Process Water Supply System 2014

Data summarized from 10/2013~ 09/2014 Updated date: 15/08/2015

Frequency of calibration: once per year.

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
1	SW Heat Exchanger Outlet Temp.	TIRCA-1101	Deionized Water System (1F)	Temprature (Ametek ITC-320A)	Temprature 70℃ ± 0.7℃ 80℃ ± 0.8℃ 90℃ ± 0.8℃	12/12/2013	Passed
2	Soft Water Tank Drain Temp.	TRS-1181		Temprature (Ametek ITC-320A)	Temprature 70℃ ± 0.6℃ 80℃ ± 0.6℃ 90℃ ± 0.7℃		Passed
3	Row Temp.	TRS-1201		Temprature (Ametek ITC-320A)	Temprature 70℃ ± 0.6℃ 80℃ ± 0.6℃ 90℃ ± 0.7℃		Passed
4	UFW Heater Outlet Temp.	TIRCA-3102	UFW Distribution System (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.9℃ 120℃ ± 1.0℃ 130℃ ± 1.0℃	11/12/2013	Passed
5	UFW Heater Inlet Temp.	TRS-3101		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
6	UFW Feed Tank Return Temp.	TRS-3103		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
7	UFW Tank Temp.	TRS-4101	UFW Generation (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	13/12/2013	Passed
8	UFW Return Temp.	TRS-4102		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
9	VF-4102 SIP	TRS-4181		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
10	P-4101 SIP	TRS-4182		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
11	UFW Return SIP Temp.	TRS-4183		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
12	P-4102 Temp.	TRS-4184		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
13	UFW-① SIP Temp.	TRSU-181	Freeze Drying Room (Use Point) (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	12/12/2013	Passed
14	UFW-② SIP Temp.-1	TRSU-281	Washing Room 3 (Use Point) (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	12/12/2013	Passed
15	UFW-② SIP Temp.-2	TRSU-282		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
16	UFW-③ SIP Temp.-1	TRSU-381	Washing Room 2 (Use Point) (2F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	11/12/2013	Passed
17	UFW-③ SIP Temp.-2	TRSU-382		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
18	UFW-④ SIP Temp.	TRSU-481	Disinfection Room 2 (2F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
19	UFW-⑤ SIP Temp.	TRSU-581	Disinfection Room 3 (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	12/12/2013	Passed
20	Condenser Outlet Temp.	TIRCA-6101	WFI Generation (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.9℃ 120℃ ± 1.0℃ 130℃ ± 1.0℃	20/12/2013	Passed
21	WFI Cooler Outlet Temp.	TRA-6102		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.6℃ 120℃ ± 0.6℃ 130℃ ± 0.9℃		Passed
22	WFI Heater Outlet Temp.	TIRCA-7103	WFI Distribution System (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.9℃ 120℃ ± 1.0℃ 130℃ ± 1.0℃		Passed
23	WFI Tank Temp.	TRS-7101	WFI Distribution System (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
24	WFI Return Temp.	TRS-7102		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
25	WFI Generation Outlet SIP Temp.	TRS-7181		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
26	P-7101 SIP Temp.	TRS-7182		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
27	WFI Return SIP Temp.	TRS-7183		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
28	HE -7101 Outlet SIP Temp.	TRS-7184		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
29	VF-7101 SIP Temp.	TRS-7185		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
30	WFI-① SIP Temp	TRS-W181	Vial Washing & Sterilization Rm (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
31	LC-WFI2 SIP Temp.-1	TRS-W281	Washing Room 3 (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
32	LC-WFI2 SIP Temp.-2	TRS-W282		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	19/12/2013	Passed
33	LC-WFI3 SIP Temp.-1	TRS-W381		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
34	LC-WFI3 SIP Temp.-2	TRS-W382		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
35	LC-WFI2 SIP Temp.-3	TRS-284	Filling Room (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	19/12/2013	Passed
36	LC-WFI4 SIP Temp.-1	TRS-W481	Media Preparatin Room (2F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
37	LC-WFI4 SIP Temp.-2	TRS-W482		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
38	WFI-⑤ SIP Temp	TRS-W581	Laundry Room (2F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	18/12/2013	Passed
39	LC-WFI6 SIP Temp.-1	TRS-W681	Washing Room 1 (2F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
40	LC-WFI6 SIP Temp.-2	TRS-W682		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
41	UFW&WFI SIP Temp.	TRS-5101	PS Unit (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	11/12/2013	Passed
42	UFW Return Pressure	PICA-4101	UFW Generation	Pressure (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa		Passed

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
43	Pure Steam Pressure	PICA-5101	PS Unit	Pressure (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	23/12/2013	**Passed**
44	Pure Steam Pressure	PICA-6101	WFI Generation	Pressure Cal equip.	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa		**Passed**
45	WFI Return Pressure	PICA-7101	WFI Distribution System	Pressure (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa		**Passed**
46	Sensor for measuring TOC, Conductivity of water production system	-	Water production system	TOC, Conductivity	TOC: 500ppb: ±50; 250ppb: ±20 Conductivity: ±1%	17/09/2014& 18/09/2014	**Passed**

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Summary Result Table of Maintenance Validation for Equipments - 2014

Data summarized from 10/2013~ 09/2014 Updated date: 15/08/2015

Frequency of maintenance validation: once per year.

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
1	Vial Sterilizing Machine	BE-03691	FP	Air Velocity; cleanliness; Appearance of HEPA filter	• Check of air velocity in the tunnel. The result of each zone is: 80% is average ± 20% 100% is average ± 30% • Cleanliness: - Implement at Infeed zone, Numeber of 0.3 µm particles are less than 0.01% compared with upper stream. - Implement at cooling zone, Numeber of 0.3 µm particles are less than 0.01% compared with upper stream. - Implement in depyrogenation tunnel, Must be satisfying class 5(DIN EN ISO 14644-1) 0.5µm ≤100, no 5.0µm • Appearance of Hepa filter: No color change compared to the original color (white) No holes in filter surface Flat surface, no deformation.	6/3/2014	Passed
2	Clean Bench B	G264920501	QC	Filter Leakage & Air Velocity, Air Volume	• Air velocity and Air Volume The average air velocity shall be within ±20% of specification (0.3m/sec). The air volume shall be within ±20% of specification. • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	13/02/2014	Passed
3	Clean Bench B	G264930501	QC			13/02/2014	Passed
4	Clean Bench B	G264930502	QC			13/02/2014	Passed
5	Clean Bench A	G264940501	QC			13/02/2014	Passed
6	Clean Bench C	G264910501	BP			6/5/2014	Passed
7	Clean Bench D	G264890501	BP			6/5/2014	Passed
8	Clean Bench E	G264880502	BP			6/5/2014	Passed
9	Clean Bench D	G264890502	BP			26/03/2014	Passed
10	Clean Bench D	G264890503	BP			26/03/2014	Passed
11	Clean Bench B	G264930503	BP			26/03/2014	Passed
12	Clean Bench E	G264870501	BP			26/03/2014	Passed
13	Clean Bench F	G264960501	BP			31/03/2014	Passed
14	Clean Bench E	G264880501	MP			26/02/2014	Passed
15	Clean Bench A	G264900501	MP			26/02/2014	Passed
16	Clean Bench C	G264950501	FP			4/3/2014	Passed
17	Clean Bench E	G264970501	FP			4/3/2014	Passed
18	Laminar Flow Unit	G242550501	FP			6/3/2014	Passed
19	Laminar Flow Unit	G242560501	FP			4/3/2014	Passed
20	Laminar Flow Unit	G242570501	FP			4/3/2014	Passed
21	Laminar Flow Unit	G242580501	MP			27/02/2014	Passed
22	Laminar Flow Unit	G242590501	BP			26/03/2014	Passed
23	Laminar Flow Unit B	5114-01277-CB100	QC - Chemica	Filter Leakage & Air Velocity, Air Volume	• Air velocity and Air Volume The average air velocity more than specification (≥0.35m/sec). • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	13/02/2014	Passed
24	Biological Safety Cabine	NSC-IIA-1800	BP	Filter Leakage & Circulated Air Velocity, Exhausted Air Velocity	• Circulated air velocity: 0.35 ± 0.025 m/sec • Exhausted air velocity: 0.53 ± 0.025 m/sec • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	5/5/2014	Passed
25	Biological Safety Cabine	NSC-IIA-1200(9721	QC			13/02/2014	Passed
26	Biological Safety Cabine	NSC-IIA-1200(9721	QC			13/02/2014	Passed
27	Laminar flow	200-00921-1101	BP	Filter Leakage & Air Velocity, Air Volume	• Air velocity and Air Volume The average air velocity more than specification (≥0.3m/sec). • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	26/03/2014	Passed
28	Laminar flow	200-00921-1102	BP-MP			2/26/2014	Passed
29	Laminar flow	200-009209-1101	FP			4/3/2014	Passed
30	Laminar flow	200-009211-1102	FP			4/3/2014	Passed

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Summary Result Table of Calibration for Equipment -2014

Data summarized from 10/2013~ 09/2014 Updated date: 15/08/2015

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
1	QC	Autoclave B	Chamber temp. sensor	TE1-1	111 , 121 , 131(oC)	≤±0.5(oC)	AMETEK ITC-320A	1	07/12/2013	Passed
			Chamber temp. sensor CH 1-Recorder	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)			07/12/2013	Passed
			Jacket temp. sensor	TE2	111 , 121 , 131(oC)	≤±0.5(oC)		3	Not done (*)	
			Chamber temp. sensor	TE3-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	07/12/2013	Passed
			Chamber temp. sensor CH.2	TE3-2	111 , 121 , 131(oC)	≤±0.5(oC)			07/12/2013	Passed
			Filter drain temp. sensor	TE4-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	07/12/2013	Passed
			Filter drain temp. sensor CH3-Recorder	TE4-2	111 , 121 , 131(oC)	≤±0.5(oC)			07/12/2013	Passed
			Chamber temp. sensor	TE5-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	07/12/2013	Passed
			Chamber temp. sensor CH4 - Recorder	TE5-2	111 , 121 , 131(oC)	≤±0.5(oC)			07/12/2013	Passed
			Chamber temp. sensor CH5 - Recorder	TE 6	111 , 121 , 131(oC)	≤±0.5(oC)		1	07/12/2013	Passed
			Chamber temp. sensor CH6 - Recorder	TE 7	111 , 121 , 131(oC)	≤±0.5(oC)		1	07/12/2013	Passed
			Chamber pressure sensor	PE - 1-1	0,100,200,300,-90(kPa)	≤±0.5(kPa)	AMETEK CPC200C	1	07/12/2013	Passed
			Chamber pressure sensor CH 12 - Recorder	PE - 1-2	0,100,200,300,-90(kPa)	≤±0.5(kPa)			07/12/2013	Passed
			Chamber pressure sensor	PI1	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	Not done (*)	
			Chamber pressure sensor	PI2	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	Not done (*)	
			Jacket pressure sensor	PI3	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		3	07/12/2013	Passed
2	QC	Incubator A (Q'ty: 3)	Chamber temp. sensor	TE1-1	40,30,20(oC)	≤±1(oC)	AMETEK ITC-155A	3	26/12/2013	Passed
			Chamber temp. sensor (recorder)	TE1-2	40,30,20(oC)	20oC: ≤± 0.5(oC) 30oC: ≤±		1	26/12/2013	Passed
			Chamber temp. sensor	TE2-1	40,30,20(oC)	≤±1(oC)		3	26/12/2013	Passed
			Chamber temp. sensor (recorder)	TE2-2	40,30,20(oC)	20oC: ≤± 0.5(oC) 30oC: ≤±		1	26/12/2013	Passed
			Chamber temp. sensor	TE3-1	50,40,30(oC)	≤±1(oC)		3	26/12/2013	Passed
			Chamber temp. sensor (recorder)	TE3-2	50,40,30(oC)	30oC: ≤± 0.5(oC) 40oC: ≤±0.5(oC) 50oC: ≤±		1	26/12/2013	Passed
3	QC	Incubator B	Chamber temp. sensor	TE1	40,30,20(oC)	≤±1(oC)	AMETEK ITC-155A	3	26/12/2013	Passed
			Chamber temp. sensor (recorder)	TE2				1	26/12/2013	Passed
4	QC	Incubator C (Q'ty: 3)	Chamber temp. sensor	TE1-1	40,30,25(oC)	≤±1(oC)	AMETEK ITC-155A	3	26/12/2013	Passed
			Chamber temp. sensor (recorder)	TE1-2				1	26/12/2013	Passed
			Chamber temp. sensor	TE2-1	40,30,25(oC)	≤±1(oC)		3	26/12/2013	Passed
			Chamber temp. sensor (recorder)	TE2-2				1	26/12/2013	Passed
			Chamber temp. sensor	TE3-1	70,60,50,40,30,25(oC)	≤±1(oC)		3	26/12/2013	Passed
			Chamber temp. sensor (recorder)	TE3-2				1	26/12/2013	Passed
5	QC	Vacuum dry oven	Chamber temp. sensor	TE1	50,60,70	≤±1(oC)	AMETEK ITC-155A	1	20/01/2013	Passed

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
6	QC	CO2 Incubator A	Chamber temp. sensor	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	10/12/2013	Passed
			Chamber temp. sensor (recorder)	TE2	30,40,50(oC)	30oC: ≤± 0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±		1	10/12/2013	Passed
			CO2 mesuring sensor	COE1	3,5,7(%)	≤±1(%)	FYRITE BACHARAC H GAS ANALIZER	1	10/12/2013	Passed
7	QC	CO2 Incubator B	Champer temp. sensor	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	Not done (*)	
			Champer temp. sensor (recorder)	TE2	30,40,50(oC)	30oC: ≤± 0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±		1	10/12/2013	Passed
			CO2 measuring sensor	COE1	3,5,7(%)	≤±1(%)	FYRITE BACHARAC H GAS ANALIZER	1	10/12/2013	Passed
8	QC	CO2 Incubator C	Champer temp. sensor	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	Not done (*)	
			Champer temp. sensor (recorder)	TE2	30,40,50(oC)	30oC: ≤± 0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±		1	10/12/2013	Passed
			CO2 measuring sensor	COE1	3,5,7(%)	≤±1(%)	FYRITE BACHARAC H GAS ANALIZER	1	10/12/2013	Passed
9	QC	Egg Incubator	Champer temp. sensor (recorder)	TE1-2	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	1	Not done because of not being in use in 2014	-
			Champer temp. sensor	TE1-1	30,40,50(oC)	30oC: ≤± 0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±		2		
10	QC	Lab. Autoclave for Chemical	Champer temperature sensor-Recorder	TE1	110,120,130(oC)	≤±1(oC)	AMETEK ITC-320A	1	13/12/2013	Passed
			Champer temperature sensor	TE2	110,120,130(oC)	≤±0.8(oC)		2	13/12/2013	Passed
			Champer pressure sensor	PG1	0.1, 0.12, 0.14(Mpa)	≤±0.01(Mpa)	AMETEK CPC200C	1	13/12/2013	Passed
11	QC	Lab. Autoclave for Biological	Champer temperature sensor-Recorder	TE1	110,120,130(oC)	≤±1(oC)	AMETEK ITC-320A	1	21/01/2014	Passed
			Champer temperature sensor	TE2	110,120,130(oC)	≤±0.8(oC)		2	Not done (*)	
			Champer pressure sensor	PG1	0.1, 0.12, 0.14(Mpa)	≤±0.01(Mpa)	AMETEK CPC200C	1	21/01/2014	Passed
12	QC	Dry Oven	Champer temp. sensor (indicator channel)	TE1	100,125,250(oC)	100: ≤±0.61(oC) 125: ≤±0.64(oC) 250: ≤±0.82(oC)	AMETEK ITC-320A	1	17/12/2013	Passed
			Champer temp. sensor (recorder)	TE2	100,125,250(oC)	100: ≤±0.57(oC) 125: ≤±0.63(oC) 250: ≤±0.92(oC)		1	17/12/2013	Passed
			Overheat temp. sensor (indicator channel)	TE3	100,125,250(oC)	100: ≤±3.5(oC) 125: ≤±3.5(oC) 250: ≤±3.5(oC)		1	17/12/2013	Passed
			Pressure sensor (control panel)	PE1-1	0,150,300(Pa)	0: ≤±7(Pa) 150: ≤±5(Pa) 300: ≤±5.5(Pa)	AMETEK CPC 200C	1	17/12/2013	Passed
			Pressure sensor (recorder)	PE1-2	0,150,300(Pa)				17/12/2013	Passed

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
13	QC	Freezer -30℃ (Q'ty: 4) (Model: MDF-U537B)	Champer temp. sensor	TE1-1	-30(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T 1	3	Not done (*)	
			Temp. sensor (recorder)	TE1-2	-30(oC)	≤±7(oC)		1	21/01/2014	Passed
			Champer temp. sensor	TE2-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE2-2	-30(oC)	≤±7(oC)		1	21/01/2014	Passed
			Champer temp. sensor	TE3-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE3-2	-30(oC)	≤±7(oC)		1	21/01/2014	Passed
			Champer temp. sensor	TE4-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE4-2	-30(oC)	≤±7(oC)		1	21/01/2014	Passed
14	QC	Freezer : -70℃ (Q'ty: 3) (Model: MDF-U581)	Champer temp. sensor	TE1-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T 1	3	Not done (*)	
			Temp. sensor (recorder)	TE1-2	-70(oC)	≤±7(oC)		1	21/01/2014	Passed
			Champer temp. sensor	TE2-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE2-2	-70(oC)	≤±7(oC)		1	21/01/2014	Passed
			Champer temp. sensor	TE3-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE3-2	-70(oC)	≤±7(oC)		1	21/01/2014	Passed
15	QC	Refrigerator 5℃ (Q'ty: 2)	Champer temp. sensor (equip.: 50302925)	TE1-1	5(oC)	≤±3(oC)	HYBRID RECORDER & SENSOR T 1	3	Not done (*)	
			Temp. sensor (recorder) (equip.: 50302925)	TE1-2	5(oC)	≤±3(oC)		1	21/01/2014	Passed
			Champer temp. sensor (equip.: 50302926)	TE2-1	5(oC)	≤±3(oC)		3	Not done (*)	
			Temp. sensor (recorder) (equip.: 50302926)	TE2-2	5(oC)	≤±3(oC)		1	21/01/2014	Passed
16	MP	Autoclave A-2	Champer temp. sensor	TE1-1	111 , 121 , 131(℃)	≤±0.5(oC)	AMETEK ITC-320A	1	09/12/2013	Passed
			Champer temp. sensor (recorder) CH.1	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Jacket temp. sensor	TE2	111 , 121 , 131(oC)	≤±0.5(oC)		3	09/12/2013	Passed
			Champer temp. sensor	TE3-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	09/12/2013	Passed
			Champer temp. sensor (recorder) CH.2	TE3-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Waste watert temp. sensor	TE4-1	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Waste watert temp. sensor CH.3	TE4-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Champer temp. sensor	TE5-1	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Champer temp. sensor (recorder) CH.4	TE5-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Champer temp. sensor (recorder) CH.5	TE 6	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Champer temp. sensor (recorder) CH.6	TE 7	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Champer pressure sensor	PE - 1-1	0,100,200,300,400,-90(kPa)	≤±5(kPa)	AMETEK CPC200C	1		
			Champer pressure sensor (recorder CH12)	PE - 1-2	0,100,200,300,400,-90(kPa)					
			Champer pressure sensor	PI 1	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	09/12/2013	Passed
			Champer pressure sensor	PI 2	0.4,0.3,0.2,0.1,-0.08(Mpa)			2	09/12/2013	Passed
			Jacket pressure sensor	PI 3	0.4,0.3,0.2,0.1,-0.08(Mpa)			3	09/12/2013	-

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
17	BP	Dry Oven A3	Champer temp. sensor (indicator channel)	TE1	100,125,250(oC)	100: ≤±0.61(oC) 125: ≤±0.64(oC) 250: ≤±0.82(oC)	AMETEK ITC-320A	1	20/02/2014	Passed
			Champer temp. sensor (recorder)	TE2	100,125,250(oC)	100: ≤±0.57(oC) 125: ≤±0.63(oC) 250: ≤±0.92(oC)		1		
			Overheat temp. sensor (indicator channel)	TE3	100,125,250(oC)	100: ≤±3.5(oC) 125: ≤±3.5(oC) 250: ≤±3.5(oC)		1		
			Pressure sensor (control panel)	PE1-1	0,150,300(Pa)	0: ≤±7(Pa) 150: ≤±5(Pa) 300: ≤±5.5(Pa)	AMETEK CPC200C	1		
			Pressure sensor (recorder)	PE1-2	0,150,300(Pa)					
18	BP	Dry Oven A2	Champer temp. sensor (indicator channel)	TE1	100,125,250(oC)	100: ≤±0.61(oC) 125: ≤±0.64(oC) 250: ≤±0.82(oC)	AMETEK ITC-320A	1	21/02/2014	Passed
			Champer temp. sensor (recorder)	TE2	100,125,250(oC)	100: ≤±0.57(oC) 125: ≤±0.63(oC) 250: ≤±0.92(oC)		1		
			Overheat temp. sensor (indicator channel)	TE3	100,125,250(oC)	100: ≤±3.5(oC) 125: ≤±3.5(oC) 250: ≤±3.5(oC)		1		
			Pressure sensor (control panel)	PE1-1	0,150,300(Pa)	0: ≤±7(Pa) 150: ≤±5(Pa) 300: ≤±5.5(Pa)	AMETEK CPC200C	1		
			Pressure sensor (recorder)	PE1-2	0,150,300(Pa)					
19	MP	Refrigerator (Sanyo-MPR-1410R)	Champer temp.sensor	TE1-1	4(°C)	≤±3 (oC)	HYBRID RECORDER & SENSOR T 1	1	18/12/2013	Passed
			Temp. sensor (recorder)	TE1-2	4 (°C)	≤±3(oC)		1		
20	BP	Autoclave A-3	Champer temp. sensor	TE1-1	111 , 121 , 131(°C)	≤±0.5(oC)	AMETEK ITC-320A	1	19/02/2014	Passed
			Champer temp. sensor (recorder) CH.1	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Jacket temp. sensor	TE2	111 , 121 , 131(oC)	≤±0.5(oC)		3	Not done (*)	
			Champer temp. sensor	TE3-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	19/02/2014	Passed
			Champer temp. sensor (recorder) CH.2	TE3-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Waste watert temp. sensor	TE4-1	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Waste watert temp. sensor CH.3	TE4-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Champer temp. sensor	TE5-1	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Champer temp. sensor (recorder) CH.4	TE5-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Champer temp. sensor (recorder) CH.5	TE 6	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Champer temp. sensor (recorder) CH.6	TE 7	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Champer pressure sensor	PE - 1-1	0,100,200,300,-90(kPa)	≤±5(kPa)	AMETEK CPC200C	1		
			Champer pressure sensor (recorder CH12)	PE - 1-2	0,100,200,300,-90(kPa)					
			Champer pressure sensor	PI 1	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	Not done (*)	
			Champer pressure sensor	PI 2	0.4,0.3,0.2,0.1,-0.08(Mpa)			2	Not done (*)	
			Jacket pressure sensor	PI 3	0.4,0.3,0.2,0.1,-0.08(Mpa)			3	Not done (*)	

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
21	BP	Egg Incubator	Champer temp. sensor	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	Not done because of not being in use in 2014	-
			Champer temp. sensor (recorder)	TE2	30,40,50(oC)	30oC: ≤± 0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±		1		-
			Humidity sensor - recorder channel	HE1	70(%)	≤±5(%)	TR72U	1		-
22	BP	Incubator for egg stock	Champer temp. sensor	TE1	10,15,20 (oC)	≤±1(oC)	AMETEK ITC-155A	2		
			Champer temp. sensor (recorder)	TE2	10,15,20 (oC)	10oC: ≤± 0.4(oC) 15oC: ≤± 0.5(oC)		1		-
23	BP+MP	Freezer -30℃ MDF-U537D (Q'ty: BP: 2; MP: 2)	Champer temp. sensor	TE1-1	-30(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T I	3	Not done (*)	
			Temp. sensor (recorder)	TE1-2	-30(oC)	≤±7(oC)		1	19/12/2013	Passed
			Champer temp. sensor	TE2-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE2-2	-30(oC)	≤±7(oC)		1	19/12/2013	Passed
			Champer temp. sensor	TE3-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE3-2	-30(oC)	≤±7(oC)		1	19/12/2013	Passed
			Champer temp. sensor	TE4-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE4-2	-30(oC)	≤±7(oC)		1	19/12/2013	Passed
24	BP	Freezer:-70℃ (Q'ty: 4) Model: MDF-U581	Champer temp. sensor	TE1-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T I	3	Not done (*)	
			Temp. sensor (recorder)	TE1-2	-70(oC)	≤±7(oC)		1	18/12/2013	Passed
			Champer temp. sensor	TE2-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE2-2	-70(oC)	≤±7(oC)		1	18/12/2013	Passed
			Champer temp. sensor	TE3-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE3-2	-70(oC)	≤±7(oC)		1	18/12/2013	Passed
			Champer temp. sensor	TE4-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE4-2	-70(oC)	≤±7(oC)		1	18/12/2013	Passed
25	BP	Freezer -70℃ (Q'ty: 4; Model: MDF-U72V)	Champer temp. sensor	TE1-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T I	3	Not done (*)	
			Temp. sensor (recorder)	TE1-2	-70(oC)	≤±7(oC)		1	24/07/2014	Passed
			Champer temp. sensor	TE2-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE2-2	-70(oC)	≤±7(oC)		1	18/12/2013	Passed
			Champer temp. sensor	TE3-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE3-2	-70(oC)	≤±7(oC)		1	18/12/2013	Passed
26	BP	Freezer:-70℃ (Q'ty: 1; Model: MDF-U74V)	Champer temp. sensor	TE4-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T I	3	Not done (*)	
			Temp. sensor (recorder)	TE4-2	-70(oC)	≤±7(oC)		1	18/12/2013	Passed

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
27	FP	Vial washing machine	Temp. sensor (circulated water)	B210	40,60,100(oC)	≤±2(oC)	AMETEK ITC-320A	1	26/02/2014	Passed
			Pressure sensor	PIA 110	950,500,0(kPa)	≤±8(kPa)	AMETEK CPC200C	1		
			Pressure sensor	PIA 120	950,500,0(kPa)	≤±30(kPa)		1		
			Pressure sensor	PIA 121	250,125,0(kPa)	≤±30(kPa)		1		
			Pressure sensor	PIA 130	950,500,0(kPa)	≤±30(kPa)		1		
28	FP	Vial Sterilizing machine	Temp. sensor of zone 1 (recorder)	TE 211	280,300,320(oC)	280: ≤±2.0(oC) 300: ≤±2.2(oC) 320: ≤±2.4(oC)	AMETEK ITC-320A	1	26/02/2014	Passed
			Temp. sensor of zone 2 (recorder)	TE 213	280,300,320(oC)	280: ≤±2.0(oC) 300: ≤±2.2(oC) 320: ≤±2.4(oC)		1		
29	FP	Autoclave A-1	Champer temp. sensor	TE1-1	111 , 121 , 131(°C)	≤±0.5(oC)	AMETEK ITC-320A	1	25/02/2014	Passed
			Champer temp. sensor (recorder) CH.1	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)			25/02/2014	Passed
			Jacket temp. sensor	TE2	111 , 121 , 131(oC)	≤±0.5(oC)		3	25/02/2014	Passed
			Champer temp. sensor	TE3-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) CH.2	TE3-2	111 , 121 , 131(oC)	≤±0.5(oC)			25/02/2014	Passed
			Waste watert temp. sensor	TE4-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	25/02/2014	Passed
			Waste water temp. sensor CH.3	TE4-2	111 , 121 , 131(oC)	≤±0.5(oC)			25/02/2014	Passed
			Champer temp. sensor	TE5-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) CH.4	TE5-2	111 , 121 , 131(oC)	≤±0.5(oC)			25/02/2014	Passed
			Champer temp. sensor (recorder) CH.5	TE 6	111 , 121 , 131(oC)	≤±0.5(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) CH.6	TE 7	111 , 121 , 131(oC)	≤±0.5(oC)		1	25/02/2014	Passed
			Champer pressure sensor	PE - 1-1	0,100,200,300,-90(kPa)	≤±5(kPa)	AMETEK CPC200C	1	25/02/2014	Passed
			Champer pressure sensor (recorder CH12)	PE - 1-2	0,100,200,300,-90(kPa)	≤±5(kPa)			25/02/2014	Passed
			Champer pressure sensor	PI 1	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	25/02/2014	Passed
			Champer pressure sensor	PI 2	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	25/02/2014	Passed
			Jacket pressure sensor	PI 3	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		3	25/02/2014	Passed

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
30	FP	Freeze dryer	Champer temp. sensor (recorder) (product 1 temp)	TE101	120,20,0(oC)	≤±1(oC)	AMETEK ITC-155A	1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 2 temp)	TE102	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 3 temp)	TE103	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 4 temp)	TE104	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 5 temp)	TE105	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 6 temp)	TE106	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 7 temp)	TE107	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 8 temp)	TE108	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 9 temp)	TE109	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 10 temp)	TE110	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 11 temp)	TE111	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 12 temp)	TE112	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Champer temp. sensor (recorder) (product 13 temp)	TE113	120,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Sillicol oil inlet temp. sensor	TE201	30,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Sillicol oil outlet temp. sensor	TE201 A	30,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Sillicol oil outlet temp. sensor	TE202	30,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Consender coil 1 temp. sensor	TE203	30,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Consender coil 2 temp. sensor	TE204	30,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Consender coil 3 temp. sensor	TE205	30,20,0(oC)	≤±1(oC)		1	25/02/2014	Passed
			Chamber dain temp. sensor	TE212	130,120,110(oC)	≤±1(oC)		1	25/02/2014	Passed
			Consender dain temp. sensor	TE212 A	130,120,110(oC)	≤±1(oC)		1	25/02/2014	Passed
			Consender dain temp. sensor	TE213	130,120,110(oC)	≤±1(oC)		1	25/02/2014	Passed
			Consender dain temp. sensor	TE213 A	130,120,110(oC)	≤±1(oC)		1	25/02/2014	Passed
			Filter drain temp. sensor	TE214	130,120,110(oC)	≤±1(oC)		1	25/02/2014	Passed
			Filter drain temp. sensor	TE214 A	130,120,110(oC)	≤±1(oC)		1	25/02/2014	Passed
31	EN	Hybrid recorder (Q'ty: 2)	Temp. sensors	NA	According to specification of equipment and sensors	According to specification of equipment and sensors	Multifuntion calibrator CA 71	1	10/02/2014	Passed

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
32	Animal Lab	Autoclave	Temp. sensor	TE1-1	111 , 121 , 131(oC)	≤±0.5(oC)	AMETEK ITC-155A	1	10/10/2013	Passed
			Temp. sensor	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)		1	10/10/2013	Passed
			Pressure sensor	PE1	-90;0;100;200;300 (kPa)	≤±0.5(kPa)		1	10/10/2013	Passed
			Pressure sensor	PE2	-0.09;0;0.1;0.2;0.3;0.4 (Mpa)	≤±0.02(MPa)		1	10/10/2013	Passed
			Pressure sensor	PE3	-0.09;0;0.1;0.2;0.3;0.4 (Mpa)	≤±0.02(MPa)	AMETEK CPC200C	1	10/10/2013	Passed
			Pressure sensor	PE4	0;0.1;0.2;0.3;0.4 (Mpa)	≤±0.02(MPa)		1	10/10/2013	Passed
			Pressure sensor	PE5	0;0.1;0.2;0.3;0.4 (Mpa)	≤±0.02(MPa)		1	10/10/2013	Passed
			Pressure sensor	PE6	0;0.2;0.4;00.6;0.8;1.0 (	≤±0.02(MPa)		1	10/10/2013	Passed

Remark: (*): not expired

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Result of Analytical Validation of QC - 2014&2015

Updated Date: 15/08/2015

No.	Name of test	Protocol No.	Implementation Date	Result
1	Potency test	Rb02-PQ-01	10/2014	Passed
2	Test for dectection of Encephalitozoon cuniculi	Rb02-PQ-02	09/01/2015	Passed

POLYVAC

Result of Analytical method transferring validation of QC - 2014&2015

Updated Date: 15/08/2015

No.	Name of test	Protocol No.	VAL Date	Result
1	SPF Pathology test	Rb02-TV-02	15/04/2014	Passed
2	Test for dectection of Encephalitozoon cuniculi	Rb02-TV-04	14/04/2014	Passed
3	Innoculation of rabbit	Rb02-TV-05	11/03/2014 ~ 15/04/2014	Passed
4	Innoculation of rabbit kidney cell culture	Rb02-TV-06	10/04/2014 ~ 14/05/2014	Passed
5	Potency test for rubella bulk product by PFU method	Rb02-TV-08	14/03/2014 ~ 27/03/2014	Passed
6	Marker test	Rb02-TV-09	12/03/2014 ~ 20/05/2014	Passed
7	SPF rabbit health monitoring during quarantine period	Rb09-TV-01	28/07/2014~ 20/08/2014	Passed
8	Identification test	MR02-TV-02	05/01/2015 ~12/01/2015	Passed
9	Thermal stability test	MR02-TV-01	05/01/2015 ~15/01/2015	Passed

POLYVAC

Result of Contract Calibration for Equipments - 2014

Updated date: 15/08/2015

No.	Name of equipment	Q'ty	Dept.	Manufacturer	Model	Serial	Freq. (year)	CAL date	Result
1	Intergrity test machine	2	MP+BP	Millipore	XIT4S0001	IT40332	1	23/4/2014	Passed
2			FP		XIT4S0001	IT40001		23/4/2014	Passed
3	Intergrity test machine	1	MP	Pall	Part No:FFSXC	22289326	2	14/06/2014	Passed
4	Particle counter A2400	4	FP	Hach Ultra	A2400	50601041	1	17/8/2014	Passed
5			BP			50601042		16/'01/2014	Passed
6			QC			50601043		14/06/2014	Passed
7			MP			1105060001		19/6/2014	Passed
8	Particle counter 237B	1	EN	Hach Ultra	237B	071200024	1	18/09/2014	Passed
9	Particle counter (portable) 227B	2	FP	Hach Ultra	227B	51200049	1	17/8/2014	Passed
10						51200047		17/8/2014	Passed
11	Air Sampler B (M Air T)	1	MP	Millipore	Cat No.: ATBPUMP01	276	1	10/7/2014	Passed
12	Air Sampler A (MD 8)	2	FP	Sartorius	MD8 Air port 16757	17601126	1	14/07/2014	Passed
13			QC	Sartorius	MD8 Air port 16757	17601125		23/05/2014	Passed
14	Spectrophometer	1	QC	Helios Gamma	-	UVG 150540	2	5/12/13	Passed
15	Weight	30	các phòng	-	-	Serial	2	08/09/2014	Passed
16	Pressure sensor of Freeze Drying machine	2	FP	Edward		076012021	2	26/05/2014	Passed
17						66179601		26/05/2014	Passed
18	Temperature Calibrator	1	EN	AMETEK	ITC-320 A 115/230V+PE	552656-00181	1	18/09/2014	Passed
19	Pressure Calibrator	1	EN	AMETEK	IPI300CBXXIN DG	1611107	1	18/09/2014	Passed

No.	Name of equipment	Q'ty	Dept.	Manufacturer	Model	Serial	Freq. (year)	CAL date	Result
20	Pressure Calibrator	1	EN	Halstrup-walcher GmbH	KAL 200	9609.0016AA190574	1	18/09/2014	Passed
21	Thermo-Hygro Recorder	15	EN	T&D Japan	TR72U	-	2	18/09/2014	Passed
22	Digital temperature indicator	1	EN	AMETEK	DTI-1000A	564803-00193	1	18/09/2014	Passed
23	Dry block temperature calibrator	1	EN	AMETEK	ITC-155A	560279-00634	1	18/09/2014	Passed
24	Anemometer	1	EN	Kanomax	6541	635537	1	18/09/2014	Passed
25	Thermometer	1	EN	Sato-Japan		1621	3	18/09/2014	Passed
26	Multifuntion calibrator	1	EN	Yokogawa Japan	CA71	T1FC047	1	18/09/2014	Passed
27	Particle counter	1	EN	Particle measuring system	LasairIII_310B	98067	1	06/10/2014	Passed

Result of IQ, OQ, CAL for new equipments -2014 & 2015

Updated Date: 15/08/2015

No.	Name of equipment	dept.	Q'ty	Maker	Model	Objects of validation				Progress	Result
						IQ	OQ	CAL	PQ		
1	Surface temperature thermometer	Bulk	1	Anritus, Japan	AP – 810 (S)	-	-	o	-	Finished. (confirmed the CAL certificate of maker, Cal date: 07/10/2013)	Passed
2	Deep freezer		4	PANASONIC	MDF-U74V-PE	o	o	o	-	Finished. (Implementation date: 22/07/2014)	Passed
3				PANASONIC	MDF-U74V-PE	o	o	o	-		
4				PANASONIC	MDF-U74V-PE	o	o	o	-		
5				PANASONIC	MDF-U74V-PE	o	o	o	-		
6	Recorder for Freezer		1	YOKOGAWA - Japan	µR20000 (Code: 437112/2)	o	o	o	-	Finished. (Implementation date: 15/01/2015)	Passed
7	Pooling tank 10L		68	NITTO KINZOKU - Japan	Order made	o	o	-	-	Finished. (Implementation date: 19/05/2014)	Passed
8	Dispenser 100ml		1	Shirasama, Japan	Riko JH	o	o	-	-	Finished. (Implementation date: 04/07/2014)	Passed
9	Dispenser 10ml		1	Shirasama, Japan	Jiko JA	o	o	-	-	Finished. (Implementation date: 04/07/2014)	Passed
10	Alcohol sprayer		2	Hach ultra, Japan	HDI9000	-	-	-	-	-	-
11					HDI9000	-	-	-	-	-	-
12	Particle counter		3	Hach ultra, Japan	A2400/2408	-	-	o	-	Finished. (confirmed the CAL certificate of maker, Cal date: 07/12/2014; 09/12/2014; 11/12/2014)	Passed
13						-	-	o	-		Passed
14						-	-	o	-		Passed
15	Air sampler	Bulk	2	Sartorius	MD8	-	-	o	-	Finished. (confirmed the CAL certificate of maker, Cal date: 07/10/2013)	Passed
16						-	-	o	-		Passed
17		QC	1			-	-	o	-		Passed
18	CO2 Incubator	QC	1	PANASONIC	MCO-19AIC-PE	o	o	o	o	Finished. (Implementation date: 28/02/2014)	Passed
19	Deep freezer		1	Sanyo	MDF-U74V-PE	o	o	o	-	Finished. (Implementation date: 30/07/2014)	Passed
20	Compressor		1	Gast - USA	DOA-P504-BN	o	o	-	-	Finished. (Implementation date: 15/04/2014)	Passed
21	Automated plate preparation system		1	Systec - Germany	Media fill	o	o	-	-	Finished. (Implementation date: 22/08/2014)	Passed
22	Centrifugation		1	Kokusan	H60R	o	o	o	-	Finished. (Implementation date: 16/05/2014)	Passed

No.	Name of equipment	dept.	Q'ty	Maker	Model	Objects of validation				Progress	Result
						IQ	OQ	CAL	PQ		
23	Electrical balance	Animal lab	2	Shimadzu	BW12KH	o	o	o	-	Finished. (Implementation date: 04/04/2014)	Passed
24				Shimadzu	BW12KH	o	o	o	-	Finished. (Implementation date: 04/04/2014)	Passed
25	Clinical Thermometer		1	TATEYAMA KAGAKU	D717	o	-	o	-	Finished. (Implementation date: 04/07/2014)	Passed
26	Refrigerator for wasted animals		1	Toshiba	GR-RG66FVDA (GU)	-	-	-	-		
27	Filtration and Sterilization system for drinking water for animal		1	chưa rõ thông tin	chưa rõ thông tin	o	o	-	-	Finished. (Implementation date: 01/07/2014)	Passed
28	Tissue embedding System	Patholo gy	1	SAKURA FINETEK	EM-J2-5233	-	-	-	-	-	-
29	Automatic tissue processor		1	SAKURA FINETEK	Tek VIP 5 Jr	-	-	-	-	-	-
30	Paraffin Oven		2	SAKURA FINETEK	PM-401-II	-	-	-	-	-	-
31	Paraffin Oven					-	-	-	-	-	-
32	Microtome		1	THEMOR SCENTIFIC	HM430	-	-	-	-	-	-
33	Tisue Floating Water		1	SAKURA FINETEK	PS-110WH	-	-	-	-	-	-
34	Slide Warmer		1	SAKURA FINETEK	PS-53	-	-	-	-	-	-
35	Camera System for the Microscope, BX53		1	OLYMPUS	DP73	-	-	-	-	-	-
36	Stand stirrer	Mediu m	1	IKA - EUROSTAR (USA)	EURO-ST20 D	o	o	-	-	Finished. (Implementation date: 29/04/2014)	Passed
37	Vacuum cleaner with HEPA filter for clean room	Mediu m	1	PHILIPS - Netherland	FC9228	-	-	-	-	-	-
38	Larminar Flow	FP	2	Airtech		o	o	-	o	Finished IQ, OQ (Implementation date: from 18/02/2014 to 21/02/2014). PQ: 1 time for static condition (12/2014); 3 times for operation condition (12/2014; 01/2015; 03/2015)	Passed
39	TOC calibration kit Conductivity calibration kit	Engine ering	1	Mettler Toledo	Model: 5000 TOC System Suitability Te	-	-	o	-	Finished. (confirmed the CAL certificate of maker, Cal date: 24/09/2013; 05/12/2013)	Passed
40	Conductivity calibration kit				Model: 1885 kit calibration system 770 max	-	-	o	-		Passed
41	Particle counter	Engine ering	1	Particle measuring systems (PMS)	Lasair III – 310B	-	-	o	-	Finished. (confirmed the CAL certificate of maker, Cal date: 12/12/2013)	Passed

Remarks: - : Not applicable; o: applicable

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Summary Results of PQ, MFT/PST, PV- 2015

Data summarized from 10/2014~ 08/2015 Updated date: 15/08/2015

Dept.	Type of validation	Protocol No.	Machine Name & PQ Items	Freq. (year)	PQ content	Summary of condition	Number of Implementation (depent on type of validation)		Acceptance Criteria	Implementation Date	Result
							Periodical VAL	Prospective VAL			
BP	Re-PQ	C03-RePQ-17	Gowning validation	1	Confirmation of qualificated people	9 people	1	-	Microorganism (Contact Plate)	14/04/2015	Passed
	RePQ	C03-RePQ-07	Dryoven A2	1	Effect of sterilization	Loading 1	1	-	BI:(-), Temp.&Time: ≧190℃, ≧30min.	22/01/2015	Passed
	RePQ	C03-PQ-08	Autoclave A2	1	Effect of sterilization	Loading 1	1	-	BI:(-) Temp.&Time: ≧121℃, ≧20min. Dev.temp.:±2℃, F0:≧12	22/01/2015	Passed
	RePQ	C03-PQ-09	Autoclave A2	1	Effect of sterilization	Loading 5	1	-		27/01/2015	Passed
	RePQ	C03-RePQ-20	Autoclave A2	1	Effect of sterilization	Loading 3	1	-		21/01/2015	Passed
	RePQ	C03-RePQ-03	Fomaline fumigation (for egg disinfection & rabbit kidney taking room)	1	Effect of sanitation by formaline	Grade:B,C (Rabbit kidney cell taking room)	1	-	BI:≧3 log reduction, Residual formalin: ≦0.1ppm	12/04/2015	Passed
	RePQ	C03-RePQ-24	Incubation 1 (without loading)		Temp. distribution	Temp.: 37 deg.C Without loading	1		37 ±1 deg.C	30/01/2015~12/02/2015	Passed
			Incubation 2 (without loading)	-	Temp. distribution	Temp.: 30 deg.C Without loading	1		30 ±1 deg.C	30/01/2015~12/02/2015	Passed
	PQ	C03-PQ-21	Gowning validation	-	Confirmation of qualificated people	3 new staffs	-	3	Microorganism (Contact Plate)	1st: 14/10/2014 2nd: 20/10/2014 3rd: 21/10/2014	Passed
	PQ	C03-PQ-23	Dryoven A2	-	Effect of sterilization	Loading 4	-	3	BI:(-) Temp.&Time: ≧190℃, ≧30min. FI: ≥32	16, 19, 20/01/2015	Passed
	PQ	C03-PQ-25	Enviroment monitoring for changing room after upgrading	-	Confirmation of environmental condition	Grade: D (at static)	-	1	Microorganism:Airborn organism, settling plate, Contact plate; Airbon particle: ≦5μm, > 5μm	09/04/2015~22/04/2015	Passed
	PQ	Rb03-PQ-26	Confirmation of all process for Virus manufacturing	-	Confirmation of all process for Virus manufacturing	Same as normal production	-	1	Process control items Lot uniformity	17/04/2015~05/05/2015	Failed (contamination deviation)
	PQ	Rb03-PQ-26	Confirmation of all process for rubella bulk product manufacturing	-	Confirmation for all processes	Same as normal production	-	1	Meet all criteria for rubella vaccine	05/06/2015~23/06/2015	Passed
	PV	C03-PV-01	Process validation for rubella bulk product manufacturing	-	Confirmation for all processes	Same as normal production	-	3	Meet all criteria for rubella vaccine	11, 12/2014	Failed
	PV	C03-PV-01	Process validation for rubella bulk product manufacturing	-	Confirmation for all processes	Same as normal production	-	3	Meet all criteria for rubella vaccine	scheduled to be done in 08,09/2015	In progress
FP	Re-PQ	C04-RePQ-09	Moisture content of rubber stopper after drying by Autoclave	2	Qualification of drying Time	(Set Parameter) Vacuum dry time:90min Hot Dry time:90min.	1		Rubber Stopper for WFI:≦ 0.5% Rubber Stopper for Freeze Dry: ≦0.3%	09/03/2015	Passed
	Re-PQ	M04-RePQ-31	Tunnel Sterilizer	1	Effect of de-endotoxin (6000EU)	(Set Parameter) Hot zone temp.: 270℃ Belt Speed:137mm/min	1	-	Endotoxin: ≧3 log reduction Max Temp.:≧250℃,	02/04/2015	Passed
	Re-PQ	M04-RePQ-19	Gowning validation	1	Confirmation of qualificated people	7 people	1	-	Microorganism (Contact Plate)	03/03/2015	Passed
	RePQ	C04-PQ-24	Autoclave A1	2	Effect of sterilization	Loading 7	1	-	BI:(-) Temp.&Time: ≧121℃, ≧20min. Dev.temp.:±2℃, F0:≧12	12/03/2015	Passed
	RePQ	C04-PQ-25	Autoclave A1	2	Effect of sterilization	Loading 8	1	-		11/03/2015	Passed
	RePQ	C04-PQ-26	Autoclave A1	2	Effect of sterilization	Loading 9	1	-		10/03/2015	Passed
	RePQ	C04-PQ-27	Autoclave A1	2	Effect of sterilization	Loading 10	1	-		13/03/2015	Passed
	PQ	C04-PQ-20	Gowning validation	-	Confirmation of qualificated people	5 new staffs		3	Microorganism (Contact Plate)	1st: 17/12/2015; 2nd: 22/12/2015; 3rd: 24/12/2015	Passed
	RePQ	C04-RePQ-04	Vial washing	2	Effective of washing	Set parameter	1	-	≥10μm: <6000 particles/Vial ≥25μm: <600 particles/Vial	09/02/2015	Passed
	RePQ	C04-RePQ-08	Tool washing	2	Effective of washing	By manual	1	-	TOC :≦1000ppb Conductivity: ≤2.1 μS/Cm at 25 deg.C Visible observation: no dusty and dry.	11, 12/08/2015	Waiting the QC test
	RePQ	C04-RePQ-05	CIP for Freeze drying chamber	2	Effective of washing	Set parameter	1	-	TOC :≦1000ppb Conductivity ≤2.1 μS/Cm at 25 deg.C Visible observation: no dusty and dry.	15~17/08/2015	Waiting the QC test
	PQ	C04-PQ-01	Virus inactivation by hot water	-	Effect of virus inactivation by heat	Temp.: ≥80 deg.C Time: ≥ 10 min	-	-	No observation of virus after inactivation	25/12/2014 22/01/2015 05/03/2015	Passed
	PQ	C04-PQ-02	Environment monitoring for changing room after upgrading and 2 new installed Laminar flow units	-	Confirmation of environmental condition	Grade: A, C, D (at static and operation)	-	static: 1 time Dynamic: 3 times	Microorganism:Airborn organism, settling plate, Contact plate; Airbon particle: ≦5μm, > 5μm	Static monitoring: 12/2014 Dynamic monitoring: 12/2014; 01/2015; 03/2015	Passed

Dept.	Type of validation	Protocol No.	Machine Name & PQ Items	Freq. (year)	PQ content	Summary of condition	Number of Implementation (depent on type of validation)		Acceptance Criterin	Implementation Date	Result
							Periodical VAL	Prospective VAL			
	PQ	MR04-PQ-03	Confirmation of all process for MR final product manufacturing	-	Confirmation of all process for final product manufacturing	Same as normal production	-	1	Process control items Lot uniformity	Implemented in 11~15/08/2015	Waiting the QC test
	MFT	M04-ReMFT	Process simulation test for final production.	6 months	Effect of aseptic manipulation and environment.	SCD agar	1	-	No contamination found for all lots	08/04/2015	Passed
										scheduled to implement in 09/2015	Not done
	PV	-	Process validation for MR final product manufacturing	-	Confirmation of all process for final product manufacturing	Same as normal production	-	3	Meet all criteria for measles vaccine	scheduled to be done in 10~11/2015	Not done
QC	Re-PQ	M02-RePQ-36	Gowning validation	1	Confirmation of qualificated people	6 people	1	-	Microorganism (Contact Plate)	09/03/2015	Passed
	Re-PQ	M02-RePQ-37	Autoclave B	2	Effect of sterilization	Loading 1	1	-	BI:(-) Temp.&Time: ≧121℃,≧20min. Dev.temp.±2℃, F0:≧12	07/11/2014	Passed
	Re-PQ	M02-RePQ-38	Autoclave B	2	Effect of sterilization	Loading 2	1	-		07/11/2014	Passed
	Re-PQ	M02-RePQ-40	Autoclave D	2	Effect of sterilization	Loading 2	1	-	BI:(-) Temp.&Time: ≧121℃,≧20min. Dev.temp.±2℃, F0:≧12	06/11/2014	Passed
	PQ	MR02-PQ-01	Establish the titer parameter range for in-house rubella refference	-	Validated titer parameter range	10 times of potency test for reference sample	-	1	Parameter range: Average ± 2SD	12/2013 ~ 04/2014 (Titer range: 3.9~4.2 lg PFU/0.5ml)	Passed
	PQ	C02-PQ-03	Formaline fumigation after upgrading changing room	-	Effect of sanitation by formaline	Grade:B,C	-	1 (revalidation after changing)	BI:≧3 log reduction, Residual formalin:≦0.1ppm	15~17/05/2015	Passed
	PQ	C02-PQ-11	Enviroment monitoring for changing room after upgrading	-	Confirmation of environmental condition	Grade: B, C, D (at static) (for changing room)	-	1	Microorganism:Airborn organism, settling plate, Contact plate; Airbon particle:≦5μm, > 5μm	30/01/2015	Passed
MP	Re-PQ	C05-RePQ-11	Gowning validation	1	Confirmation of qualificated people	6 people	1	-	Microorganism (Contact Plate)	13/02/2015	Passed
	Re-PQ	C05-RePQ-23	Autoclave A2	2	Effect of sterilization	Loading 05	1	-	BI:(-) Temp.&Time: ≧121℃,≧20min. Dev.temp.±2℃, F0:≧12	07/01/2015	Passed
	Re-PQ	C05-RePQ-19	Tool washing	2	Effective of washing	By manual	1	-	TOC : ≦1000ppb Conductivity: ≦2 1 μS/Cm at 25 deg.C Visible observation: no dusty and dry.	13/05/2015	Passed
	PQ	C05-PQ-03	Transferring tools and materials into clean rooms (with different clean grades)		Qualification of SOP	(Rout) NC→D, D→C		3	Microorganism (Contact Plate)	1st: 20/07/2015 2nd: 21/07/2015 3rd: 22/07/2015	Passed
	PQ	C05-PQ-01	Enviroment monitoring for medium preparation room after upgrading to C grade.	-	Confirmation of environmental condition	Grade C (at static and operation)	-	static: 1 time Dynamic: 3 times	Microorganism:Airborn organism, settling plate, Contact plate; Airbon particle:≦5μm, > 5μm	At static: 02~04/02/2015 At dynamic: 10, 11, 12/02/2015	Passed
AL	RePQ	M09-PQ-01	Autoclave	1	Effect of sterilization	Loading pattern 1	1	-	BI:(-) CI: color change	25/12/2014	Passed
	RePQ	M09-PQ-02	Autoclave	1	Effect of sterilization	Loading pattern 2	1	-		06/01/2015	Passed
	RePQ	M09-PQ-04	Autoclave	1	Effect of sterilization	Loading pattern 3	1	-		06/01/2015	Passed

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Summary result table of Calibration for HVAC - 2015

Data summarized from 10/2014~ 08/2015 *Updated:* 17/08/2015

No.	Name of Equipment	Place	Method	Criteria	Implementation date	Pass/ Fail	Freq. (year)
1	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-2	Final dept.	Temperature (Thermohygro recorder- TRU-72U)	± 0.81℃	23/03/2015	Passed	1
2	TED-P-101-2 SENSOR AND RP-1 RECORDER - FREEZER RM-2						
3	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-1						
4	TED-P-101-2 SENSOR AND RP-1 RECORDER - FREEZER RM-1						
5	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - COLD RM-4						
6	TED-P-101-2 SENSOR AND RP1 REORDER - COLD RM-4						
7	TED-P-101-2 SENSOR AND RP-1-2 INDICATOR - COLD RM-3						
8	TED-P-101-2 SENSOR AND RP-1 RECORDER- COLD RM-3						
9	THE-P-102 SENSOR AND TI-P-102 INDICATOR- FILLING RM				12/03/2015	Passed	2
10	THE-P-103 SENSOR AND TI-P-103 INDICATOR- CLEAN RM5						
11	THE-P-101 SENSOR AND TI-P-101 INDICATOR- CAPING RM1						
12	THE-P-104 SENSOR AND TI-P-104 INDICATOR- VIAL WASHING RM1						
13	THE-P-104 SENSOR AND HI-P-104 INDICATOR- VIAL WASHING RM1						
14	THE-P-105 SENSOR AND TI-P-105 WASHING RM3						
15	THE-P-102 SENSOR AND HI-P-102 INDICATOR- FILLING RM		Humidity (Thermohygro recorder- TRU-72U)	± 5.0%	12/03/2015	Passed	2
16	THE-P-103 SENSOR AND HI-P-103 INDICATOR- CLEAN RM5						
17	THE-P-101 SENSOR AND HI-P-101 INDICATOR- CAPING RM1						
18	THE-P-105 SENSOR AND HI-P-105 WASHINH RM3						
19	PdIA-P-101 CAPPING RM - CORRIDOR 7		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different Pressure ± 2.0Pa	11/03/2015	Passed	1
20	PdIA-P-102 FILLING RM-CAPPING RM						
21	PdIA-P-103 CLEAN RM5-CORRIDOR7						
22	PdIA-P-104 IN9-2 - CORRIDOR7						
23	PdIA-P-105 FILLING RM - VIAL WASHING RM						
24	PdIA-P-106 ANTE RM6 - CORRIDOR7						
25	PdIA-P-107 VIAL WASHING RM - CORRIDOR7						
26	TED-P-103-2 SENSOR AND RP-2-2 INDICATOR - COLD RM-2	Bulk and medium depts.	Temperature (Thermohygro recorder- TRU-72U)	± 0.81℃	29/01/2015	Passed	1
27	TED-P-103-2 SENSOR AND RP-2 RECORDER - COLD RM-2						
28	TED-P-103-4 SENSOR AND TIC-P103-2 INDICATOR - COLD RM-2						
29	TED-P-104-1 SENSOR AND RP-2-3 INDICATOR - INCUBATION RM-1						
30	TED-P-104-1 SENSOR AND RP-2 RECORDER - INCUBATION RM-1						
31	TED-P-104-2 SENSOR AND TIC-P104-1 INDICATOR - INCUBATION RM-1						
32	TED-P-103-1 SENSOR AND RP-2 RECORDER - INCUBATION RM-2						
33	TED-P-103-1 SENSOR AND RP-2-1 INDICATOR - INCUBATION RM-2						
34	TED-P-103-3 SENSOR AND TIC P103-1 INDICATOR - INCUBATION RM-2						
35	TED-P-105-1 SENSOR AND RP-2-4 INDICATOR - COLD RM-1						
36	TED-P-105-1 SENSOR AND RP-2- µ2000 RECORDER - COLD RM-1						
37	THE-P-201 SENSOR AND TI-P-201 THAWING RM				30/01/2015	Passed	2
38	THE-P-202 SENSOR AND TI-P-202 CLEAN RM3						
39	THE-P-203 SENSOR AND TI-P-203 CLEAN RM4						
40	THE-P-206 SENSOR AND TI-P-206 DISINFECTION RM1						
41	THE-P-204 SENSOR AND TI-P-204 DISINFECTION RM2						
42	THE-P-205 SENSOR AND TI-P-205 WASHING RM1						
43	THE-P-207 SENSOR AND TI-P-207 MEDIA PREPARATION RM1.						
44	THE-P-209 SENSOR AND TI-P-209 CLEAN RM1.						
45	THE-P-210 SENSOR AND TI-P-210 CLEAN RM2.						
46	THE-P-208 SENSOR AND TI-P-208 CUTTING RM						
47	THE-P-211 SENSOR AND TI-P-211 STERILEFILTRATION RM2						
48	THE-P-212 SENSOR AND TI-P-212 OBSERVATION RM2						
49	THE-P-201 SENSOR AND HI-P-201 THAWING RM		Humidity (Thermohygro recorder- TRU-72U)	± 5.0%	30/01/2015	Passed	2
50	THE-P-202 SENSOR AND HI-P-202 CLEAN RM3						
51	THE-P-203 SENSOR AND HI-P-203 CLEAN RM4						
52	THE-P-206 SENSOR AND HI-P-206 DISINFECTION RM1						
53	THE-P-204 SENSOR AND HI-P-204 DISINFECTION RM2						
54	THE-P-205 SENSOR AND HI-P-205 WASHING RM1						
55	THE-P-207 SENSOR AND HI-P-207 MEDIA PREPARATION RM1						
56	THE-P-209 SENSOR AND HI-P-209 MEDIA PREPARATION RM1						
57	THE-P-210 SENSOR AND HI-P-210 CLEAN RM2						
58	THE-P-208 SENSOR AND HI-P-208 CUTTING RM						
59	THE-P-211 SENSOR AND HI-P-211 STERILEFILTRATION RM2						
60	THE-P-212 SENSOR AND HI-P-212 OBSERVATION RM2						

No.	Name of Equipment	Place	Method	Criteria	Implementation date	Pass/ Fail	Freq. (year)
61	PdIA-P-201 THAWING RM - CORRIDOR5	Bulk and medium depts.	Pressure (Difference pressure gauge KAL84 HALSTRUP)	± 2.0Pa	29/01/2015	Passed	1
62	PdIA-P-202 CLEAN RM3 - CORRIDOR5						
63	PdIA-P-203 CLEAN RM4 - CORRIDOR5						
64	PdIA-P-204 ANTE RM4 - CORRIDOR5						
65	PdIA-P-205 DISINFECTION RM2 - CORRIDOR5						
66	PdIA-P-206 WASHING RM1 - CORRIDOR5				28/01/2015	Passed	
67	PdIA-P-207 DISINFECTION RM1 - CORRIDOR5						
68	PdIA-P-208 MEDIA PREPERATION RM - CORRIDOR5						
69	PdIA-P-209 CLEAN RM1 - CORRIDOR6						
70	PdIA-P-210 CLEAN RM2 - CORRIDOR6						
71	PdIA-P-211 CUTTING RM - CORRIDOR6						
72	PdIA-P-212 STRELLEFILTRATION RM - CORRIDOR6						
73	PdIA-P-213 ANTE RM1 - CORRIDOR6						
74	PdIA-P-214 CENTRIFUGATION & OBSERVATION RM1 - CORRIDOR6						
75	PdIG-P-203 PR11 - DISINFECTION RM2						
76	PdIG-P-204 PR7 - ANTE RM4						
77	PdIG-P-205 PR6 - CORRIDOR3						
78	THE-P-215 SENSOR AND TI-P-215 CLEAN RM6	QC	Temprature (Thermohygro recorder- TRU-72U)	± 0.81℃	04/02/2015	Passed	2
79	THE-P-216 SENSOR AND TI-P-216 CLEAN RM7						
80	THE-P-213 SENSOR AND TI-P-213 CLEAN RM8						
81	THE-P-214 SENSOR AND TI-P-214 PREPERATION RM						
82	TED-P-107-2 SENSOR AND TIC P107-1 INDICATOR - INCUBATION RM-3				04/02/2015	Passed	1
83	TED-P-107-2 SENSOR AND RP-3 - µ2000 RECORDER INCUBATION RM-3						
84	TED-P-107-2 SENSOR AND RP-3-2-INDICATOR - INCUBATION RM-3						
85	TED-P-107-1 SENSOR AND RP-3-2-INDICATOR - COLD RM-5						
86	TED-P-107-1 SENSOR AND RP-3- µ2000 RECORDER COLD RM-5						
87	THE-P-215 SENSOR AND HI-P-215 CLEAN RM6		Humidity (Thermohygro recorder- TRU-72U)	± 5.0%	04/02/2015	Passed	2
88	THE-P-216 SENSOR AND HI-P-216 CLEAN RM7						
89	THE-P-213 SENSOR AND HI-P-213 CLEAN RM8						
90	THE-P-214 SENSOR AND HI-P-214 PREPERATION RM						
91	PdIA-P-215 PREPARATION RM - CORRIDOR10		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different Pressure ± 2.0Pa	04/02/2015	Passed	1
92	PdIA-P-216 CLEAN RM8 - CORRIDOR10						
93	PdIA-P-217 IN12 - CHANGING RM12						
94	PdIA-P-218 CLEAN RM6 - CORRIDOR10						
95	PdIA-P-219 CLEAN RM7 - CORRIDOR10						
96	PdIG-P-201 OUT 11-2 - PERFORMANCE TEST RM						
97	PdIG-P-202 IN11-2 - CHANGING RM11						
98	Rabbit Test	Animal lab	Temprature (Thermohygro recorder- TRU-72U)	Temprature ± 0.81℃	26/03/2015	Passed	2
99	Guinea Pig Test						
100	Quaratine Rm1						
101	Mice Test Rm 1						
102	Mice Test Rm 2						
103	Quaratine Rm 2						
104	Rabbit Test		Humidity (Thermohygro recorder- TRU-72U)	Humidity ± 5.0%	26/03/2015	Passed	2
105	Guinea Pig Test						
106	Quaratine Rm1						
107	Mice Test Rm 1						
108	Mice Test Rm 2						
109	Quaratine Rm 2						
110	PdIA_A-101 DIRTY CORRIDOR1 - CORRIDOR1A		Pressure (Difference pressure gauge	Different Pressure	26/03/2015	Passed	1
111	PdIA_A-102 ANTE RM - CORRIDOR1A						
112	PdIA_A-103 DIRTY CORRIDOR2 - CORRIDOR1A						

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Summary result table of Maintenance validation for HVAC - 2015

Data summarized from 10/2014~ 08/2015 *Updated:* 17/08/2015

Frequency of maintenance validation: once per year.

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
1	Ante room 6	101-01	Final Dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	2015/10/3	Passed
2		101-02				2015/10/3	Passed
3		101-03				2015/10/3	Passed
4	Clean room 5	101-04				2015/10/3	Passed
5		101-05				2015/10/3	Passed
6	Filling room	101-06				2015/10/3	Passed
7		101-07				2015/10/3	Passed
8		101-08				2015/10/3	Passed
9		101-09				2015/10/3	Passed
10		101-10				2015/10/3	Passed
11		101-11				2015/10/3	Passed
12		101-12				2015/10/3	Passed
13		101-13				2015/10/3	Passed
14		101-14				2015/10/3	Passed
15		101-15				2015/10/3	Passed
16	Al 9-1	101-16				2015/10/3	Passed
17	Al 9-2	101-17				2015/10/3	Passed
18	In 9-2	101-18				2015/10/3	Passed
19	Al	101-19				2015/10/3	Passed
20	Capping room	102-01				2015/10/3	Passed
21		102-02				2015/10/3	Passed
22	In 9-1	102-03				2015/10/3	Passed
23	PR 14	102-04				2015/10/3	Passed
24	Washing rm 3	102-05				2015/10/3	Passed
25		102-06				2015/10/3	Passed
26		102-07				2015/10/3	Passed
27		102-08				2015/10/3	Passed
28		102-09				2015/10/3	Passed
29		102-10				2015/10/3	Passed
30	Vial&Sterili rm	102-11				2015/10/3	Passed
31		102-12				2015/10/3	Passed
32		102-13				2015/10/3	Passed
33		102-14				2015/10/3	Passed
34		102-15				2015/10/3	Passed
35	In Out 10	102-16				2015/10/3	Passed
36	Pr 16	102-17				2015/10/3	Passed
37	Disinfection rm 3	102-18				2015/10/3	Passed
38	Pr 15	102-19				2015/10/3	Passed
39	Corridor 4	201-01	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	29/01/2015	Passed
40		201-02				29/01/2015	Passed
41		201-03				29/01/2015	Passed
42	Pr 8	201-04				29/01/2015	Passed
43	Freezing rm	201-05				29/01/2015	Passed
44	Thawing	201-06				29/01/2015	Passed
45	Refrigerator rm 2	201-07				29/01/2015	Passed
46		201-08				29/01/2015	Passed
47	Storage 4	201-09				29/01/2015	Passed
48	In 5	201-10				29/01/2015	Passed
49	Refrigerator rm 2	201-11				29/01/2015	Passed
50	Corridor 3	202-01				23/01/2015	Passed
51		202-02				23/01/2015	Passed
52	Clean rm 4	202-03				23/01/2015	Passed
53		202-04				23/01/2015	Passed
54		202-05				23/01/2015	Passed
55		202-06				23/01/2015	Passed

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
56	Clean rm 3	202-07				23/01/2015	Passed
57		202-08				23/01/2015	Passed
58		202-09				23/01/2015	Passed
59		202-10				23/01/2015	Passed
60	Ante rm 4	202-11	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	23/01/2015	Passed
61		202-12				23/01/2015	Passed
62	Disinfection rm 2	202-13				23/01/2015	Passed
63		202-14				23/01/2015	Passed
64	Storage 3	202-15				23/01/2015	Passed
65	Pr 6	202-16				23/01/2015	Passed
66	Al 6	202-17				23/01/2015	Passed
67	In 6	202-18				23/01/2015	Passed
68	Ante rm 3	202-19				23/01/2015	Passed
69		202-20				23/01/2015	Passed
70	Pr 7	202-21				23/01/2015	Passed
71	Pr 11	202-22				23/01/2015	Passed
72	Corridor 2	203-01				22/01/2015	Passed
73		203-02				22/01/2015	Passed
74		203-03				22/01/2015	Passed
75		203-04				22/01/2015	Passed
76	Centri&Observa	203-05				22/01/2015	Passed
77		203-06				22/01/2015	Passed
78	Storage 2	203-07				22/01/2015	Passed
79	Refrigerator rm 1	203-08				22/01/2015	Passed
80		203-09				22/01/2015	Passed
81		203-10				22/01/2015	Passed
82	Pr 5	203-11				22/01/2015	Passed
83	In 4-2	203-12				22/01/2015	Passed
84	Centri&Observa	203-13				22/01/2015	Passed
85	Clean rm 1	204-01				20/01/2015	Passed
86		204-02				20/01/2015	Passed
87		204-03				20/01/2015	Passed
88		204-04				20/01/2015	Passed
89	Clean rm 2	204-05	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	20/01/2015	Passed
90		204-06				20/01/2015	Passed
91		204-07				20/01/2015	Passed
92		204-08				20/01/2015	Passed
93	Ante rm 1	204-09				20/01/2015	Passed
94		204-10				20/01/2015	Passed
95		204-11				20/01/2015	Passed
96		204-12				20/01/2015	Passed
97	Corridor 1	204-13				20/01/2015	Passed
98		204-14				20/01/2015	Passed
99	Storage 1	204-15				20/01/2015	Passed
100	Sterile Filtration	204-16				20/01/2015	Passed
101		204-17				20/01/2015	Passed
102	Cutting rm	204-18				20/01/2015	Passed
103		204-19				20/01/2015	Passed
104	Al 4	204-20				20/01/2015	Passed
105	In 4-1	204-21				20/01/2015	Passed
106	Pr 13	204-22				20/01/2015	Passed
107	Ante rm 2	204-23				20/01/2015	Passed
108	Pr 14	204-24				20/01/2015	Passed
109	Pr 3	204-25				20/01/2015	Passed
110	Pr2	204-26				20/01/2015	Passed
111	Disinfection rm 1	261-01				28/01/2015	Passed
112	In 3-1	261-02				28/01/2015	Passed

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
113	Media Preparation	262-01				28/01/2015	Passed
114		262-02				28/01/2015	Passed
115	Pr 12	262-03				28/01/2015	Passed
116	In 3-2	262-04				28/01/2015	Passed
117	Check weight	262-05				28/01/2015	Passed
118	Storage 6	212-01				21/01/2015	Passed
119	Storage 5	212-02				21/01/2015	Passed
120	Laundry rm	212-03				21/01/2015	Passed
121		212-04				21/01/2015	Passed
122	Washing rm 1	212-05	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	21/01/2015	Passed
123		212-06				21/01/2015	Passed
124		212-07				21/01/2015	Passed
125		212-08				21/01/2015	Passed
126		212-09				21/01/2015	Passed
127		212-10				21/01/2015	Passed
128		212-11				21/01/2015	Passed
129		212-12				21/01/2015	Passed
130	In Out 7	212-13				21/01/2015	Passed
131	Washing rm 2	212-14				21/01/2015	Passed
132		212-15				21/01/2015	Passed
133		212-16				21/01/2015	Passed
134		212-17				21/01/2015	Passed
135	Pr 9	212-18				21/01/2015	Passed
136	Storage 7	212-19				21/01/2015	Passed
137	Pr 1	212-20				21/01/2015	Passed
138	Pr 10	212-21				21/01/2015	Passed
139	Observation Area	208-01	QC	Leak test & Ventilation frequency measurement		2/2/2015	Passed
140		208-02				2/2/2015	Passed
141	Refrigerator rm 3	208-03				2/2/2015	Passed
142		208-04				2/2/2015	Passed
143	Clean rm 7	208-05				2/2/2015	Passed
144		208-06				2/2/2015	Passed
145	Incubation rm 2	208-07				2/2/2015	Passed
146	Clean rm 6	208-08				2/2/2015	Passed
147		208-09				2/2/2015	Passed
148	Pr 19	208-10				2/2/2015	Passed
149	Al 11-1	208-11				2/2/2015	Passed
150	In 11-1	208-12				2/2/2015	Passed
151	Clean rm 8	209-01				2/2/2015	Passed
152		209-02				2/2/2015	Passed
153		209-03				2/2/2015	Passed
154	Preparation rm	209-04				2/2/2015	Passed
155		209-05				2/2/2015	Passed
156	Al 12-2	209-06				2/2/2015	Passed
157	Al 12-1	209-07				2/2/2015	Passed
158	In 12	209-08				2/2/2015	Passed
159	Performance test	211-01				2/2/2015	Passed
160		211-02				2/2/2015	Passed
161	AL 11-2	211-03				2/2/2015	Passed
162	In 11-2	211-04				2/2/2015	Passed
163	Dirty corridor 1	101-01				26/03/2015	Passed
164	Quarantine rm 1	101-02				26/03/2015	Passed
165	Material out 1	101-03				26/03/2015	Passed
166	Inoculation rm 1	101-04				26/03/2015	Passed
167	Rabbits test rm	101-05				26/03/2015	Passed
168	Inoculation rm 2	101-06				26/03/2015	Passed
169	Guinea Pigs test rm	101-07				26/03/2015	Passed

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
170	Clean Corridor 1	101-08	Nhà động vật			26/03/2015	Passed
171	Ante rm	101-09				26/03/2015	Passed
172	Ante rm	102-01				26/03/2015	Passed
173	Clean corridor 2	102-02				26/03/2015	Passed
174	Autopsy rm 2	102-03				26/03/2015	Passed
175	Quarantine rm 2	102-04				26/03/2015	Passed
176	Mice Test rm 1	102-05				26/03/2015	Passed
177	Inoculation rm3	102-06				26/03/2015	Passed
178	Mice Test rm 2	102-07				26/03/2015	Passed
179	Inoculation rm 4	102-08				26/03/2015	Passed
180	Dirty corridor 2	102-09				26/03/2015	Passed

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Summary Result Table of Calibration for Process Water Supply System 2015

Data summarized from 10/2014~ 08/2015 *Updated:* 17/08/2015

Frequency of calibration: once per year.

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
1	SW Heat Exchanger Outlet Temp.	TIRCA-1101	Deionized Water System (1F)	Temperature (Ametek ITC-320A)	Temperature 70℃ ± 0.7℃ 80℃ ± 0.8℃ 90℃ ± 0.8℃	24/12/2014	Passed
2	Soft Water Tank Drain Temp.	TRS-1181		Temperature (Ametek ITC-320A)	Temperature 70℃ ± 0.6℃ 80℃ ± 0.6℃ 90℃ ± 0.7℃		Passed
3	Row Temp.	TRS-1201		Temperature (Ametek ITC-320A)	Temperature 70℃ ± 0.6℃ 80℃ ± 0.6℃ 90℃ ± 0.7℃		Passed
4	UFW Heater Outlet Temp.	TIRCA-3102	UFW Distribution System (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.9℃ 120℃ ± 1.0℃ 130℃ ± 1.0℃	26/12/2014	Passed
5	UFW Heater Inlet Temp.	TRS-3101		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
6	UFW Feed Tank Return Temp.	TRS-3103		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
7	UFW Tank Temp.	TRS-4101	UFW Generation (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	27/12/2014	Passed
8	UFW Return Temp.	TRS-4102		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
9	VF-4102 SIP	TRS-4181		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
10	P-4101 SIP	TRS-4182		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
11	UFW Return SIP Temp.	TRS-4183		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
12	P-4102 Temp.	TRS-4184		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
13	UFW-① SIP Temp.	TRSU-181	Freeze Drying Room (Use Point) (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	26/12/2014	Passed
14	UFW-② SIP Temp.-1	TRSU-281	Washing Room 3 (Use Point) (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	26/12/2014	Passed
15	UFW-② SIP Temp.-2	TRSU-282		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	26/12/2014	Passed

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
16	UFW-③ SIP Temp.-1	TRSU-381	Washing Room 2 (Use Point) (2F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	25/12/2014	Passed
17	UFW-③ SIP Temp.-2	TRSU-382		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
18	UFW-④ SIP Temp.	TRSU-481	Disinfection Room 2 (2F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
19	UFW-⑤ SIP Temp.	TRSU-581	Disinfection Room 3 (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	26/12/2014	Passed
20	Condenser Outlet Temp.	TIRCA-6101	WFI Generation (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.9℃ 120℃ ± 1.0℃ 130℃ ± 1.0℃	30/12/2014	Passed
21	WFI Cooler Outlet Temp.	TRA-6102		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.6℃ 120℃ ± 0.6℃ 130℃ ± 0.9℃	30/12/2014	Passed
22	WFI Heater Outlet Temp.	TIRCA-7103	WFI Distribution System (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.9℃ 120℃ ± 1.0℃ 130℃ ± 1.0℃	31/12/2014	Passed
23	WFI Tank Temp.	TRS-7101	WFI Distribution System (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	31/12/2014	Passed
24	WFI Return Temp.	TRS-7102		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	31/12/2014	Passed
25	WFI Generation Outlet SIP Temp.	TRS-7181		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	31/12/2014	Passed
26	P-7101 SIP Temp.	TRS-7182		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	31/12/2014	Passed
27	WFI Return SIP Temp.	TRS-7183		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	31/12/2014	Passed
28	HE -7101 Outlet SIP Temp.	TRS-7184		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	31/12/2014	Passed
29	VF-7101 SIP Temp.	TRS-7185		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	31/12/2014	Passed
30	WFI-① SIP Temp	TRS-W181	Vial Washing & Sterilization Rm (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	29/12/2014	Passed
31	LC-WFI2 SIP Temp.-1	TRS-W281	Washing Room 3 (1F)	Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
32	LC-WFI2 SIP Temp.-2	TRS-W282		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
33	LC-WFI3 SIP Temp.-1	TRS-W381		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
34	LC-WFI3 SIP Temp.-2	TRS-W382		Temperature (Ametek ITC-320A)	Temperature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃		Passed
35	LC-WFI2 SIP Temp.-3	TRS-284	Filling Room (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	29/12/2014	Passed
36	LC-WFI4 SIP Temp.-1	TRS-W481	Media Preparatin Room (2F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	30/12/2014	Passed
37	LC-WFI4 SIP Temp.-2	TRS-W482		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	30/12/2014	Passed
38	WFI-⑤ SIP Temp	TRS-W581	Laundry Room (2F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	25/12/2014	Passed
39	LC-WFI6 SIP Temp.-1	TRS-W681	Washing Room 1 (2F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	30/12/2014	Passed
40	LC-WFI6 SIP Temp.-2	TRS-W682		Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	30/12/2014	Passed
41	UFW&WFI SIP Temp.	TRS-5101	PS Unit (1F)	Temprature (Ametek ITC-320A)	Temprature 110℃ ± 0.8℃ 120℃ ± 0.8℃ 130℃ ± 0.9℃	24/12/2014	Passed
42	UFW Return Pressure	PICA-4101	UFW Generation	Pressure (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	27/12/2014	Passed
43	Pure Steam Pressure	PICA-5101	PS Unit	Pressure (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	30/12/2014	Passed
44	Pure Steam Pressure	PICA-6101	WFI Generation	Pressure Cal equip.	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	30/12/2014	Passed

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
45	WFI Return Pressure	PICA-7101	WFI Distribution System	Pressure (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ±	31/12/2014	Passed
46	Sensor for measuring TOC, Conductivity of water production system	-	Water production system	TOC, Conductivity	TOC: 500ppb: ±50; 250ppb: ±20 Conductivity: ±1%	Not done (*)	Passed

Remark: (*): not expired of calibration effective period

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Summary Result Table of Maintenance Validation for Equipments - 2015

Data summarized from 10/2014~ 08/2015 *Updated:* 17/08/2015

Frequency of maintenance validation: once per year.

No	Name of Equipment	Code No	Place	Method	Criteria	Implementation date	Pass/ Fail
1	Vial Sterilizing Machine	BE-03691	FP	Air Velocity; cleanliness; Appearance of HEPA filter	• Check of air velocity in the tunnel. The result of each zone is: 80% is average ± 20% 100% is average ± 30% • Cleanliness: - Implement at Infeed zone. Number of 0.3 µm particles are less than 0.01% compared with upper stream. - Implement at cooling zone. Number of 0.3 µm particles are less than 0.01% compared with upper stream. - Implement in dehydrogenation tunnel. Must be satisfying class 5(DIN EN ISO 14644-1) 0.5µm ≤100, no 5.0µm • Appearance of Hepa filter: No color change compared to the original color (white) No holes in filter surface Flat surface, no deformation.	01/04/2015	Passed
2	Clean Bench B	G264920501	QC	Filter Leakage & Air Velocity, Air Volume	• Air velocity and Air Volume The average air velocity shall be within ±20% of specification (0.3m/sec). The air volume shall be within ±20% of specification. • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	03/02/2015	Passed
3	Clean Bench B	G264930501	QC			03/02/2015	Passed
4	Clean Bench B	G264930502	QC			03/02/2015	Passed
5	Clean Bench A	G264940501	QC			04/02/2015	Passed
6	Clean Bench C	G264910501	BP			27/01/2015	Passed
7	Clean Bench D	G264890501	BP			27/01/2014	Passed
8	Clean Bench E	G264880502	BP			27/01/2015	Passed
9	Clean Bench D	G264890502	BP			28/01/2016	Passed
10	Clean Bench D	G264890503	BP			30/01/2015	Passed
11	Clean Bench B	G264930503	BP			28/01/2015	Passed
12	Clean Bench E	G264870501	BP			28/01/2015	Passed
13	Clean Bench F	G264960501	BP			28/01/2015	Passed
14	Clean Bench E	G264880501	MP			26/01/2015	Passed
15	Clean Bench A	G264900501	MP			26/01/2016	Passed
16	Clean Bench C	G264950501	FP			13/03/2015	Passed
17	Clean Bench E	G264970501	FP			13/03/2015	Passed
18	Laminar Flow Unit	G242550501	FP			13/03/2015	Passed
19	Laminar Flow Unit	G242560501	FP			13/03/2015	Passed
20	Laminar Flow Unit	G242570501	FP			13/03/2015	Passed
21	Laminar Flow Unit	G242580501	MP			28/01/2015	Passed
22	Laminar Flow Unit	G242590501	BP			28/01/2015	Passed
23	Laminar Flow Unit B	5114-01277-CB100	QC - Chemica	Filter Leakage & Air Velocity, Air Volume	• Air velocity and Air Volume The average air velocity more than specification (≥0.35m/sec). • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	04/02/2015	Passed
24	Biological Safety Cabine	NSC-IIA-1800	BP	Filter Leakage & Circulated Air Velocity, Exhausted Air Velocity	• Circulated air velocity: 0.35 ± 0.025 m/sec • Exhausted air velocity: 0.53 ± 0.025 m/sec • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	27/01/2015	Passed
25	Biological Safety Cabine	SC-IIA-1200(97212030805)	QC			03/02/2015	Passed
26	Biological Safety Cabine	SC-IIA-1200(97211030805)	QC			03/02/2015	Passed
27	Laminar flow	200-00921-1101	BP	Filter Leakage & Air Velocity, Air Volume	• Air velocity and Air Volume The average air velocity more than specification (≥0.3m/sec). • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	28/01/2015	Passed
28	Laminar flow	200-00921-1102	BP-MP			28/01/2015	Passed
29	Laminar flow	200-009209-1101	FP			13/03/2015	Passed
30	Laminar flow	200-009209-1101	FP			13/03/2015	Passed
31	Laminar flow	200-009211-1102	FP			13/03/2015	Passed
32	Laminar Flow Unit	200-020474-1301	FP			13/03/2015	Passed
33	Laminar Flow Unit	200-020475-1301	FP			13/03/2015	Passed

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Summary Result Table of Calibration for Equipment -2015

Data summarized from 10/2014~ 08/2015 *Updated:* 17/08/2015

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
1	QC	Autoclave B	Chamber temp. sensor	TE1-1	111 , 121 , 131(oC)	≤±0.5(oC)	AMETEK ITC-320A	1	05/11/2014	Passed
			Chamber temp. sensor CH 1-Recorder	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)			05/11/2014	Passed
			Jacket temp. sensor	TE2	111 , 121 , 131(oC)	≤±0.5(oC)		3	Not done (*)	
			Chamber temp. sensor	TE3-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	05/11/2014	Passed
			Chamber temp. sensor CH.2	TE3-2	111 , 121 , 131(oC)	≤±0.5(oC)			05/11/2014	Passed
			Filter drain temp. sensor	TE4-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	05/11/2014	Passed
			Filter drain temp. sensor CH3-Recorder	TE4-2	111 , 121 , 131(oC)	≤±0.5(oC)			05/11/2014	Passed
			Chamber temp. sensor	TE5-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	05/11/2014	Passed
			Chamber temp. sensor CH4 - Recorder	TE5-2	111 , 121 , 131(oC)	≤±0.5(oC)			05/11/2014	Passed
			Chamber temp. sensor CH5 - Recorder	TE 6	111 , 121 , 131(oC)	≤±0.5(oC)		1	05/11/2014	Passed
			Chamber temp. sensor CH6 - Recorder	TE 7	111 , 121 , 131(oC)	≤±0.5(oC)		1	05/11/2014	Passed
			Chamber Pressure sensor	PE - 1-1	0,100,200,300,-90(kPa)	≤±0.5(kPa)	AMETEK CPC200C	1	05/11/2014	Passed
			Chamber Pressure sensor CH 12 - Recorder	PE - 1-2	0,100,200,300,-90(kPa)	≤±0.5(kPa)			05/11/2014	Passed
			Chamber Pressure sensor	PI1	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	05/11/2014	Passed
			Chamber Pressure sensor	PI2	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	05/11/2014	Passed
			Jacket Pressure sensor	PI3	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		3	Not done (*)	
2	QC	Incubator A (Q'ty: 3)	Chamber temp. sensor	TE1-1	40,30,20(oC)	≤±1(oC)	AMETEK ITC-155A	3	Not done (*)	
			Chamber temp. sensor (recorder)	TE1-2	40,30,20(oC)	20oC: ≤±0.5(oC) 30oC: ≤±0.5(oC) 40oC: ≤±0.6(oC)		1	02/10/2014	Passed
			Chamber temp. sensor	TE2-1	40,30,20(oC)	≤±1(oC)		3	Not done (*)	
			Chamber temp. sensor (recorder)	TE2-2	40,30,20(oC)	20oC: ≤±0.5(oC) 30oC: ≤±0.5(oC) 40oC: ≤±0.6(oC)		1	02/10/2014	Passed
			Chamber temp. sensor	TE3-1	50,40,30(oC)	≤±1(oC)		3	Not done (*)	
			Chamber temp. sensor (recorder)	TE3-2	50,40,30(oC)	30oC: ≤±0.5(oC) 40oC: ≤±0.5(oC) 50oC: ≤±0.6(oC)		1	02/10/2014	Passed
3	QC	Incubator B	Chamber temp. sensor	TE1	40,30,20(oC)	≤±1(oC)	AMETEK ITC-155A	3	Not done (*)	
			Chamber temp. sensor (recorder)	TE2				1	02/10/2014	Passed
4	QC	Incubator C (Q'ty: 3)	Chamber temp. sensor	TE1-1	40,30,25(oC)	≤±1(oC)	AMETEK ITC-155A	3	Not done (*)	
			Chamber temp. sensor (recorder)	TE1-2				1	2014/2/10	Passed
			Chamber temp. sensor	TE2-1	40,30,25(oC)	≤±1(oC)		3	Not done (*)	
			Chamber temp. sensor (recorder)	TE2-2				1	2014/2/10	Passed
			Chamber temp. sensor	TE3-1	70,60,50,40,30,25(oC)	≤±1(oC)		3	Not done (*)	
			Chamber temp. sensor (recorder)	TE3-2				1	2014/2/10	Passed
5	QC	Vacuum dry oven	Chamber temp. sensor	TE1	50,60,70	≤±1(oC)	AMETEK ITC-155A	1	13/11/2014	Passed
6	QC	CO2 Incubator A	Chamber temp. sensor	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	Not done (*)	
			Chamber temp. sensor (recorder)	TE2	30,40,50(oC)	30oC: ≤±0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±0.7(oC)		1	01/10/2014	Passed
			CO2 mesuring sensor	COE1	3,5,7(%)	≤±1(%)	FYRITE BACHARACH GAS ANALIZER	1	01/10/2014	Passed
7	QC	CO2 Incubator B	Chamber temp. sensor	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	01/10/2014	
			Chamber temp. sensor (recorder)	TE2	30,40,50(oC)	30oC: ≤±0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±0.7(oC)		1	01/10/2014	Passed
			CO2 measuring sensor	COE1	3,5,7(%)	≤±1(%)	FYRITE BACHARACH GAS ANALIZER	1	01/10/2014	Passed

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
8	QC	CO2 Incubator C	Chamber temp. sensor	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	01/10/2014	
			Chamber temp. sensor (recorder)	TE2	30,40,50(oC)	30oC: ≤±0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±0.7(oC)		1	01/10/2014	Passed
			CO2 measuring sensor	COE1	3,5,7(%)	≤±1(%)	FYRITE BACHARACH GAS ANALIZER	1	01/10/2014	Passed
9	QC	Egg Incubator	Chamber temp. sensor (recorder)	TE1-2	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	1	14/11/2014	Passed
			Chamber temp. sensor	TE1-1	30,40,50(oC)	30oC: ≤±0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±0.7(oC)		2	14/11/2014	Passed
10	QC	Lab. Autoclave for Chemical	Chamber temperature sensor-Recorder	TE1	110,120,130(oC)	≤±1(oC)	AMETEK ITC-320A	1	15/01/2015	Passed
			Chamber temperature sensor	TE2	110,120,130(oC)	≤±0.8(oC)		2	15/01/2015	Passed
			Chamber Pressure sensor	PG1	0.1, 0.12, 0.14(Mpa)	≤±0.01(Mpa)	AMETEK CPC200C	1	15/01/2015	Passed
11	QC	Lab. Autoclave for Biological	Chamber temperature sensor-Recorder	TE1	110,120,130(oC)	≤±1(oC)	AMETEK ITC-320A	1	05/11/2014	Passed
			Chamber temperature sensor	TE2	110,120,130(oC)	≤±0.8(oC)		2	05/11/2014	Passed
			Chamber Pressure sensor	PG1	0.1, 0.12, 0.14(Mpa)	≤±0.01(Mpa)	AMETEK CPC200C	1	05/11/2014	Passed
12	QC	Dry Oven	Chamber temp. sensor (panel indicator)	TE1	100,125,250(oC)	100: ≤±0.61(oC) 125: ≤±0.64(oC) 250: ≤±0.82(oC)	AMETEK ITC-320A	1	05/11/2014	Passed
			Chamber temp. sensor (recorder)	TE2	100,125,250(oC)	100: ≤±0.57(oC) 125: ≤±0.63(oC) 250: ≤±0.92(oC)		1	05/11/2014	Passed
			Overheat temp. sensor (indicator panel)	TE3	100,125,250(oC)	100: ≤±3.5(oC) 125: ≤±3.5(oC) 250: ≤±3.5(oC)		1	05/11/2014	Passed
			Pressure sensor (control panel)	PE1-1	0,150,300(Pa)	0: ≤±7(Pa) 150: ≤±5(Pa) 300: ≤±5.5(Pa)	AMETEK CPC 200C	1	05/11/2014	Passed
			Pressure sensor (recorder)	PE1-2	0,150,300(Pa)				05/11/2014	Passed
13	QC	Freezer -30℃ (Q'ty: 4) (Model: MDF-U537B)	Chamber temp. sensor	TE1-1	-30(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T I	3	08/10/2014	Passed
			Temp. sensor (recorder)	TE1-2	-30(oC)	≤±7(oC)		1	08/10/2014	Passed
			Chamber temp. sensor	TE2-1	-30(oC)	≤±7(oC)		3	08/10/2014	Passed
			Temp. sensor (recorder)	TE2-2	-30(oC)	≤±7(oC)		1	08/10/2014	Passed
			Chamber temp. sensor	TE3-1	-30(oC)	≤±7(oC)		3	08/10/2014	Passed
			Temp. sensor (recorder)	TE3-2	-30(oC)	≤±7(oC)		1	08/10/2014	Passed
			Chamber temp. sensor	TE4-1	-30(oC)	≤±7(oC)		3	08/10/2014	Passed
			Temp. sensor (recorder)	TE4-2	-30(oC)	≤±7(oC)		1	08/10/2014	Passed
14	QC	Freezer : -70℃ (Q'ty: 4) (Model: MDF-U581)	Chamber temp. sensor	TE1-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T I	3	08/10/2014	Passed
			Temp. sensor (recorder)	TE1-2	-70(oC)	≤±7(oC)		1	08/10/2014	Passed
			Chamber temp. sensor	TE2-1	-70(oC)	≤±7(oC)		3	08/10/2014	Passed
			Temp. sensor (recorder)	TE2-2	-70(oC)	≤±7(oC)		1	08/10/2014	Passed
			Chamber temp. sensor	TE3-1	-70(oC)	≤±7(oC)			08/10/2014	Passed
			Temp. sensor (recorder)	TE3-2	-70(oC)	≤±7(oC)			08/10/2014	Passed
			Chamber temp. sensor	TE4-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE4-2	-70(oC)	≤±7(oC)		1	08/10/2014	Passed
15	QC	CO_2 Incubator C	Temp. sensor - Chamber temp. display channel	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	Not done (*)	
			Temp. sensor - Chamber temp. recorder channel kênh ghi nhiệt độ khoang	TE2	30,40,50(oC)	30oC: ≤±0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±0.7(oC)		1	01/10/2014	Passed
			Sensor nồng độ C02	COE1	3,5,7(%)	≤±1(%)	FYRITE BACHARACH GAS ANALIZER	1	01/10/2014	Passed

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
16	QC	Refrigerator 5°C (Q'ty: 2)	Chamber temp. sensor (equip.: 50302925)	TE1-1	5(oC)	≤±3(oC)	HYBRID RECORDER & SENSOR T 1	3	08/10/2014	Passed
			Temp. sensor (recorder) (equip.: 50302925)	TE1-2	5(oC)	≤±3(oC)		1	08/10/2014	Passed
			Chamber temp. sensor (equip.: 50302926)	TE2-1	5(oC)	≤±3(oC)		3	08/10/2014	Passed
			Temp. sensor (recorder) (equip.: 50302926)	TE2-2	5(oC)	≤±3(oC)		1	08/10/2014	Passed
17	MP	Autoclave A-2	Chamber temp. sensor	TE1-1	111 , 121 , 131(°C)	≤±0.5(oC)	AMETEK ITC-320A	1	05/12/2014	Passed
			Chamber temp. sensor (recorder) CH.1	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Jacket temp. sensor	TE2	111 , 121 , 131(oC)	≤±0.5(oC)		3	Not done (*)	
			Chamber temp. sensor	TE3-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	05/12/2014	Passed
			Chamber temp. sensor (recorder) CH.2	TE3-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Waste watert temp. sensor	TE4-1	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Waste watert temp. sensor CH.3	TE4-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Chamber temp. sensor	TE5-1	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Chamber temp. sensor (recorder) CH.4	TE5-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Chamber temp. sensor (recorder) CH.5	TE 6	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Chamber temp. sensor (recorder) CH.6	TE 7	111 , 121 , 131(oC)	≤±0.5(oC)		1		
			Chamber Pressure sensor	PE - 1-1	0,100,200,300,400,-90(kPa)	≤±5(kPa)	AMETEK CPC200C	1		
			Chamber Pressure sensor (recorder CH12)	PE - 1-2	0,100,200,300,400,-90(kPa)					
			Chamber Pressure sensor	PI 1	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	Not done (*)	
			Chamber Pressure sensor	PI 2	0.4,0.3,0.2,0.1,-0.08(Mpa)			2	Not done (*)	
			Jacket Pressure sensor	PI 3	0.4,0.3,0.2,0.1,-0.08(Mpa)			3	Not done (*)	
18	BP	Dry Oven A3	Chamber temp. sensor (panel indicator)	TE1	100,125,250(oC)	100: ≤±0.61(oC) 125: ≤±0.64(oC) 250: ≤±0.82(oC)	AMETEK ITC-320A	1	12/01/2015	Passed
			Chamber temp. sensor (recorder)	TE2	100,125,250(oC)	100: ≤±0.57(oC) 125: ≤±0.63(oC) 250: ≤±0.92(oC)		1	12/01/2015	Passed
			overheat temp. sensor (indicator panel)	TE3	100,125,250(oC)	100: ≤±3.5(oC) 125: ≤±3.5(oC) 250: ≤±3.5(oC)		1	12/01/2015	Passed
			pressure sensor (control panel)	PE1-1	0,150,300(Pa)	0: ≤±7(Pa) 150: ≤±5(Pa) 300: ≤±5.5(Pa)	AMETEK CPC200C	1	13/01/2015	Passed
			pressure sensor (recorder)	PE1-2	0,150,300(Pa)					Passed
19	BP	Dry Oven A2	Chamber temp. sensor (panel indicator)	TE1	100,125,250(oC)	100: ≤±0.61(oC) 125: ≤±0.64(oC) 250: ≤±0.82(oC)	AMETEK ITC-320A	1	12/01/2015	Passed
			Chamber temp. sensor (recorder)	TE2	100,125,250(oC)	100: ≤±0.57(oC) 125: ≤±0.63(oC) 250: ≤±0.92(oC)		1	12/01/2015	Passed
			Overheat temp. sensor (indicator panel)	TE3	100,125,250(oC)	100: ≤±3.5(oC) 125: ≤±3.5(oC) 250: ≤±3.5(oC)		1	12/01/2015	Passed
			Pressure sensor (control panel)	PE1-1	0,150,300(Pa)	0: ≤±7(Pa) 150: ≤±5(Pa) 300: ≤±5.5(Pa)	AMETEK CPC200C	1	13/01/2015	Passed
			Pressure sensor (recorder)	PE1-2	0,150,300(Pa)					Passed
20	MP	Refrigerator (Sanyo-MPR-1410R)	Chamber temp.sensor	TE1-1	4(°C)	≤±3 (oC)	HYBRID RECORDER & SENSOR T 1	1	10.12.2014	Passed
			Temp. sensor (recorder)	TE1-2	4 (°C)	≤±3(oC)		1	10.12.2014	Passed

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
21	BP	Autoclave A-3	Chamber temp. sensor	TE1-1	111 , 121 , 131(°C)	≤±0.5(oC)	AMETEK ITC-320A	1	13/01/2015	Passed
			Chamber temp. sensor (recorder) CH.1	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)				
			Jacket temp. sensor	TE2	111 , 121 , 131(oC)	≤±0.5(oC)		3	Not done (*)	
			Chamber temp. sensor	TE3-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	13/01/2015	Passed
			Chamber temp. sensor (recorder) CH.2	TE3-2	111 , 121 , 131(oC)	≤±0.5(oC)			13/01/2015	Passed
			Waste water temp. sensor	TE4-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	13/01/2015	Passed
			Waste water temp. sensor CH.3	TE4-2	111 , 121 , 131(oC)	≤±0.5(oC)			13/01/2015	Passed
			Chamber temp. sensor	TE5-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	13/01/2015	Passed
			Chamber temp. sensor (recorder) CH.4	TE5-2	111 , 121 , 131(oC)	≤±0.5(oC)			13/01/2015	Passed
			Chamber temp. sensor (recorder) CH.5	TE 6	111 , 121 , 131(oC)	≤±0.5(oC)		1	13/01/2015	Passed
			Chamber temp. sensor (recorder) CH.6	TE 7	111 , 121 , 131(oC)	≤±0.5(oC)		1	13/01/2015	Passed
			Chamber Pressure sensor	PE - 1-1	0,100,200,300,-90(kPa)	≤±5(kPa)	AMETEK CPC200C	1	14/01/2015	Passed
			Chamber Pressure sensor (recorder CH12)	PE - 1-2	0,100,200,300,-90(kPa)				14/01/2015	Passed
			Chamber Pressure sensor	PI 1	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	14/01/2015	Passed
			Chamber Pressure sensor	PI 2	0.4,0.3,0.2,0.1,-0.08(Mpa)			2	14/01/2015	Passed
			Jacket Pressure sensor	PI 3	0.4,0.3,0.2,0.1,-0.08(Mpa)			3	Not done (*)	
22	BP	Egg Incubator	Chamber temp. sensor	TE1	30,40,50(oC)	≤±1(oC)	AMETEK ITC-155A	2	09/01/2015	Passed
			Chamber temp. sensor (recorder)	TE2	30,40,50(oC)	30oC: ≤±0.5(oC) 40oC: ≤±0.6(oC) 50oC: ≤±0.7(oC)		1	09/01/2015	Passed
			Humidity Sensor - recorder channel	HE1	70(%)	≤±5(%)	TR72U	1	31/03/2015	Passed
23	BP	Incubator for egg stock	Chamber temp. sensor	TE1	10,15,20 (oC)	≤±1(oC)	AMETEK ITC-155A	2	09/01/2015	
			Chamber temp. sensor (recorder)	TE2	10,15,20 (oC)	10oC: ≤±0.4(oC) 15oC: ≤±0.5(oC) 20oC: ≤±0.5(oC)		1	09/01/2015	-
24	BP+MP	Freezer -30℃ MDF-U537D (Q'ty: BP: 2; MP: 2)	Chamber temp. sensor	TE1-1	-30(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T 1	3	Not done (*)	
			Temp. sensor (recorder)	TE1-2	-30(oC)	≤±7(oC)		1	11.12.2014	Passed
			Chamber temp. sensor	TE2-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE2-2	-30(oC)	≤±7(oC)		1	11.12.2014	Passed
			Chamber temp. sensor	TE3-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE3-2	-30(oC)	≤±7(oC)		1	16/01/2015	Passed
			Chamber temp. sensor	TE4-1	-30(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE4-2	-30(oC)	≤±7(oC)		1	12/02/2015	Passed
25	BP	Freezer:-70℃ (Q'ty: 4) Model: MDF-U581	Chamber temp. sensor	TE1-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T 1	3	Not done (*)	
			Temp. sensor (recorder)	TE1-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
			Chamber temp. sensor	TE2-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE2-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
			Chamber temp. sensor	TE3-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE3-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
			Chamber temp. sensor	TE4-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE4-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
26	BP	Freezer -70℃ (Q'ty: 3; Model: MDF-U72V)	Chamber temp. sensor	TE1-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T 1	3	Not done (*)	
			Temp. sensor (recorder)	TE1-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
			Chamber temp. sensor	TE2-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE2-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
			Chamber temp. sensor	TE3-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor (recorder)	TE3-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed

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TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
27	BP	Freezer:-70℃ (Q'ty: 1; Model: MDF-U74V)	Chamber temp. sensor	TE4-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T 1	3	Not done (*)	
			Temp. sensor (recorder)	TE4-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
28	BP	Freezer:-70℃ (Q'ty: 4; Model: MDF-U74V-PE)	Chamber temp.sensor - recorder channel	TE1-1	-70(oC)	≤±7(oC)	HYBRID RECORDER & SENSOR T 1	3	Not done (*)	
			Temp. sensor - Recorder	TE1-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
			Chamber temp.sensor - recorder channel	TE2-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor - Recorder	TE2-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
			Chamber temp.sensor - recorder channel	TE3-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor - Recorder	TE3-2	-70(oC)	≤±7(oC)		1	16/01/2015	
			Chamber temp.sensor - recorder channel	TE4-1	-70(oC)	≤±7(oC)		3	Not done (*)	
			Temp. sensor - Recorder	TE4-2	-70(oC)	≤±7(oC)		1	16/01/2015	Passed
29	FP	Vial washing machine	Temp. sensor (circulated water)	B210	40,60,100(oC)	≤±2(oC)	AMETEK ITC-320A	1	03/2/2015	Passed
			Pressure sensor	PIA 110	950,500,0(kPa)	≤±8(kPa)	AMETEK CPC200C	1		
			Pressure sensor	PIA 120	950,500,0(kPa)	≤±30(kPa)		1		
			Pressure sensor	PIA 121	250,125,0(kPa)	≤±30(kPa)		1		
			Pressure sensor	PIA 130	950,500,0(kPa)	≤±30(kPa)		1		
30	FP	Vial Sterilizing machine	Temp. sensor of zone 1 (recorder)	TE 211	280,300,320(oC)	280: ≤±2.0(oC) 300: ≤±2.2(oC) 320: ≤±2.4(oC)	AMETEK ITC-320A	1	03/2/2015	Passed
			Temp. sensor of zone 2 (recorder)	TE 213	280,300,320(oC)	280: ≤±2.0(oC) 300: ≤±2.2(oC) 320: ≤±2.4(oC)		1		
31	FP	Autoclave A-1	Chamber temp. sensor	TE1-1	111 , 121 , 131(°C)	≤±0.5(oC)	AMETEK ITC-320A	1	04/02/2015	Passed
			Chamber temp. sensor (recorder) CH.1	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)				Passed
			Jacket temp. sensor	TE2	111 , 121 , 131(oC)	≤±0.5(oC)		3	Not done (*)	
			Chamber temp. sensor	TE3-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	04/02/2015	Passed
			Chamber temp. sensor (recorder) CH.2	TE3-2	111 , 121 , 131(oC)	≤±0.5(oC)				Passed
			Waste watert temp. sensor	TE4-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	04/02/2015	Passed
			Waste watert temp. sensor CH.3	TE4-2	111 , 121 , 131(oC)	≤±0.5(oC)				Passed
			Chamber temp. sensor	TE5-1	111 , 121 , 131(oC)	≤±0.5(oC)		1	03/02/2015	Passed
			Chamber temp. sensor (recorder) CH.4	TE5-2	111 , 121 , 131(oC)	≤±0.5(oC)				Passed
			Chamber temp. sensor (recorder) CH.5	TE 6	111 , 121 , 131(oC)	≤±0.5(oC)		1	03/02/2015	Passed
			Chamber temp. sensor (recorder) CH.6	TE 7	111 , 121 , 131(oC)	≤±0.5(oC)		1	03/02/2015	Passed
			Chamber Pressure sensor	PE - 1-1	0,100,200,300,-90(kPa)	≤±5(kPa)	AMETEK CPC200C	1	06/02/2015	Passed
			Chamber Pressure sensor (recorder CH12)	PE - 1-2	0,100,200,300,-90(kPa)	≤±5(kPa)				Passed
			Chamber Pressure sensor	PI 1	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	06/02/2015	Passed
			Chamber Pressure sensor	PI 2	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		2	06/02/2015	Passed
			Jacket Pressure sensor	PI 3	0.4,0.3,0.2,0.1,-0.08(Mpa)	≤±0.0065(MPa)		3	Not done (*)	
32	FP	Freeze dryer	Chamber temp. sensor (recorder) (product 1 temp)	TE101	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 2 temp)	TE102	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 3 temp)	TE103	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 4 temp)	TE104	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 5 temp)	TE105	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 6 temp)	TE106	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 7 temp)	TE107	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 8 temp)	TE108	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 9 temp)	TE109	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 10 temp)	TE110	120,20,0(oC)	≤±1(oC)		1		
			Chamber temp. sensor (recorder) (product 11 temp)	TE111	120,20,0(oC)	≤±1(oC)		1		

TT	Dept.	Name of Equip.	Items		CAL point	Criteria	Calibrator	Freq. (year)	CAL date	Result
			sensor name	code						
			Chamber temp. sensor (recorder) (product 12 temp)	TE112	120,20,0(oC)	≤±1(oC)	AMETEK ITC-155A	1	28/01/2015 ~ 02/02/2015	Passed
			Chamber temp. sensor (recorder) (product 13 temp)	TE113	120,20,0(oC)	≤±1(oC)		1		
			Sillicol oil inlet temp. sensor	TE201	30,20,0(oC)	≤±1(oC)		1		
			Sillicol oil outlet temp. sensor	TE201A	30,20,0(oC)	≤±1(oC)		1		
			Sillicol oil outlet temp. sensor	TE202	30,20,0(oC)	≤±1(oC)		1		
			Consender coil 1 temp. sensor	TE203	30,20,0(oC)	≤±1(oC)		1		
			Consender coil 2 temp. sensor	TE204	30,20,0(oC)	≤±1(oC)		1		
			Consender coil 3 temp. sensor	TE205	30,20,0(oC)	≤±1(oC)		1		
			Chamber dain temp. sensor	TE212	130,120,110(oC)	≤±1(oC)		1		
			Consender dain temp. sensor	TE212A	130,120,110(oC)	≤±1(oC)		1		
			Consender dain temp. sensor	TE213	130,120,110(oC)	≤±1(oC)		1		
			Consender dain temp. sensor	TE213A	130,120,110(oC)	≤±1(oC)		1		
			Filter drain temp. sensor	TE214	130,120,110(oC)	≤±1(oC)		1		
			Filter drain temp. sensor	TE214A	130,120,110(oC)	≤±1(oC)		1		
33	EN	Hybrid recorder (Q'ty: 2)	Temp. sensors	NA	According to specification of equipment and sensors	According to specification of equipment and sensors	Multifuntion calibrator CA 71	1	Not done (*)	
34	Animal Lab	Autoclave	Temp. sensor	TE1-1	111 , 121 , 131(oC)	≤±0.5(oC)	AMETEK ITC-155A	1	02/10/2014	Passed
			Temp. sensor	TE1-2	111 , 121 , 131(oC)	≤±0.5(oC)		1	02/10/2014	Passed
			Pressure sensor	PE1	-90;0;100;200;300 (kPa)	≤±0.5(kPa)	AMETEK CPC200C	1	02/10/2014	Passed
			Pressure sensor	PE2	-0.09;0;0.1;0.2;0.3;0.4 (Mpa)	≤±0.02(MPa)		1	02/10/2014	Passed
			Pressure sensor	PE3	-0.09;0;0.1;0.2;0.3;0.4 (Mpa)	≤±0.02(MPa)		1	02/10/2014	Passed
			Pressure sensor	PE4	0;0.1;0.2;0.3;0.4 (Mpa)	≤±0.02(MPa)		1	02/10/2014	Passed
			Pressure sensor	PE5	0;0.1;0.2;0.3;0.4 (Mpa)	≤±0.02(MPa)		1	02/10/2014	Passed
			Pressure sensor	PE6	0;0.2;0.4;00.6;0.8;1.0 (	≤±0.02(MPa)		1	02/10/2014	Passed
35	BP	Water bath (Q'ty: 2)	Temperature sensor	TE1	36.0; 37.0; 38.0 (oC)	≤±1(oC)	DTI 1000A	1	15/01/2015	Passed
			Temperature sensor	TE2	25; 26; 27; 28; 29 and 55; 56; 57; 58; 59; 60 (oC)	≤±1(oC)		1	15/01/2015	Passed
36	BP	Temperature sensor (in disinfection room)	Temperature sensor	TE1	60;70;80 (oC)	≤±5(oC)	AMETEK ITC-155A	1	15/01/2015	Passed
37	FP	Temperature sensor (in disinfection room)	Temperature sensor	TE1	60; 80; 100 (oC)	≤±5(oC)	AMETEK ITC-155A	1	21/01/2015	Passed
38	BP	Pressurized pump	Pressure sensor	PE1	0.02; 0.04; 0.06; 0.08; 0.1	≤±0.0065(MPa)	AMETEK CPC200C	1	15/01/2015	Passed
			Pressure sensor	PE2	0.01; 0.02; 0.03	≤±0.0065(MPa)		1	15/01/2015	Passed
			Pressure sensor	PE3	-0.08; -0.07; -0.06;; -0.05;-0.04; -0.03;	≤±0.0065(MPa)		1	15/01/2015	Passed

Remark: (*): not expired of calibration effective period

POLYVAC

Result of Contract Calibration for Equipments - 2015

Data summarized from 10/2014~ 09/2015 *Updated:* 17/08/2015

No.	Name of equipment	Q'ty	Dept.	Manufacturer	Model	Serial	Freq. (year)	CAL Date	Result
1	Intergrity test machine	2	MP+BP	Millipore	XIT4S0001	IT40332	1	22/04/2015	Passed
2			FP		XIT4S0001	IT40001		23/04/2015	Passed
3	Intergrity test machine	1	MP	Pall	Part No:FFSXC	22289326	2	15/07/2015	Passed
	Particle counter A2400	7	BP	Hach Ultra	A2400	1312060004	1	17/04/2015	Passed
						1312060005		17/04/2015	Passed
						1312060006		17/04/2015	Passed
4			FP	Hach Ultra	A2400	50601041		31/07/2015	Passed
5			BP			50601042		20/04/2015	Passed
6			QC			50601043		07/07/2015	Passed
7			MP			1105060001		07/07/2015	Passed
8	Particle counter 237B	1	EN	Hach Ultra	237B	071200024	1	Not done (*)	Passed
9	Particle counter (portable) 227B	2	FP	Hach Ultra	227B	51200049	1	03/08/2015	Passed
10						51200047		03/08/2015	Passed
11	Air Sampler B (M Air T)	1	MP	Millipore	Cat No.: ATBPUMP01	276	1	Out of operation	
	Air Sampler A (MD 8)	2	QC	Sartorius	MD8 Air port 16757	29601659	1	15/01/2015	Passed
			BTP	Sartorius	MD8 Air port 16757	29601658		07/01/2015	Passed
			BTP	Sartorius	MD8 Air port 16757	29606445		07/01/2015	Passed
12			TP	Sartorius	MD8 Air port 16757	17601126		14/07/2015	Passed
13			QC	Sartorius	MD8 Air port 16757	17601125		15/01/2015	Passed
14	Spectrophotometer	1	QC	Helios Gamma	-	UVG 150540	2	Not done (*)	
15	Weight	30	Depts.	-	-	Serial	2	Not done (*)	

No.	Name of equipment	Q'ty	Dept.	Manufacturer	Model	Serial	Freq. (year)	CAL Date	Result
16	Pressure sensor of Freeze Drying machine	2	FP	Edward		076012021	2	Not done (*)	
17						66179601		Not done (*)	
18	Temperature Calibrator	1	EN	AMETEK	ITC-320 A 115/230V+PE	552656-00181	1	Not done (*)	
19	Pressure Calibrator	1	EN	AMETEK	IPI300CBXXINDG	1611107	1	Not done (*)	
20	Pressure Calibrator	1	EN	Halstrup-walcher GmbH	KAL 200	9609.0016AA190574	1	Not done (*)	
21	Thermo-Hygro Recorder	15	EN	T&D Japan	TR72U	-	2	Not done (*)	
22	Digital temperature indicator	1	EN	AMETEK	DTI-1000A	564803-00193	1	Not done (*)	
23	Dry block temperature calibrator	1	EN	AMETEK	ITC-155A	560279-00634	1	Not done (*)	
24	Anemometer	1	EN	Kanomax	6541	635537	1	Not done (*)	
25	Thermometer	1	EN	Sato-Japan		1621	3	Not done (*)	
26	Multifuntion calibrator	1	EN	Yokogawa Japan	CA71	T1FC047	1	Not done (*)	
27	Particle counter	1	EN	Particle measuring system	LasairIII_310B	98067	1	Not done (*)	
28	TOC calibration kit Conductivity calibration kit	1	EN	Mettler Toledo	Model: 5000 TOC System Suitability Te	-	2	Not done (*)	
29	Conductivity calibration kit	1	EN	Mettler Toledo	Model: 1885 kit calibration system 770 max	-	2	Not done (*)	

Remark: (*): not expired of calibration effective period

List of GMP Related Documents and SOP

1. LIST OF GMP DOCUMENTS

1-Aug-15

No.	Name of Documents	Doc. No	Priority	Preparing progress	QA Approval	Remarks
1) Standard document						
1	Production control	SD-01	4	100%	Approved	
2	Sanitation control	SD-02	6	100%	Approved	
3	Quality control	SD-03	3	100%	Approved	
4	Validation	SD-04	6	100%	Approved	
5	Change control	SD-05	4	100%	Approved	
6	Product annual review	SD-06	1	100%	Approved	
7	Education and Training	SD-07	1	100%	Approved	
8	Handling abnormal and deviation	SD-08	1	100%	Approved	
9	Risk management	SD-09	0	100%	Approved	
10	Policy for self inspection	SD-10	3	100%	Approved	
11	Policy for leadership	SD-11	0	100%	Approved	
12	Knowledge management	SD-12	0	70%		
13	Quality objective review	SD-13	0	100%	Approved	
14	CAPA procedure	SD-14	0	100%	Approved	
15	Biosafety control	SD-15	0	100%	Approved	
16	Procedure of handling with contamination found in enviroment monitorin	SD-16	0	100%	Approved	
17	Policy for trend analysis	SD-17	2	100%	Approved	
2) MF						
1	MF -Rubella- Measles	M01-MF	4	90%		
3) Manuals						
1	Quality Manual	01-QM	4	100%	Approved	

2. LIST OF SOPs

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
				preparing	non preparing	due date	
BULK PRODUCTION DEPARTMENT							
1	Changing to enter grade C	C03-SOP-01-01	X				
2	Changing to enter grade D	C03-SOP-01-02	X				
3	Sanitize grade A, B,C area	C03-SOP-02-01	X				
4	Sanitation of grade D	C03-SOP-02-02	X				
5	Sanitation of upgraded area	C03-SOP-02-04	X				
6	Procedure to evaluate result of environmental monitoring of clean room	C03-SOP-03-01	X				
7	Procedure to count particle in air	C03-SOP-03-03	X				
8	Procedure to count microorganism in air	C03-SOP-03-04	X				
9	Procedure to count surface microorganism	C03-SOP-03-05	X				
10	Receive SPF rabbit	Rb03-SOP-04-01	X				
11	Procedure to collect rabbit kidney	Rb03-SOP-04-02	X				
12	Collect kidney membrane and Cut rabbit kidney	Rb03-SOP-04-03	X				
13	Prepare medium for trypsination	Rb03-SOP-04-04	X				
14	Trypsin rabbit kidney cell	Rb03-SOP-04-05	X				
15	Dispense and centrifuge cell suspension	Rb03-SOP-04-06	X				
16	Collect cell after centrifugal	Rb03-SOP-04-07	X				
17	Sample to count cell	Rb03-SOP-04-08	X				
18	Procedure to count cell	Rb03-SOP-04-09	X				
19	Dispense suspension and culture cell	Rb03-SOP-04-10	X				
20	Procedure to prepare virus suspension for injection	Rb03-SOP-05-01	X				
21	Procedure to inject Rubella virus	Rb03-SOP-05-02	X				
22	Procedure to add medium after injection	Rb03-SOP-05-03	X				
23	Prepare washing Hank and M-199 for the changing	Rb03-SOP-05-04	X				
24	Procedure of washing Hank's and the medium changing	Rb03-SOP-05-05	X				
25	Evaluate CGI-CPE and harvest vaccine	Rb03-SOP-05-06	X				
26	Procedure of virus suspension pooling	Rb03-SOP-06-01	X				
27	Procedure of filtration of bulk suspension	Rb03-SOP-06-02	X				

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
				preparing	non preparing	due date	
28	Procedure of dispensing Vaccine of bulk into tank 10L	Rb03-SOP-06-03	X				
29	Procedure to sample bulk	Rb03-SOP-06-04	X				
30	Procedure to keep virus seed, bulk and virus sample	Rb03-SOP-07-01	X				
31	Procedure to thaw vaccine	C03-SOP-07-02	X				
32	Prepare implement for trypsination	Rb03-SOP-08-01	X				
33	Prepare implement for virus injection	C03-SOP-08-02	X				
34	Prepare implement for the Hank and M-199 for the changing	C03-SOP-08-04	X				
35	Prepare implement for pooling-filtration	C03-SOP-08-05	X				
36	Prepare clothes	C03-SOP-08-06	X				
37	Procedure to check tank 10L	C03-SOP-08-07	X				
38	Raw Material Storage	C03-SOP-08-08	X				
39	Dispense $NaHCO_3$	C03-SOP-08-09	X				
40	Prepare medium for bulk production	C03-SOP-08-10	X				
41	Prepare Iode alcohol	C03-SOP-08-11	X				
42	Procedure to inactivate craft serum	C03-SOP-08-12	X				
43	Procedure to check integrity of membrane	C03-SOP-08-13	X				
44	Wash and rinse production implement	C03-SOP-08-14	X				
45	Handle virus infected implement	C03-SOP-10-01	X				
46	Handle with new glass roux	C03-SOP-10-02	X				
47	Procedure to handle with new rubber stopper	C03-SOP-10-03	X				
48	Transport material and implement	C03-SOP-10-05	X				
49	Procedure to operate electronic balance CW1P1-150IG-L	C03-SOP-11-05	X				
50	Procedure to operate electronic balance LE2202S & TE2101	C03-SOP-11-06	X				
51	Procedure to use Clean bench	C03-SOP-11-07	X				
52	Procedure to use Safety cabinet NSC-HA-1800	C03-SOP-11-08	X				
53	Procedure to use and sterilize UFW - 4 used point	C03-SOP-11-10	X				
54	Procedure to use thermal stabilizer TR - 4	C03-SOP-11-17	X				
55	Procedure to use attemperation tank TRW - 170	C03-SOP-11-18	X				
56	Procedure to use dispenser	C03-SOP-11-20	X				
57	Procedure to use magnetic stirrer DP-1M	C03-SOP-11-21	X				
58	Procedure to use CWE-130 washer	C03-SOP-11-24	X				
59	Procedure to use Integri test EXACTA	C03-SOP-11-25	X				
60	Procedure to use magnetic stirrer HPS-500R	C03-SOP-11-26	X				
61	Procedure to use clothes dryer	C03-SOP-11-27	X				
62	Procedure to use centrifugal HL-7	C03-SOP-11-29	X				
63	Procedure to use UV light	C03-SOP-11-34	X				
64	Procedure to use Recorder	C03-SOP-11-35	X				
65	SOP of installing and collecting sensor and BI in PQ Autoclave	C03-SOP-12-01	X				
66	SOP of installing and collecting sensor and BI in PQ of Dry Oven	C03-SOP-12-02	X				
67	SOP of installing and collecting BI in fumigation PQ	C03-SOP-12-04	X				
	Total		67				
FINAL PRODUCTION DEPARTMENT							
1	Procedure to enter and exit D grade area	C04-SOP-01-02	X				
2	Procedure to enter and exit grade A, B, C area	C04-SOP-01-03	X				
3	Sanitize grade A,B, C area	C04-SOP-02-01	X				
4	Sanitize grade D area	C04-SOP-02-02	X				
5	Sanitize upgraded area	C04-SOP-02-03	X				
6	Sanitate passroom,passbox and changing room	C04-SOP-02-04	X				
7	Procedure to count bacteria living in air	C04-SOP-03-01	X				
8	Procedure to count particle in air	C04-SOP-03-02	X				
9	Follow temperature of cold store	C04-SOP-03-04	X				
10	Procedure to count surface bacteria	C04-SOP-03-05	X				
11	Vial washing and sterilization	C04-SOP-04-01	X				
12	Prepare Final Measles - Rubella bulk	C04-SOP-05-01	X				
13	Vaccine filling	C04-SOP-05-02	X				
14	Vaccine freeze drying	C04-SOP-05-03	X				
15	WFI filling	C04-SOP-05-04	X				
16	Capping	C04-SOP-06-01	X				
17	Check freeze dried vaccine by eyes	C04-SOP-06-02	X				
18	Check WFI by eyes	C04-SOP-06-03	X				
19	Labeling	C04-SOP-06-04	X				

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
				preparing	non preparing	due date	
20	Package	C04-SOP-06-05	X				
21	Sterilize production implement by autoclave	C04-SOP-06-06	X				
22	Nhập nguyên vật liệu đóng ống	C04-SOP-07-01	X				
23	Receive and keep material for filling	C04-SOP-07-02	X				
24	Receive thawed bulk	C04-SOP-07-03	X				
25	Order and receive medium	C04-SOP-07-04	X				
26	Keep vaccine before and after package	C04-SOP-07-05	X				
27	Keep WFI before and after package	C04-SOP-07-06	X				
28	Release vaccine and WFI	C04-SOP-07-07	X				
29	Sample raw material	C04-SOP-07-08	X				
30	Carry implement, raw to through Pass room - Pass box	C04-SOP-07-09	X				
31	Transpor vaccin final pdoduct	C04-SOP-07-11	X				
32	Procedure to check integrity of filter membrane	C04-SOP-07-12	X				
33	Wash implement for final bulk preparation	C04-SOP-08-02	X				
34	Pack implement for vaccine preparation to sterilize	C04-SOP-08-03	X				
35	Prepare implement for vaccine preparation	C04-SOP-08-04	X				
36	Wash implement for vaccine filling	C04-SOP-08-05	X				
37	Pack implement for filling vaccine to be sterilized	C04-SOP-08-06	X				
38	Prepare Measles vaccine filling implement	C04-SOP-08-07	X				
39	Wash and close Tank 70 liters	C04-SOP-08-08	X				
40	Prepare aluminum cap for capping	C04-SOP-08-09	X				
41	Wash WFI filling implement	C04-SOP-08-10	X				
42	Prepare sterilized clothes	C04-SOP-08-11	X				
43	Prepare implement for WFI filling	C04-SOP-08-12	X				
44	Prepare filling implement of WFI for sterilization	C04-SOP-08-13	X				
45	Prepare capping implement	C04-SOP-08-14	X				
46	Prepare to sterilize rubber stopper for filling	C04-SOP-08-15	X				
47	Prepare sterilized clothes of grade C, D area	C04-SOP-08-16	X				
48	Handle implement and clothes after filling of Measles vaccine	C04-SOP-08-18	X				
49	Prepare, operate and handle vial washing machine	C04-SOP-09-01(1)	X				
50	Sanitize vial washing machine	C04-SOP-09-01(2)	X				
51	Assemble, maintain and replace components of vial washing and sterilization machine	C04-SOP-09-01(3)	X				
52	Calibrate vial washing and sterilization machine	C04-SOP-09-01(4)	X				
53	Prepare, operate and handle filling machine	C04-SOP-09-02(1)	X				
54	Sanitize filling machine	C04-SOP-09-02(2)	X				
55	Assemble, maintain and replace components of filling machine	C04-SOP-09-02(3)	X				
56	Prepare, operate and handle tray loading machine	C04-SOP-09-03(1)	X				
57	Sanitize tray loading machine	C04-SOP-09-03(2)	X				
58	Assemble, maintain and replace components of tray loading machine	C04-SOP-09-03(3)	X				
59	Prepare, operate and handle capping machine	C04-SOP-09-04(1)	X				
60	Sanitize capping machine	C04-SOP-09-04(2)	X				
61	Assemble, maintain and replace components of capping machine	C04-SOP-09-04(3)	X				
62	Prepare, operate and handle labeler machine	C04-SOP-09-05(1)	X				
63	Sanitize labeler machine	C04-SOP-09-05(2)	X				
64	Assemble, maintain and replace components of labeling machine	C04-SOP-09-05(3)	X				
65	Operate freeze drying machine	C04-SOP-09-06(1)	X				
66	Sanitate freeze drying machine	C04-SOP-09-06(2)	X				
67	CIP of freeze drying machine	C04-SOP-09-06(3)	X				
68	SIP of freeze drying machine	C04-SOP-09-06(4)	X				
69	Assemble, maintain and replace components of freeze drying machine	C04-SOP-09-06(5)	X				
70	Calibrate freeze drying	C04-SOP-09-06(6)	X				
71	Check leakage of freeze drying machine	C04-SOP-09-06(7)	X				
72	Operate electronic balance TE313S	C04-SOP-09-07	X				
73	Use clean bench	C04-SOP-09-08	X				
74	Procedure of using and sterilizing WFI-2 supplying point	C04-SOP-09-09	X				
75	Procedure to use and sterilize WFI-3 supply point	C04-SOP-09-10	X				
76	Procedure to use and sterilize UF-2 supply point	C04-SOP-09-11	X				
77	Procedure to use and sterilize UF-5 supply point	C04-SOP-09-12	X				
78	Using UV light	C04-SOP-09-13	X				

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
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79	Set up and collect sensor in sterilizing rubber stopper	C04-SOP-10-01	X				
80	Set up and collect BI in sterilizing rubber stopper	C04-SOP-10-02	X				
81	Set up and collect sensor in sterilizing aluminum cap and implement	C04-SOP-10-03	X				
82	Set up and collect BI in sterilizing aluminum cap and implement	C04-SOP-10-04	X				
83	Set up and collect sensor in sterilizing clothes and sanitation implement	C04-SOP-10-05	X				
84	Set up and collect BI in sterilizing clothes and sanitation implement	C04-SOP-10-06	X				
85	Set up and collect sensor in sterilizing freeze drying frame	C04-SOP-10-07	X				
86	Set up and collect BI in sterilizing freeze drying machine and cap	C04-SOP-10-08	X				
87	Set up and collect BI in fumigating formalin	C04-SOP-10-09	X				
88	Set up and collect sensor in vial sterilization	C04-SOP-10-10	X				
89	Set up and disassemble Endotoxin vial in vial sterilization	C04-SOP-10-11	X				
90	Measure temperature and humidity of clean room	C04-SOP-10-12	X				
91	Handle falling and broken vial during production	C04-SOP-10-13	X				
92	Medium filling	C04-SOP-11-01	X				
93	Operate freeze drying machine in medium filling	C04-SOP-11-02	X				
94	Check volume of solution for filling	C04-SOP-12-05	X				
95	Adjust filling volume	C04-SOP-12-06	X				
96	Sample vial during washing	C04-SOP-12-08	X				
97	Sample rubber stopper after sterilization and drying	C04-SOP-12-09	X				
98	Sampling in final production	C04-SOP-12-10	X				
99	Sample filling raw	C04-SOP-12-11	X				
100	Calibrate sensor K	C04-SOP-12-12	X				
	Total		**100**				
MEDIUM PRODUCTION DEPARTMENT							
1	Changing to enter grade C area	C05-SOP-01-01	X				
2	Changing to enter grade D area	C05-SOP-01-02	X				
3	Sanitation of D, C and non-graded area	C05-SOP-02-01	X				
4	Procedure to count bacteria living in air	C05-SOP-03-01	X				
5	Procedure to count particle in air	C05-SOP-03-02	X				
6	Procedure to count bacteria in the surface	C05-SOP-03-03	X				
7	Procedure to count bacteria, particle in pneumatic system	C05-SOP-03-04	X				
8	Procedure to monitor environment in clean room	C05-SOP-03-06	X				
9	Operate electronic balance CW1P1-300-IG-L	C05-SOP-04-02	X				
10	Operate electronic balance CP 16001S	C05-SOP-04-03	X				
11	Operate electronic balance LE2202S	C05-SOP-04-04	X				
12	Operate electronic balance FBG64EDE-S	C05-SOP-04-05	X				
13	Operate thermal addition stirrer	C05-SOP-04-08	X				
14	Operate stand stirrer	C05-SOP-04-09	X				
15	Use clean bench E	C05-SOP-04-13	X				
16	Use clean bench C	C05-SOP-04-14	X				
17	Operate Air sampler	C05-SOP-04-17	X				
18	Operate Pall integrity testing machine	C05-SOP-04-22	X				
19	Use fridge SANYO MPR-1410R	C05-SOP-04-23	X				
20	Wash implement used for medium and solution production	C05-SOP-05-01	X				
21	Prepare packing implement for medium and solution production	C05-SOP-05-02	X				
22	Using UV light	C05-SOP-05-03	X				
23	Carry implement, raw to through Pass room - Pass box	C05-SOP-05-04	X				
24	Wash and prepare implement for water sampling	C05-SOP-05-10	X				
25	Tight filtration system	C05-SOP-06-01	X				
26	Open filtration system	C05-SOP-06-02	X				
27	Procedure to check integrity of membrane	C05-SOP-06-03	X				
28	Prepare phenol 0.1% solution	C05-SOP-06-04	X				
29	Sterilized alcohol filtration	C05-SOP-06-05	X				
30	Prepare medium to wash polypepton	C05-SOP-06-06	X				
31	Prepare Glucose 25%	C05-SOP-06-07	X				

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32	Prepare MEM 5x	C05-SOP-06-08	X				
33	Prepare F12	C05-SOP-06-09	X				
34	Prepare Glutamine 3%	C05-SOP-06-10	X				
35	Sample medium	C05-SOP-06-11	X				
36	Procedure of standard manipulation for production of SCD for MFT	C05-SOP-06-12	X				
37	Procedure of standard manipulation of production for vaccine dilution	C05-SOP-06-13	X				
38	Procedure of standard manipulation for production of Stabilizer	C05-SOP-06-14	X				
39	Procedure of standard manipulation for production of Lactabumine hydrolysate	C05-SOP-06-15	X				
40	Procedure of standard manipulation for production of M199/PR(+)	C05-SOP-06-16	X				
41	Procedure of standard manipulation for production of M199/PR(-)	C05-SOP-06-17	X				
42	Procedure of standard manipulation for production of .CMF -Hanks	C05-SOP-06-18	X				
43	Procedure of standard manipulation for production of Hank/PR (-)	C05-SOP-06-19	X				
44	Procedure of standard manipulation for production of NaHCO3	C05-SOP-06-20	X				
45	Procedure of standard manipulation for production of Tripsin	C05-SOP-06-21	X				
46	Procedure of standard manipulation for production of EK	C05-SOP-06-22	X				
47	Keep and control chemical usage	C05-SOP-07-01	X				
48	Procedure to keep medium	C05-SOP-07-04	X				
49	Number lot and write the label	C05-SOP-08-04	X				
50	Procedure to use and sterilize WFI 4 used point	C05-SOP-09-01	X				
51	Procedure to sample water at points of WFI system	C05-SOP-10-01	X				
52	Procedure to sample water at points of UFW system	C05-SOP-10-02	X				
53	Procedure to sample PS	C05-SOP-10-03	X				
54	Procedure to sample water after exchange Ion and RO	C05-SOP-10-04	X				
55	Sample to testing Mycoplasma of Gelatin raw	C05-SOP-10-06	X				
56	Set up and collect BI and Sensor (sterilize implement- loading patern 5)	C05-SOP-11-08	X				
57	Set up and collect BI during formalin fumigation	C05-SOP-11-09	X				
	Total		57				
QC DEPARTMENT							
(BIOLOGICAL)							
1	Procedure to enter and exit control area	C02-SOP-01-01	X				
2	Procedure to enter and exit of material	C02-SOP-01-02	X				
3	Procedure to enter and exit of material after sterilization	C02-SOP-01-03	X				
4	Procedure to enter and exit of wasted material and dirty implement	C02-SOP-01-04	X				
5	Procedure to sanitize upgraded area	C02-SOP-02-01	X				
6	Sanitize grade C area	C02-SOP-02-02	X				
7	Sanitize grade B area	C02-SOP-02-03	X				
8	Procedure to count speck of dust in air	C02-SOP-03-01	X				
9	Procedure to count bacteria living in air	C02-SOP-03-02	X				
10	Procedure to count surface bacteria	C02-SOP-03-03	X				
11	Evaluate result of environmental monitoring	C02-SOP-03-06	X				
12	Check water microorganism	C02-SOP-04-01	X				
13	Check sensitivity of agar	C02-SOP-04-03	X				
14	Check sensitivity of medium LMI, LMII	C02-SOP-04-04	X				
15	Receive and check Sodium Chloride (NaCl)	C02-SOP-04-05	X				
16	Receive and check Postassium Chloride (KCl)	C02-SOP-04-06	X				
17	Check sensotivity of Thioglycolate- Soybean casein	C02-SOP-04-07	X				
18	Receive and check Sodium Phosphate (Na2PHO4.12H2O)	C02-SOP-04-08	X				
19	Receive and check Mono Potassium Phosphate (KH2PO4)	C02-SOP-04-09	X				
20	Receive and check Glucose D(+) - C6H12O6	C02-SOP-04-10	X				
21	Receive and check Phenol red (C19H14O5S)	C02-SOP-04-11	X				
22	Receive and check Bicarbonnate (NaHCO3)	C02-SOP-04-12	X				
23	Receive and check Magnesium sunlphate (MgSO4.7H2O)	C02-SOP-04-13	X				
24	Receive and check Magnesium chloride (MgCl 2. 6H20)	C02-SOP-04-14	X				
25	Receive and check Calcium chloride (CaCl2)	C02-SOP-04-15	X				

No	Document Name	SOP No.	Status				Remarks
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26	Receive and check M-199(E)/PR(-)	C02-SOP-04-16	X				
27	Receive and check M-199(E)	C02-SOP-04-17	X				
28	Receive and check Sodium Hydrogen	C02-SOP-04-18	X				
29	Receive and check D-Sorbitol	C02-SOP-04-19	X				
30	Receive and check Lactose Monohydrate	C02-SOP-04-20	X				
31	Receive and check Gelatine	C02-SOP-04-21	X				
32	Receive and check Lactalbumin Hydrolysate	C02-SOP-04-22	X				
33	Receive and check Trypsin	C02-SOP-04-23	X				
34	Receive and check Kanamycin Sulfate	C02-SOP-04-24	X				
35	Receive and check Erythromycin	C02-SOP-04-25	X				
36	Receive and check SCD	C02-SOP-04-26	X				
37	Receive and check Newborn Cafserum	C02-SOP-04-27	X				
38	Cell growth checking	C02-SOP-04-28	X				
39	Procedure of checking the cell inhibiting agent (NR method)	C02-SOP-04-29	X				
40	Procedure to received final sample	C02-SOP-05-01	X				
41	Procedure to dispense and keep final bulk	C02-SOP-05-03	X				
42	Test on finding virus causing red blood cell absorption	C02-SOP-05-05	X				
43	Mycoplasma test	C02-SOP-05-07	X				
44	Sterilization test	C02-SOP-05-08	X				
45	Test of foreign agent on FL	C02-SOP-05-09	X				
46	Test of foreign agent on vero	C02-SOP-05-10	X				
47	Potency test	C02-SOP-05-11	X				
48	Procedure to confirm remaining alive virus after inactivation	C02-SOP-05-16	X				
49	Testing procedure to confirm to remove cell	C02-SOP-05-17	X				
50	Procedure to receive sample, follow to use sample, keep sample and dismiss sample	C02-SOP-08-02	X				
51	Procedure to passage FL cell	C02-SOP-09-01	X				
52	Procedure to passage vero cell	C02-SOP-09-02	X				
53	Procedure of GM growing medium preparation	C02-SOP-10-01	X				
54	Medium preparation procedure to maintain MM	C02-SOP-10-02	X				
55	Sterilized steam of medium used for verification	C02-SOP-10-03	X				
56	Procedure to produce SCD agar	C02-SOP-10-04	X				
57	Procedure to produce M Air T cattset agar	C02-SOP-10-05	X				
58	Procedure to proliferativate virus seed	C02-SOP-11-01	X				
59	Procedure to proliferativate Mycoplasma	C02-SOP-11-02	X				
60	Set up and collect thermal sensor (Autoclave B)	C02-SOP-14-01	X				
61	Set up and collect BI for all autoclave	C02-SOP-14-02	X				
62	Set up and collect thermal sensor for incubator A,B,C,D	C02-SOP-14-03	X				
63	Procedure in receiving and culturing BI for all autoclave	C02-SOP-14-04	X				
64	Set up and collect thermal sensor for vacuum drying oven.	C02-SOP-14-05	X				
65	Set up and collect BI for Formalin fumigation	C02-SOP-14-06	X				
66	Procedure to measure CO2 concentration (CO2 incubator)	C02-SOP-14-08	X				
67	Set up and collect BI for fumigation and Dry Oven	C02-SOP-14-11	X				
68	Receive and culture agar for environmental monitoring	C02-SOP-14-14	X				
69	Read the result and evaluate MFT	C02-SOP-14-15	X				
70	Set up and collect BI for DryOven	C02-SOP-14-17	X				
71	Handle dirty implement	C02-SOP-15-01	X				
72	Wash implement	C02-SOP-15-02	X				
73	Procedure in preparing implement for autoclave	C02-SOP-15-04	X				
74	Procedure to wash implement and tube for TOC test	C02-SOP- 15-05	X				
75	Procedure to take WFI used in QC	C02-SOP- 15-06	X				
76	Procedure to check growing of LH	C02-SOP-16-01	X				
77	Test Growth Promotion for M199/PR(+), M199/PR(-) medium	C02-SOP-16-02	X				
78	Procedure to follow CO_2 usage	C02-SOP-16-03	X				
79	Procedure of gas usage	C02-SOP-16-04	X				
80	Procedure to receive rabbit SPF	Rb02-SOP-04-01	X				
81	Procedure to transport and delivery rabbit SPF	Rb02-SOP-04-03	X				
82	Procedure to inject rabbit	Rb02-SOP-05-01	X				
83	Procedure to receive and keep Rubella bulk sample	Rb02-SOP-05-02	X				

No	Document Name	SOP No.	Status				Remarks
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84	Encephalitozoon cuniculi test	Rb02-SOP-05-03	X				
85	Check to control cell	Rb02-SOP-05-04	X				
86	Test of foreign agent on PRK cell	Rb02-SOP-05-06	X				
87	Marker test	Rb02-SOP-05-07	X				
88	Potency test by method PFU	Rb02-SOP-05-11	X				
89	Procedure to passage PRK cell	Rb02-SOP-09-02	X				
90	Procedure to passage and count cell PRK	Rb02-SOP-09-03	X				
91	Procedure to passage and keep cell BHK21	Rb02-SOP-09-04	X				
92	Procedure to produce Rubella antigen	Rb02-SOP-11-01	X				
93	Evaluate PST for Bulk production	Rb02-SOP-14-20	X				
94	Potency test by method ABC	MR02-SOP-05-11	X				
95	Identification test	MR02-SOP-05-12	X				
96	Thermal stability test (MR)	MR02-SOP-05-13	X				
97	Procedure to passage and keep cell RK13	MR02-SOP-09-01	X				
	Total		**97**				
(CHEMICAL)							
1	Test on checking status for freeze dried vaccine	C02-SOP-06-01	X				
2	Test on moisture content of freeze dried vaccine	C02-SOP-06-02	X				
3	PH measure test	C02-SOP-06-03	X				
4	Test on counting unthawed particle	C02-SOP-06-04	X				
5	Test on weight deviation for freeze dried vaccine	C02-SOP-06-05	X				
6	Test on endosmosis for freeze dried vaccine	C02-SOP-06-06	X				
7	Test on acid and alkali	C02-SOP-06-07	X				
8	Chloride test	C02-SOP-06-08	X				
9	Sulfate test	C02-SOP-06-09	X				
10	Nitrogen test from Nitrate	C02-SOP-06-10	X				
11	Nitrogen test from Nitrite	C02-SOP-06-11	X				
12	Ammonium test	C02-SOP-06-12	X				
13	Heavy metal test	C02-SOP-06-13	X				
14	KMnO4 test	C02-SOP-06-14	X				
15	Remaining scale after evaporation	C02-SOP-06-15	X				
16	Test on checking WFI volume	C02-SOP-06-16	X				
17	Foreign insoluble matter test	C02-SOP-06-17	X				
18	Test of supervising condition of clean water	C02-SOP-06-20	X				
19	TOC test	C02-SOP-06-30	X				
20	Quy trình pha dung dịch chuẩn cho hệ thống đo TOC online và ofline	C02-SOP-06-31	X				
21	Check rubber stopper perceptibly	C02-SOP-06-35	X				
22	Check foaming of rubber stopper	C02-SOP-06-36	X				
23	Conductivity test	C02-SOP-06-41	X				
24	Checking for transparent and coulor of vaccine	C02-SOP-06-43	X				
25	Test on checking appearance of aluminum cap	C02-SOP-06-44	X				
26	Test on checking appearance of rubber stopper	C02-SOP-06-45	X				
27	Test on checking appearance of vaccine vial	C02-SOP-06-46	X				
28	BSA test	C02-SOP-06-47	X				
29	Moistures content for rubber stopper	C02-SOP-06-48	X				
30	Endotoxin for checking sterilization effect	C02-SOP-06-49	X				
31	Leak test	C02-SOP-06-50	X				
32	Test on measuring alcohol concentration	C02-SOP-06-51	X				
33	Test on measuring glucose content	C02-SOP-06-52	X				
34	Autoclave B	C02-SOP-13-01	X				
35	Use Micropipet	C02-SOP-13-02	X				
36	Use Incubator D	C02-SOP-13-03	X				
37	CO_2 incubator	C02-SOP-13-04	X				
38	Rotator for microtiter plate	C02-SOP-13-05	X				
39	Safety cabinet A (1 face)	C02-SOP-13-08	X				
40	Use Clean bench	C02-SOP-13-09	X				
41	Use Incubator A	C02-SOP-13-11	X				
42	Use Incubator B	C02-SOP-13-12	X				
43	Use Incubator C	C02-SOP-13-13	X				
44	Use Incubator D	C02-SOP-13-14	X				
45	Centrifuge B	C02-SOP-13-15	X				

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
				preparing	non preparing	due date	
46	Operate Endotoxin machine (Well reader), computer and printer of Endotoxin test	C02-SOP-13-16[2]	X				
47	Autoclave D	C02-SOP-13-17	X				
48	Use Autoclave E	C02-SOP-13-18	X				
49	Operate Vacuum drying Oven	C02-SOP-13-20	X				
50	Dryer A	C02-SOP-13-21	X				
51	Dryer B	C02-SOP-13-22	X				
52	Use refrigerator SANYO MPR -1410R	C02-SOP-13-23	X				
53	Microscope	C02-SOP-13-27	X				
54	Use fluorescent Microscope	C02-SOP-13-28	X				
55	Water bath B	C02-SOP-13-29	X				
56	Water bath C	C02-SOP-13-30	X				
57	Compressor	C02-SOP-13-32	X				
58	Use nitrogen cylinder to keep cell	C02-SOP-13-36	X				
59	Test tube mixer	C02-SOP-13-37	X				
60	Vacuum pump	C02-SOP-13-38	X				
61	Procedure to operate electric scale (LE2202S và LE244S)	C02-SOP-13-42	X				
62	Draft chamber (DF-11AK)	C02-SOP-13-43	X				
63	Operate Pipet washing machine	C02-SOP-13-44	X				
64	Hot plate	C02-SOP-13-46	X				
65	Operate particle counter in water (KL-04)	C02-SOP-13-49	X				
66	Procedure to operate TOC measuring device (Phoenix 8000)	C02-SOP-13-50	X				
67	Conductivity meter	C02-SOP-13-51	X				
68	Constant temp.device immersion A	C02-SOP-13-53	X				
69	Operate ELISA reader and printer+C174:C198	C02-SOP-13-63	X				
70	Operate ELISA washing machine	C02-SOP-13-65	X				
71	Centrifuge (Rotofix 32)	C02-SOP-13-67	X				
72	Operate Helios spectrum	C02-SOP-13-86	X				
73	Sử dụng máy phân chia môi trường	C02-SOP-13-88	X				
74	Use nitrogen cylinder to keep cell	C02-SOP-13-89	X				
	Total		74				

Enginering department

1	Operate water production system	C06-SOP-WSO-01	X				
2	Operate and maintain filtration system	C06-SOP-WSO-02	X				
3	Prepare and add chemical	C06-SOP-WSO-03	X				
4	Operate active coal and softening system	C06-SOP-WSO-04	X				
5	Operate deionization system	C06-SOP-WSO-07	X				
6	Operate ultra filtered water generation system	C06-SOP-WSO-08	X				
7	Operate ultra filtered water distribution system	C06-SOP-WSO-09	X				
8	Operate WFI generation system	C06-SOP-WSO-11	X				
9	Operate WFI distribution system	C06-SOP-WSO-12	X				
10	Instruct to use particle creation machine TSI-TOPAS	C06-SOP-WSO-13	X				
11	Operate and maintain CT 1	C06-SOP-WSO-14	X				
12	Operate and maintain CT 2	C06-SOP-WSO-15	X				
13	Operate PS generation system	C06-SOP-WSO-16	X				
14	Calibrate water generation system	C06-SOP-CAL-38	X				
15	Calibrate HVAC system pressure displaying set	C06-SOP-CAL-60	X				
16	Calibrate cold room and incubation room by temperature	C06-SOP-CAL-63	X				
17	Calibrate temperature and humidity of HVAC system	C06-SOP-CAL-66	X				
18	Operate and maintain temperature calibration equipment AMETEK ITC - 320A	C06-SOP-CALEQ-02	X				
19	Operate and maintain pressure calibration equipment CPC320	C06-SOP-CALEQ-03	X				
20	Operate and maintain pressure calibration equipment IPI-300	C06-SOP-CALEQ-04	X				
21	Operate and maintain thermometer and hygrometer TR72U	C06-SOP-CALEQ-05	X				
22	Operate and maintain low temperature water bath EYELA PSL - 1800	C06-SOP-CALEQ-06	X				
23	Operate and maintain Hybrid Recorder	C06-SOP-CALEQ-07	X				
24	Use and maintain AMETEK ITC-155A	C06-SOP-CALEQ-08	X				
25	Operate and maintain low temperature water bath SILICON OIL BATH	C06-SOP-CALEQ-09	X				
26	Use pressure calibration machine KAL-84	C06-SOP-CALEQ-11	X				
27	Use particle counter KC-01E	C06-SOP-CALEQ-12	X				
28	Instruct to use particle creation machine TSI-TOPAS	C06-SOP-CALEQ-13	X				
29	Use pressure calibration machine KAL-200	C06-SOP-CALEQ-14	X				

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
				preparing	non preparing	due date	
30	Use Kanomax machine	C06-SOP-CALEQ-15	X				
31	Use and maintainTOC calibration equipment of water system	C06-SOP-CALEQ-16	X				
32	Use and maintain Conductivity calibration equipment of water system	C06-SOP-CALEQ-17	X				
33	Operate HVAC system	C06-SOP-HVACO -01	X				
34	Operate and maintain AHU system	C06-SOP-AHU -07	X				
35	Validate and maintain Clean Bench and Laminar Flow periodically	C06-SOP-VAL -61	X				
36	Validate and maintain Hepa Filter	C06-SOP-VAL -64	X				
37	Operate city water supply system	C06-SOP-CW-01	X				
38	Operate and maintain boiler 1	C06-SOP-BOILER-01	X				
39	Operate and maintain boiler 2	C06-SOP-BOILER-02	X				
40	Operate and maintain central chiller	C06-SOP-CHILLER-08	X				
41	Operate and maintain central compressor	C06-SOP-COMP-01	X				
42	Operate and maintain central generator 2	C06-SOP-GENE-02	X				
43	Operate and maintain central generator 1	C06-SOP-GENE-03	X				
44	Operate and maintain MDB	C06-SOP-MDB-01	X				
45	Operate and maintain wasted water treatment system	C06-SOP-WWO-01	X				
	Total		**45**				

SOP of Department

1	The first changing	C-SOP-01-01	X				
2	Procedure to check suitability of changing	C-SOP-01-02	X				
3	Procedure to sterilize by Formaline fumigation	C-SOP-02-01	X				
4	Use ethanol for grade A, B; C, D are	C-SOP-02-02	X				
5	Procedure to measure remaining Formaline concentration	C-SOP-02-03	X				
6	Procedure to manage, deliver and use chemical	C-SOP-02-04	X				
7	Procedure to control insects	C-SOP-02-05	X				
8	Procedure to control waste	C-SOP-02-06	X				
9	Procedure to collect, keep and carry toxic waste	C-SOP-02-07	X				
10	Sanitize non-grade area	C-SOP-02-08	X				
11	Procedure to sample water at points of WFI system	C-SOP-02-10	X				
12	Procedure to follow temperature, humidity and pressure deviation	C-SOP-03-01	X				
13	Calibrate thermal sensor	C-SOP-04-01	X				
14	How to write indentification Protocol	C-SOP-09-01	X				
15	Guide on writing production instruction	C-SOP-09-08	X				
16	Guide on SOP upgrading	C-SOP-09-09	X				
17	Wash and pack sterilized clothes	C-SOP-10-01	X				
18	Wash and pack the first clothes	C-SOP-10-02	X				
19	Procedure to handle during power-off	C-SOP-10-03	X				
20	Data analysis of method T-test	C-SOP-10-04	X				
21	Procedure to answer testing result	C-SOP-14-01	X				
22	Procedure to delivery and recive medium	C-SOP-14-02	X				
23	Use autoclave	C-SOP-15-01	X				
24	Use dry oven	C-SOP-15-02	X				
25	Use integrity testing machine of Millipore	C-SOP-15-03	X				
26	Procedure to use sampler in air Airport MD8	C-SOP-15-05	X				
27	Procedure to use particle counter A2400	C-SOP-15-06	X				
28	Procedure to use Formalin fumigator FOT2000	C-SOP-15-07	X				
29	Procedure to use neutralizer	C-SOP-15-08	X				
30	Procedure to use machine MIST GENERAOTAVC - 502A	C-SOP-15-10	X				
31	Procedure to use incubation and cold room	C-SOP-15-11	X				
32	Use ice maker	C-SOP-15-12	X				
33	Procedure to use deep freezer	C-SOP-15-13	X				
34	Use Measuring device of remaining Formaline concentration	C-SOP-15-14	X				
35	Use automatic alcohol sprayer	C-SOP-15-15	X				
36	Procedure to use and sterilize WFI6 used point	C-SOP-15-16	X				
37	Procedure to use and sterilize UFW3 used point	C-SOP-15-17	X				
38	Procedure to use microscope IX 51	C-SOP-15-18	X				
39	Use bag sealer	C-SOP-15-19	X				
40	Procedure to use Recoder KH66B	C-SOP-15-20	X				
41	Procedure to use Recoder AL3000	C-SOP-15-21	X				

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
				preparing	non preparing	due date	
	Total		41				
Animal lab							
1	Process to entrance and exit animal building applied for staff	C09-SOP - 01-01	x				
2	Control entrance and exit of animal and material	C09-SOP - 01-04	x				
3	Sanitize normal area	C09 -SOP - 02 - 02	x				
4	Sanitize D grade area	C09 -SOP - 02 - 03	x				
5	Process to spray insecticide for animal lab.	C09 -SOP - 02 - 06	x				
6	Monitor temperature, humidity, pressure difference	C09 -SOP - 03 - 01	x				
7	Procedure to count speck of dust in air	C09 -SOP - 03 - 02	x				
8	Procedure to count surface bacteria	C09 -SOP - 03 - 03	x				
9	Procedure to count bacteria living in air	C09 -SOP - 03 - 04	x				
10	Evaluate result of environmental monitoring	C09 -SOP - 03 - 05	x				
11	Procedure to measure remaining Formaline concentration	C09 -SOP - 03 - 06	x				
12	Process to order animal for test	C09 -SOP - 04 - 01	x				
13	Process to order material for raising animal for test	C09 -SOP - 04 - 02	x				
14	Process to receive animal for test	C09 -SOP - 04 - 03	x				
15	Procedure to raise rabbit separately	C09 -SOP - 04 - 06	x				
16	Process to receive material for raising animal for test	C09 -SOP - 04 - 07	x				
17	Control aseptic	C09 -SOP - 05 - 03	x				
18	Operate and maintain Autoclave	C09 -SOP - 06 - 01	x				
19	Use and maintain Mettertoledo electronic balance	C09 -SOP - 06 - 02	x				
20	Use and maintain balance	C09 -SOP - 06 - 03	x				
21	Use wind bolt	C09 -SOP - 06 - 04	x				
22	Use electronic thermometer	C09 -SOP - 06 - 05	x				
23	Use and maintain Shimadzu electronic balance	C09 -SOP - 06 - 06	x				
24	Process to wash clean clothes in grade D and non -grade area	C09 -SOP - 08 - 01	x				
25	Process to prepare, dry-clean clean clothes	C09 -SOP - 08 - 02	x				
26	Process to sterilize clean boot in grade D area	C09 -SOP - 08 - 03	x				
27	Process to handle dirty cage	C09 -SOP - 08 - 05	x				
28	Procedure to abrogate animal after test	C09 -SOP - 09 - 03	x				
29	Procedure to raise rabbit SPF separately	MR09 -SOP - 09 - 01	x				
30	Procedure to raise rabbit Healthy separately	Rb09 -SOP - 09 - 02	x				
31	Procedure of blooding taking, hair cutting, disinfection for SPF rabbit.	Rb09 -SOP - 09 - 03	x				
32	Procedure of checking Sendai Virus - HVJ	Rb09 -SOP - 09 - 05	x				
	Total		32				
QA							
1	Contract calibration for Equipment	01-SOP-04-03	x				
2	Material control	01-SOP-05-01	x				
3	Release control	01-SOP-06-01	x				
4	Handle with unsuitable products	01-SOP-06-02	x				
5	Training of new staff	01-SOP-07-01	x				
6	Regulation on coding system	01-SOP-09-01	x				
7	How to write SOP	01-SOP-09-02	x				
8	How to write Batch processing record	01-SOP-09-03	x				
9	How to write SPEC for raw material, intermediate product and packing material	01-SOP-09-04	x				
10	How to write validation Protocol	01-SOP-09-05	x				
11	How to write SPEC for biological materials	01-SOP-09-06	x				
12	How to write SPEC for equipement, implement, spare part of equipment	01-SOP-09-07	x				
13	Control of working seed virus	01-SOP-10-03	x				
14	Handle complain of product	01-SOP-11-01	x				
15	Inspect supply	01-SOP-12-01	x				
16	Review Batch processing records.	01-SOP-13-01	x				
17	Use documents, production and quality control record	01-SOP-13-02	x				
18	Distribute and collect of documents, records of production and quality control	01-SOP-13-03	x				
19	Replacement, repair and maintenance of equipment	01-SOP-15-01	x				
	Total		19				

LIST OF WORKING GROUPS

Updated on 15/08/2015

No.	Code	Name	Leader	Sub Leader	Expert incharge		Member							
					Leader	Sub Leader	BP	MP	FP	QA	QC	Animal Lab	Admin + Supplies	Eng
1	WG-1	Calibration/ Validation	Nguyen Dang Anh	Nguyen Thuy Huong	Dr. Lee	Dr. Katsuda	Pham Le Tuan	Nguyen Thai Hoc	Nguyen Dang Quynh	Tran Thi Phuong *(Secretary)*	Cao Xuan Ngoc	Pham Huu Tien		Dang Anh Tuan
						Ms. Mizuta	Hoang Vu Linh		Nguyen Huy Truong	Thai Hung	Nguyen Dinh Khiem			Nguyen Manh Dung
											Pham Anh Thu			
2	WG-2	Formalin Fumigation	Nguyen Xuan Hoa	Thai Hung	Dr. Katsuda	Dr. Ishikawa	Pham Le Tuan	Pham Huu Manh	Nguyen Manh Hien	Thai Hung	Nguyen Dinh Khiem	Le Van Duy		Nguyen Manh Dung
							Hoang Vu Linh		Vu Van Huy		Cao Xuan Ngoc	Pham Huu Tien		
3	WG-3	Environmental Pollution Control	Le Tuan Anh	Vu Thi Mai	Baba K	Ishikawa	Vu Thi Mai	Nguyen Thai Hoc	Nguyen Sy Ban	Nong Thi Thanh Van	Pham Thi Thuoc	Le Van Duy	Nguyen Duc Thang	Luu Van Chien
							Le Bao Trung		Nguyen Trong Nghia		Le Huyen Trang	Nguyen Van Manh		
4	WG-4	Environmental Monitoring	Pham Anh Thu	Pham Thanh Truong	Dr. Lee	Katsuda	Pham Van Khoi	Nguyen Quoc Thien	Nguyen Luong Ngoc Thanh	Le Thi Hoa (Secretary)	Pham Anh Thu	Le Van Duy		
							Lai Quynh Mai		Luong Phu Duan		Cao Xuan Ngoc			
											Nguyen Dinh Khiem			
5	WG-5	Procurement Control	Tran Trong Hai	Nong Thi Thanh Van	Ishikawa	Baba K	Pham Thanh Truong	Nguyen Phuong Lan	Luong Phu Duan	Nong Thi Thanh Van	Vu Thi Huong	Le Van Duy	Vũ Thùy Dương	Cao Minh Duc
							Nguyen Thi Khuyen *(Secretary)*		Nguyen Thi Thu		Nguyen Thi Nguyet	Pham Huu Tien		
6	WG-6	Risk Management	Tran Thi Phuong	Nguyen Manh Dung	Ms. Mizuta	Ishikawa	Pham Thanh Trueng	Nguyen Thai Hoc	Nguyen Dang Quynh	Tran Thi Phuong	Pham Anh Thu	Le Van Duy		Nguyen Manh Dung
							Pham Le Tuan		Nguyen Huy Truong	Thai Hung *(Secretary)*	Nguyen Thi Nguyet			
7	WG-7	Document Control	Le Thi Hoa	Pham Thi Phuong Thao	Ms. Mizuta	Hirayama	Pham Van Khoi	Nguyen Quoc Thien	Luong Phu Duan	Le Thi Hoa	Ngo Thi Thanh Huong	Pham Huu Tien		Dang Anh Tuan
							Le Bao Trung		Nguyen Thi Thu	Pham Thi Phuong Thao	Pham Thi Thuoc			
										Hoàng Thị Lan	Mai Huong			
8	WG-8	Clinical trial	Nguyen Thuy Huong	Nguyen Dang Hien	Dr. Lee	Dr. Nakayama			Nguyen T. Thanh Van	Pham Thi Phuong Thao (Secretary)	Ngo Thu Huong			
						Ishikawa				Le Thu Nga	Pham Anh Thu			