Ministry of Health
The Socialist Republic of Viet Nam

PROJECT COMPLETION REPORT
ON
TECHNICAL COOPERATION PROJECT
FOR
STRENGTHENING CAPACITY
FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION
IN
THE SOCIAL REPUBLIC OF VIETNAM

APRIL 2018

JAPAN INTERNATIONAL COOPERATION AGENCY (JICA)

KITASATO DAIICHI SANKYO VACCINE CO., LTD.

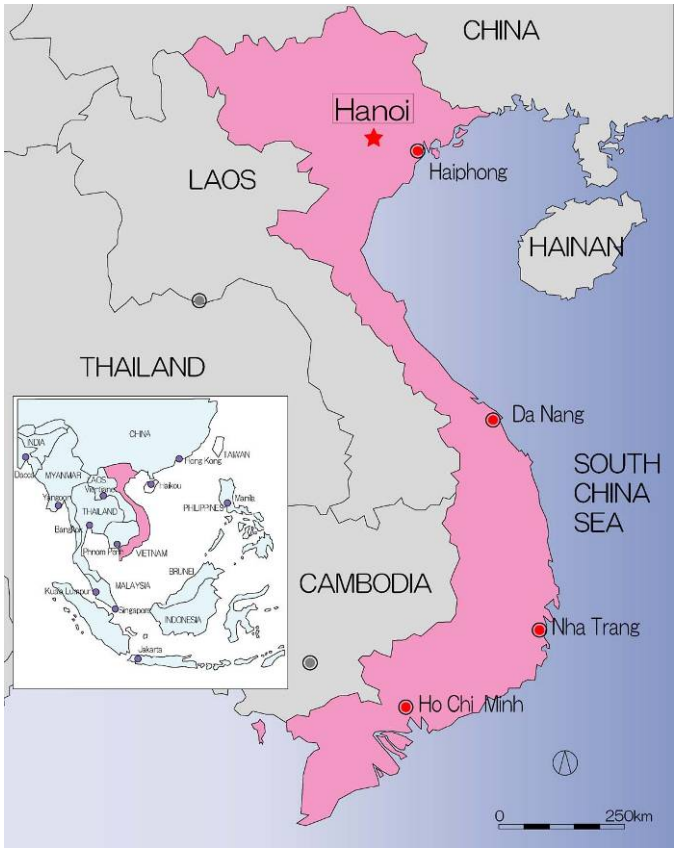
HM
JR
18-027

Contents

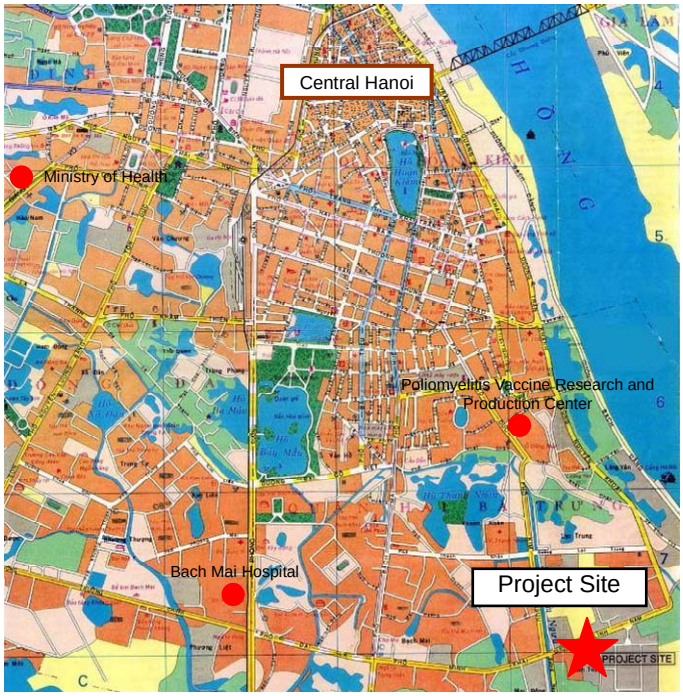
Abbreviations

Abbreviation	Formal Name
cGMP	current Good Manufacturing Practice
CRS	Congenital Rubella Syndrome
DAV	Drug Administration of Vietnam
DCVMN	Developing Countries Vaccine Manufacturers Network
EPI	Expanded Program on Immunization
GMP	Good Manufacturing Practice
JCC	Joint Coordination Committee
JICA	Japan International Cooperation Agency
KDSV	Kitasato Daiichi Sankyo Vaccine Company
MFT	Media Fill Test
M/M	Minutes of Meeting
M/M	Man-Month
MOH	Ministry Of Health
MR vaccine	Measles and Rubella vaccine
NICVB	National Institute for Control of Vaccine and Biologicals, Viet Nam
NRA	National Regulatory Authority
OPV	Oral Polio Vaccine
OVI	Objectively Verifiable Indicator
PCM	Project Cycle Management
PDM	Project Design Matrix
POLYVAC	Center for Research and Production of Vaccines and Biologicals
PQ	Performance Qualification
PST	Process Simulation Test
PV	Process Validation
QA	Quality Assurance
QC	Quality Control
R/D	Record of Discussions
SOP	Standard Operating Procedure
SPF	Specific Pathogen Free
VVM	Vaccine Vial Monitor
WHO	World Health Organization

Location Map



Map of the Socialist Republic of Viet Nam



Map of Hanoi and Location of Site

Photos of Technology Transfer Scenes

Comment: Award Ceremony for KDSV

Comment: Guests from JICA HQ

Comment: Guests from NIID, Japan

Comment: JCC No.5

Comment: Terminal Evaluation Survey

Comment: Terminal Seminar

1. Outline of the Project

1.1 Background and Outline

Since 1981, the Government of Vietnam has participated in the Expanded Program on Immunization (EPI) and continuously implemented national programs for the vaccination of children primarily against 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 Vietnam 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 immunization. As a part of these activities and in accordance with WHO recommendations, a second dose of immunization against measles was started in 2006. In addition, the successful completion of technical cooperation in the form of The Project for Strengthening Capacity for Measles Vaccine Production (hereinafter referred to as the "previous phase") undertaken during the period from March 2006 to March 2010 resulted in the start of domestic production of measles vaccine in Vietnam during 2009 at the Center for Research and Production of Vaccines and Biologicals (POLYVAC). At present, POLYVAC continues to produce measles vaccine for use in EPI programs in Vietnam.

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

Given this background, the Government of Vietnam requested the cooperation of the Government of Japan in transferring technology for the production of MR vaccine. On the basis of the request, JICA launched a technical cooperation entitled "The Project for Strengthening Capacity for Measles-Rubella Combined Vaccine Production" (hereinafter to as "the Project") from May 2013 to April 2018, with Kitasato Daiichi Sankyo Vaccine Co., Ltd. (hereinafter referred to as "KDSV") as the Japanese implementing organization and POLYVAC as the Vietnamese counterpart forming the implementation organization. The Project aims to realize the domestic production of the MR vaccine by strengthening the capacity of POLYVAC to manufacture the vaccine in conformity with WHO-current GMP (hereinafter referred to as "WHO-cGMP").

1.2 Contents of the Project

(1) Overall Goal

Spread of measles and rubella in Viet Nam is decreased.

(2) Project Objective

Measles-Rubella combined vaccine (MR vaccine) conforming to international standard (WHO-cGMP) is produced by POLYVAC.

(3) Outputs

1) Output 1: POLYVAC has proper technical capabilities as a manufacturer of MR vaccine.
2) Output 2: POLYVAC can produce MR vaccine properly complying with WHO-cGMP.

(4) Activities

Activities 1

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.

Activities 2

2-1) Establish validation system for the production and quality control, and strengthen the validation skills 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. (National Regulatory Authority).
2-5) Conduct PQ (Performance Qualification)/PV (Process Validation) for vaccine production from seed virus.
2-6) Provide necessary advices on clinical trial on MR vaccine under management of Vietnamese side.

(5) Input

1) Japanese side

Dispatch of experts, provision of equipment, staff training and share of local costs.

2) Vietnamese side

Deployment of counterparts, purchase of equipment and materials, provision of land and facilities and share of local costs

(6) Period

The period of the Project was 5 years from May 2013 to April 2018.

2. Achievements of the Project

2.1 Achievement of Output 1

"POLYVAC has proper technical capabilities as a manufacturer of MR vaccine."

The activities for Output 1 were continued from the start time of this Project and it was confirmed by the terminal evaluation that the achievements fully satisfied the given indicators. Technology transfer of MR vaccine bulk production was completed in 2015. Furthermore, technology transfer of MR vaccine final production was completed by November 2016 with the confirmation of compliance and passing of all quality tests. In addition, since technology transfer of quality testing process was conducted in parallel, this was also completed at the same time. Therefore, the objectives have been definitively achieved.

POLYVAC staff have steadily acquired technology from Project experts and have received level 4 status (capable of teaching others) or level 3 (capable of carrying out duties without expert guidance) Confirmation Certificates for all 325 processes defined in the PDM, issued by the Experts. Therefore, technology transfer necessary for MR vaccine production has been completed and POLYVAC has acquired the technology for independent production of MR vaccine.

2.2 Achievement of Output 2

"POLYVAC can produce MR vaccine properly complying with WHO-cGMP."

Similarly to Output 1, the activities for Output 2 were continued since the start of this Project and by the terminal evaluation of the Project, it was confirmed that the Output 2 fully satisfied the indicators for the achievement of the Project. Technology transfer under the Project includes not only production technology, but also guidance on the preparation of GMP documents, quality testing. The necessary documents were prepared as according to schedule along with implementation of the necessary validation and calibration which all were compliant and passed. Furthermore, POLYVAC received and passed the GMP inspection conducted by Drug Administration of Vietnam (DAV), the NRA (National Regulatory Authority) of Vietnam in April 2016 and received official certification in August 2016. Therefore, as POLYVAC has received confirmation that it has fully complied with current WHO-GMP documentation and carried out actual validation and calibration, the objectives are judged to have been achieved.

In detail, the required GMP documentation was prepared by each department in a timely manner, received QA approval, actually implemented on site and recorded in the reports. Furthermore, as noted above, the technology transfer of quality testing was conducted in parallel with transfer of technology for Rubella vaccine bulk production and MR vaccine final production and GMP documents for Quality Test Department were also prepared and implemented and appropriate precision in quality testing is being maintained.

In addition, IQ/OQ (Installation Qualification/ Operation Qualification) was also appropriately conducted for new equipment and facilities procured under the Project and confirmed to be compliant and passed. POLYVAC is also proceeding with preparations to apply for Prequalification from WHO to allow export of Measles vaccine to international organizations in the near future.

2.3 Achievement of Project Purpose

The establishment of MR vaccine production technology (Output 1) and development of WHO-cGMP compliant Quality Assurance system (Output 2) were carried according to a rigorous schedule under cooperation between POLYVAC staff and KDSV Experts. As a result, clinical trials using MR vaccine produced in compliance with WHO-cGMP were conducted in 2016 and DAV, Ministry of Health, which is the Vietnamese NRA agency responsible licensing, issued the marketing license (Registration No. QLVX-995-17) for POLYVAC produced MR vaccine (marketed as "MRVAC") on March 27, 2017, approximately one year earlier than the initial schedule. Therefore, the objective criteria for Project Purpose have been attained.

The actual progress is summarized as, the upgrading of facilities and procurement of equipment was completed on schedule during the first year (fiscal 2013) and two case studies were successfully completed for Rubella vaccine bulk production. In the second year (fiscal 2014) the third case study, PQ and PV were implemented, with successful compliance up to PQ, but PV failed due to low virus titer count. In the third year (fiscal 2015), various studies were conducted to investigate the reasons for the failure and measures to avoid repeating the mistakes. PQ and PV were repeated after the analysis and successfully completed by September 2015. In addition, technology transfer of quality testing required for Rubella vaccine bulk production was also successfully completed according to schedule as well as technology transfer of basic technology for pathological testing and breeding and rearing of SPF rabbits. Furthermore, PQ, MFT and three case studies (at 1/3 scale) for MR vaccine final production were completed by December 2015. The results became available in January 2016, with all found to be compliant and passed. Therefore, PV of MR vaccine at 1/3 scale was successfully completed and could be made available for use in clinical trials. These were also used for long term stability tests and successfully proved viability up to 27 months.

In response to changes in regulations regarding sales of vaccines in Vietnam, MR vaccine underwent small-scale trials in 4 provinces using 40,000 doses in February 2018 to reconfirm safety prior to full-scale use in EPI program. Based on their results, the vaccine will be released nationally.

3. Schedule of Project Activities

3.1 Vaccine Production Process and Results of Activity

The process for production of Measles-Rubella Combined Vaccine is shown in Figure 3.1. The transfer of technology for production of rubella vaccine bulk and the related quality control technology and the transfer of technology for final production of MR vaccine by combining the rubella vaccine bulk with measles vaccine bulk for which the technology transfer has already been completed were carried out in this Project.

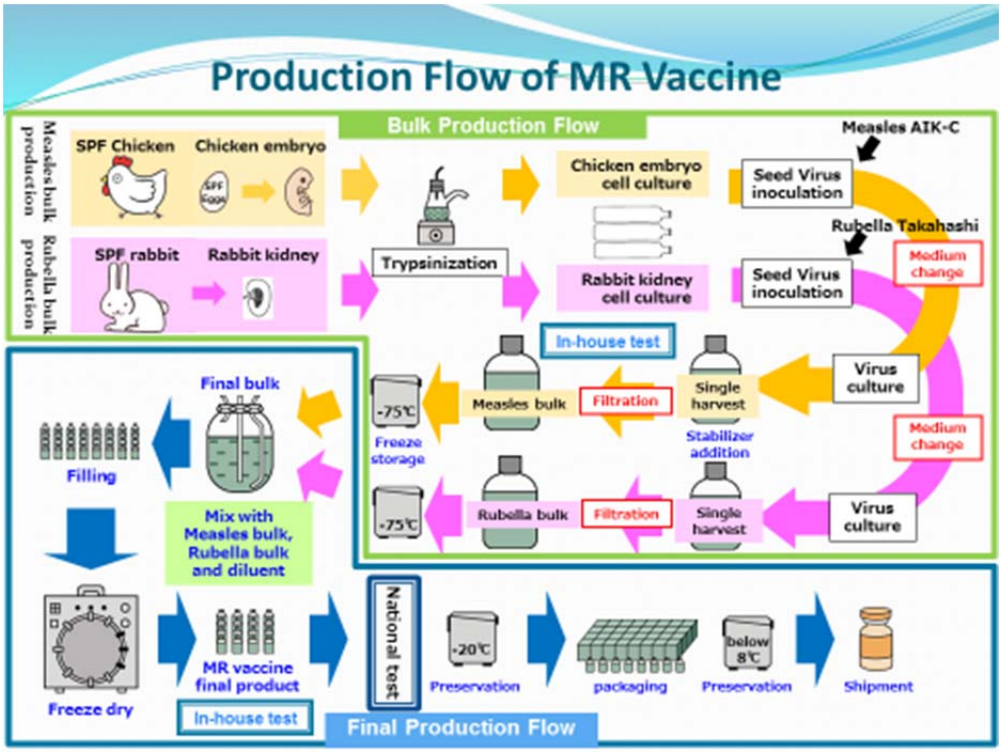


Fig. 3-1 Flowchart of Measles-Rubella Combined vaccine production process

Further, the milestones from fiscal 2013 (first year) through the final year of fiscal 2017 (fifth year) are summarized by year below.

Milestones by Year	Status Achieved
(First year: May 2013 to March 2014) Upgrade of facilities and procure equipment to enable technology transfer to using its facilities and equipment. Establish Rubella vaccine bulk production know-how and transfer technology for related quality tests, transfer basic technology for pathological tests and breeding of SPF rabbits to POLYVAC staff.	Completed successfully
(Second year: April 2014 to March 2015) Implement additional upgrades to facilities for compliance with WHO-cGMP and procurement of minor equipment to allow reliable transfer of various technologies using POLYVAC facilities. Complete technology transfer of Rubella vaccine bulk production know-how and related quality test technology. POLYVAC staff acquire basic technology for pathological tests and breeding of SPF rabbits.	Completed successfully

Milestones by Year	Status Achieved
(Third year: April 2015 to March 2016) Complete technology transfer on Rubella vaccine bulk production and MR vaccine final production (pharmaceutical production) know-how and produce tests materials for clinical trials. Furthermore, complete technology transfer of related quality tests and acquisition by POLYVAC staff of basic technology for pathological tests and breeding of SPF rabbits	Completed successfully
(Fourth year: April 2016 to March 2017) Provide necessary guidance for clinical trials of MR vaccine to be conducted by Vietnamese side and implement clinical trials. In addition, carry out analysis, study and rationalization production in order to reduce production costs of MR vaccine. Furthermore, provide guidance on research, analysis and transfer of basic technology for SPF rabbit breeding to promote improvement of the financial condition of POLYVAC.	Completed successfully
(Fifth year: April 2017 to April 2018) Transfer basic technology for adoption to MR vaccine single dose and breeding of SPF rabbits at POLYVAC, the objectives added to the third phase services contract, to enable POLYVAC to respond on its own to future issues. In addition, provide various advice for upgrading of final production line facilities and construction of conventional animal house that are related to the above two objectives and will be conducted by JICA Vietnam Office. Furthermore, continue guidance for analysis, study and rationalization production in order to reduce production costs of MR vaccine.	Transfer of basic technology completed successfully

The details of activity results were summarized per item in the following sections as defined in the PDM (Project Design Matrix).

3.2 Results of Activity for Output 1

(1) Conduct technical transfer on production of rubella vaccine bulk through the processing of producing vaccine bulk from the seed virus:

POLYVAC commenced investigations from January 2014 into the conditions (case studies) for producing Rubella vaccine bulk using primary kidneys from SPF rabbits procured from Japan, under the guidance of KDSV experts. Four case studies and optimization of production processes (finalization) were conducted by March 2015. Afterwards, PQ (Performance Qualification) of the above bulk vaccine production process was implemented in June 2015 and PQ was confirmed and passed.

After completion of PQ, POLYVAC implemented three continuous PV (Process Validation) of Rubella vaccine bulk in September 2015. Since all quality tests for PV were compliant and passed, production of Rubella vaccine bulk was established and necessary technology transfer successfully completed. In addition, POLYVAC was able to prepare GMP documentation for rubella vaccine bulk production adequately and in a timely manner.

(2) Conduct technical transfer on final bulk composition, filling, freeze-dry through the process of producing MR vaccine:

POLYVAC planned the conditions (case studies) for MR vaccine final production processes (final bulk composition, filling, freeze-drying) using Measles vaccine bulk available from previous

transfers and Rubella vaccine bulk produced by the above PQ under the guidance of KDSV experts. POLYVAC conducted three case studies between January and March 2015 and completed optimization (finalization) of the production process. Furthermore, PQ for the final production process was also completed in August 2015.

Similarly, three continuous PV at 1/3 scale for MR vaccine final production process was completed by December 2015. In addition, one lot from the above production was used for clinical trials. Furthermore, three lots were used for long term thermal stability tests and stability was finally confirmed up to 27months at the termination of the Project.

Afterwards, three continuous PV for final production processes at full scale (300, 000 doses/lot) were conducted in October 2016. Since all quality tests for PV were complaint and passed, all technology for MR vaccine final production process has been established and technology transfer to POLYVAC successfully completed.

In addition, POLYVAC was able to prepare GMP documentation for MR vaccine final production adequately and in a timely manner.

(3) Conduct technical transfer on quality control of the products:

Similarly to production departments, technology transfer for quality control tests such as animal tests, physical/chemical tests, animal inoculation test and pathological tests were conducted during dispatch of KDSV experts to Vietnam and during training in Japan in parallel with activities of 1-1 and 1-2, and were completed according to scheduled.

Technology transfer for pathological test (autopsy, pathological test, etc.) for SPF rabbits used in production of Rubella vaccine bulk production was conducted for a total two persons, one veterinarian and one Pathological Department staff from POLYVAC and the necessary technology transfer for Rubella vaccine bulk production was completed by March 2015.

Furthermore, the technology for pathological tests, used to confirm the quality of animals used to confirm the safety of the manufactured MR vaccine, is not established in Vietnam, but the pathological test technology is essential to secure safety of Measles vaccine bulk, Rubella vaccine bulk and MR vaccine at a higher level. These technologies are all new to Vietnam and continuous guidance was extended, making full use of the Project period, to raise the capability of POLYVAC staff responsible for pathology to a level where they are able to respond flexibly.

(4) Collect and examine information for lowering unit production cost of MR vaccine:

Since the first year of the Project, POLYVAC and KDSV experts have not only cooperated in gathering and analyzing information for reducing production cost, but also research, studies and experiments and have realized the following concrete results.

- Research, analysis and experiments to change from expensive Fetal Bovine Serum（FBS）to less expensive New Born Calf Serum (NBCS) were carried out to investigate reducing the costs of starting materials for rubella vaccine bulk, but a stable virus titer in the bulk vaccine could not be verified. However, the entire production process was reviewed in the course of these investigations and case studies and strict control of temperature and timing, etc. realized reproducible results in the production of high virus titer Rubella vaccine bulk using FBS. This contributed to a reduction of production costs of MR vaccine final production through a higher dilution ratio of Rubella vaccine bulk.

- The production of Measles vaccine bulk, for which technology transfer has already been completed, was revised to realize a scale up in production volume of one batch by 1.6 times, realizing a reduction in production cost of MR vaccine bulk. In addition, POLYVAC is still continuing investigations and experiments to improve titer.
- Breeding and rearing of SPF rabbits was attempted for the first time in Vietnam in order to reduce production costs and ensure a stable production of Rubella vaccine bulk. The technology transfer was conducted utilizing the existing animal house. The first offspring of 76 bunnies were born in August 2017 and two batches of Rubella vaccine bulk using SPF rabbits bred at POLYVAC were produced in December 2017. It is planned to conduct a continuous six batch production run after the Project termination in April 2018.
- Rabbits for quality tests were changed from procurement from Japan to domestically bred rabbits from another Vietnamese vaccine manufacturer in order to reduce costs. However, these rabbits were found to be infected in the quality control tests. Therefore, recommendations for improvements of the breeding facility and operations were made and implemented.
- Calibration of equipment attached to the production machinery directly effecting quality of product was initially commissioned to external agents including foreign suppliers. However, it became possible for POLYVAC to carry out the calibration by themselves by using calibrators procured by JICA Vietnam Office, realizing a reduction of commissioning fees.
- An eight hour reduction of the time required for the freeze-drying process for MR vaccine was realized through research, analysis and experiments. In addition, this made possible the entire freeze-drying process to be completed during normal weekday working hours, realizing a reduction of lighting and cooling costs as well as personnel expenses.

3.3 Results of Activity for Output 2

(1) Establish validation system for the production and quality control, and strengthen the validation skill of the staff:

POLYVAC prepared the Master Plan for upgrading of equipment and facilities and validation of production processes and quality control in 2013, the first year of the Project. The contents were reviewed and approved by QA. The procedures are carried out at regular intervals following methods and frequency stipulated in the Master Plan.

The various PQ and PV related to production of rubella vaccine bulk and final production of MR vaccine were carried out by POLYVAC staff by September 2015 and Experts from KDSV confirmed that the PQ and PV had been carried out precisely according to the Master Plan. Furthermore, Certificates of Technology Transfer were awarded to staff who had attained the prescribed levels for validation of each production process.

In addition, Experts from KDSV have confirmed that validation of various quality tests have also been conducted appropriately in parallel with the above technology transfer and that the relevant technology has been established by June 2016. Follow up was conducted for validation technology of quality tests in 2017 and completed prior to completion of the Project. Therefore, all technology transfer for bulk production, final production of MR vaccine and quality test validation have been completed.

The regular validation of facilities and equipment required under GMP has also been steadily carried out. The regular periodical calibration of equipment required to prior to validation have also been carried out according to a yearly schedule.

(2) Establish and implement quality assurance functions complying with WHO-cGMP standards:

POLYVAC has already established the QA system for Measles vaccine production, but the knowledge and experience of POLYVAC staff was not adequate for MR vaccine production except the commons elements related to GMP.
Two KDSV experts provided continuous guidance throughout the Project to POLYVAC QA staff on appropriate implementation of quality assurance compliant with WHO-cGMP for MR vaccine production. In line with technology transfer of production technology, they established the system for appropriate verification and approval of GMP related documents prepared by each department prior to the GMP inspections carried out by in April 2016.

(3) Prepare and implement necessary SOPs for the process of production, storage, carrying in/out of the products, etc.:

POLYVAC has prepared GMP related documents, such as SOP for Rubella vaccine bulk production and MR vaccine final production processes from the start of the Project and production has strictly followed the stipulated processes. Similarly, SOP for Quality Control tests have also been prepared and tests conducted as stipulated. Furthermore, SOPs are regularly reviewed according to document management provisions and appropriate revisions have been incorporated following changes to production processes.
SOPs for vaccine production, storage and receiving/shipment, etc. have been reviewed by KDSV experts for appropriateness of content. Furthermore, periodic inspections to confirm compliance with SOP (documentation check, on site inspections, etc.) are carried out regularly by QA Department in accordance with stipulations.

(4) Conduct technical transfer on preparation of documents that need to meet WHO-cGMP standard and to be approved by National Regulatory Authority (NRA):

Since Vietnamese GMP by NRA is same as the WHO-GMP, the GMP requirements requested by NRA are the same as under WHO-cGMP.
POLYVAC has prepared GMP documents as required in parallel with transfer of technology for each output and was judged compliant by the Vietnamese NRA GMP inspection authority, Drug Administration of Vietnam (DAV) in GMP inspections carried out in April 2016. DAV issued the Certificate of GMP for Measles, Rubella and MR vaccines to POLYVAC in August 2016.
This proves that Quality Assurance system compliant with GMP has been established at POLYVAC, but guidance has been continued after certification to strengthen the quality assurance functions, with follow up guidance ending in July 2017.
GMP inspections by NRA not only review “soft” components of production process and quality control, but also inspect the “physical” components of production facilities and equipment. To meet the requirements of current WHO-cGMP, upgrading of facilities were carried out from July 2014 to March 2015 under JICA assistance. The facility upgrades were planned in detail by the

Project and care was taken to not interfere with technology transfer by the Project or vaccine production by POLYVAC.

(5) Conduct Performance Qualification (OQ) and Process Validation (PV) for vaccine production from seed virus:

All PQ, PST and PV for production of Rubella vaccine bulk from seed virus (Takahashi strain) procured from KDSV was completed by October 2015. All PQ, MFT and PV for MR vaccine final production were also completed by October 2015. Therefore, all validation necessary for MR vaccine production has been successfully completed.

(6) Provide necessary advices on clinical trial on MR vaccine under management of Vietnamese side:

KDSV experts provided advice to POLYVAC on preparation of draft protocols for clinical trials compliant with international standards. POLYVAC completed preparation of the draft document according to the advice in November 2015 and submitted the document to responsible staff of Military Medical University, the implementation agency, which the responsible staff completed.
The clinical trial protocols were approved by the Ethics Committee of the Ministry of Health in April 2016 and the field trials were conducted in Ha Nam Province and Hoa Binh Province in April 2016 through in July 2016. KDSV experts attended the field trials held at local clinics, etc. as appropriate to conform the trials were being conducted properly. They also provided on site assistance to questions from field workers as appropriate.

3.4 List of Products

The list of products from fiscal 2013 (first year) through 2017 (fourth year) is included in the Appendix (8).

4. Input

4.1 Summary of Input

The input outline includes the dispatch of experts, provision of equipment, acceptance of counterpart personnel and share of the local costs for employment of national staff for operation of the Project Office by the Japanese side, and the assignment of counterparts, purchase of equipment and materials for vaccine production, share of operation and maintenance cost for facilities and equipment as well as energy expenses, provision of land and facilities by the Vietnam side. The list of counterpart staff members is included in the Appendix (9).

4.2 Actual Input

The detailed input will be described in Chapter 5 through Chapter 8. Adequate inputs were timely invested in this entire Project and contributed to the smooth progress of the Project.

5. Dispatch of Experts

5.1 List of Experts

The experts engaged in the measles-rubella combined vaccine production have extremely specialized expertise and therefore large number are required to span the full range. For example, the quality control test was divided into biology, chemistry, zoology, animal breeding and pathology, for which it was necessary to dispatch individual experts. The names of experts dispatched over the 5 years of this Project and their works are listed in Table 5-1 below.

Table 5-1 List of Experts and Works

No.	Name	Title	Description of Work
1	Setsuo ARAI	Project Manager	General management of the entire Project
2	Tomio LEE	Deputy Project Manager/ Vaccine Production Control	Assistance to PM/General guidance on vaccine production
3	Kenichi BABA	Vaccine Quality Control	General guidance on vaccine quality control /Administrative work for Counterpart personnel from Vietnam
4	Yasuhiro TSUCHIDA	Organization Administration (1)	Manager of KDSV Project Office
5	Miki TAMURA	Organization Administration (2)	Deputy Manager for KDSV Project Office (contract management, dispatch administration, finances)
		Administrative support for Trainees in Japan	Administrative work for Counterpart personnel from Vietnam
6	Shigemitsu HIRAYAMA	Production Management/GMP/Validation (1)	General guidance on production management, and GMP/Validation
7	Mika MIZUTA	GMP/Validation (2)	General guidance on quality assurance and GMP/Validation
8	Tetsuo NAKAYAMA	Quality Assurance (1)	Counsel on medical and clinical aspects of vaccine and advice on clinical trials
9	Yoshie MOTEGI	Quality Assurance (2)	Guidance on Measurement of antibody titer in Clinical Trials
10	Takashi ITO	Quality Assurance (3)	Counsel on medical and clinical aspects of vaccine and advice on clinical trials
11	Teiichiro KOGA	Quality Assurance (4)	Technical guidance on clinical trials
12	Tsuguo SASAKI	WHO-GMP	General guidance on WHO-GMP
13	Hiroki KATSUDA	Bulk production	Guidance on vaccine bulk production
14	Schuichi BABA	Final production (1)	Guidance on final production and media preparation
15	Kunihiko KOMURO	Final production (2)	Guidance on final production and media preparation
16	Manabu IKEDA	Quality Control (1)	Guidance on pathology
17	Yoshihisa TAKEDA	Quality Control (2)	Guidance on biological tests
18	Toshio KOSUGI	Quality Control (3)	Guidance on animal tests
19	Kuniji ITO	Quality Control (4)	Guidance on general administration of SPF rabbits
20	Fumikazu SAKAI	Quality Control (5)	Guidance on breeding & rearing of SPF rabbits

No.	Name	Title	Description of Work
21	Yatsuka HORII	Quality Control (6)	Guidance on microbiological tests of SPF rabbits
22	Toshikazu KUROGOHCHI	Quality Control (7)	Guidance on breeding & rearing of SPF rabbits
23	Shuzo ISHIKAWA	Engineering/Project Administration	General guidance on engineering/Project Administration
		Facility/Equipment Validation Technology	General guidance on validation of facilities/equipment
24	Yasuji MATSUMOTO	Facility validation technology (1)	Guidance on validation of air conditioning (measurement technology)
25	Atsushi SHIBATA	Facility validation technology (2)	Guidance on validation of air conditioning (GMP documentation)
26	Hirohisa KAJIOKA	Equipment validation technology (1)	Guidance on process water equipment
27	Kaoru TOMIYAMA	Equipment validation technology (2)	Guidance on autoclave sterilization equipment
28	Hiroki TAKAHASHI	Equipment validation technology (3)	Guidance on vial washing, sterilization equipment (mechanical)
29	Atsuo KOBAYASHI	Equipment validation technology (4)	Guidance on vial washing, sterilization equipment (electrical)
30	Yoshihiko KASUYA	Equipment validation technology (5)	Guidance on freeze-drying
31	Shigeru IWAMI	Equipment validation technology (6)	Guidance on freeze-drying
32	Masayuki KITANO	Equipment validation technology (7)	Guidance on laminar flow, clean bench
33	Kaname HIROSE	Equipment validation technology (8)	Guidance on calibration of all types of equipment
34	Yoshikazu TAKAHASHI	Equipment validation technology (9)	Guidance on filling, capping equipment
35	Takeshi YAMAGUCHI	Equipment validation technology (10)	Guidance on vial washing, sterilization equipment (general)
36	Hayato HIRAI	Equipment validation technology (11)	Guidance on laminar flow, clean bench

5.2 Dispatch of Experts

All experts were dispatched as short-term expert. The actual dispatch of experts from first year to fifth year are shown in Table 5-2 below. For the details, refer to the Appendix (1) attached hereto.

Table 5-2 Dispatch Record of Experts

NO.	Fiscal Year	Number of Dispatches	Dispatched persons-day	Remarks
1	2013 (1st year)	61	880	May2013-Mar.2014
2	2014 (2nd year)	59	726	Apr.2014-Mar.2015
3	2015 (3rd year)	48	641	Apr.2015-Mar.2016
4	2016 (4th year)	43	506	Apr.2016-Mar.2017
5	2017 (5th year)	49	546	Apr.2017-Apr.2018
	Total	260	3,299 (110 persons/ month)	

6. Counterpart Training

6.1 Outline of Counterpart training

Counterpart training in Japan was conducted at KDSV facilities for each department located in Kitamoto-city, Saitama, except for training in breeding and microbiological test of SPF rabbits, which were conducted at Breeding Facility and laboratory of Kitayama Labes Company located in Ina-city, Nagano. All training was completed according to the original schedule. An outline of the activities are given below.

The first counterpart training in Japan during the first year of the Project (2013) was conducted for a total 4 trainees, two for rubella vaccine bulk production, one for quality control (biological) and one for pathology over a total 60 days. The second counterpart training was conducted for a total 4 trainees, one for quality testing (biological), one for quality testing (animal) and one for quality assurance over a total 55 days. The third counterpart training was conducted for 2 trainees for SPF rabbit breeding and rearing over a total 27 days. The fourth counterpart training was conducted for a total 5 trainees, two for MR vaccine final production, one for media preparation and two for quality assurance over a total 28 days.

The first counterpart training in fiscal year 2014 was conducted for 2 trainees for rubella vaccine bulk production over a total 28 days. The second counterpart training was conducted for one trainee for pathology over a total 56 days. The third counterpart training was conducted for one trainee for quality control (biological) over 56 days and 2 trainees for quality assurance over 26 days. The fourth counterpart training was conducted for one trainee for SPF rabbit rearing over 27 days. The fifth counterpart training was conducted for a total 3 trainees, one for quality testing (animal), one for final production and one for media preparation over a total 27 days.

The first counterpart training in fiscal year 2015 was conducted for a total 4 trainees, one for rubella vaccine bulk production, one for quality control (biological) and 2 for quality assurance over a total 28 days. The second counterpart training was conducted for one trainee for SPF rabbit breeding over a total 27 days. The third counterpart training was conducted for a total 3 trainees, one for MR vaccine final production and two for facility/equipment management over a total 21 days.

The first counterpart training in fiscal year 2016 was conducted for one trainee for pathology over a total 28 days. The second counterpart training was conducted for two trainees for SPF rabbit rearing over 21 days. The third counterpart training was conducted for two trainees for facility/equipment management over 14 days and the fourth counterpart training was conducted for a total 2 trainees, one for final production and one for quality assurance over a total 28 days.

The first counterpart training in fiscal year 2017, the final year of the Project, was conducted for one trainee for pathology over a total 28 days, the second counterpart training was conducted for a total three trainees, one for rubella vaccine bulk production, one for media preparation, and one for quality assurance over a total 28 days. The third counterpart training was conducted for two trainees for microbiological test of SPF rabbits over 20 days

6.2 Participants of the Training

The actual numbers of trainees received in Japan are shown in Table 6-1 Record of Trainees below. The list of participants stating participant names, details of training, training periods is attached hereto as Appendix (2).

Table 6-1 Record of Trainees

NO.	Fiscal Year	Number of Trainees	Dispatched persons-day	Remarks
1	2013 (1st year)	15	654	First-Fourth training
2	2014 (2nd year)	10	328	First-Fifth training
3	2015 (3rd year)	8	202	First-Third training
4	2016 (4th year)	7	154	First-Fourth training
5	2017 (5th year)	6	152	First-Third training
	Total	46	1,490	

7. Upgrading of Facilities, Provision of Equipment and Equipment for Experts

7.1 Upgrading of Facilities

The existing facilities of POLYVAC were upgraded in the first year (2013) to make it possible to produce Rubella vaccine since they were originally designed for production of Measles vaccine. Further upgrading to the facilities was carried out in 2014 for compliance with WHO-cGMP. The contract was implemented by JICA, with a contract price of 19,386,000JPY for 2013 and 28,944,000JPY for 2014 and a total for the two years was 48,330,000JPY.

7.2 Provision of Equipment

JICA Vietnam Office carried out all equipment procurement under the Project. The first procurement in 2013 was for Pooling tank, deep freezer, various environment monitoring equipment for rubella vaccine bulk production, related equipment for quality testing and equipment for breeding and rearing of SPF rabbits, with a total cost of 36,204,000JPY. The second procurement carried out in 2016 was for large and small equipment for the conventional animal house and various test equipment necessary for startup of microbiological tests laboratory, with a total cost of 83,982,000JPY. The third procurement carried out in 2017 was for upgrading of the final production line to accommodate MR vaccine single dose production with a cost of 42,469,000JPY. The total for the three procurements was roughly 162,655,000JPY.

For details, refer to the Appendix (3) attached hereto.

7.3 Equipment for Experts

Equipment for experts were procured by KDSV ordering equipment included in the Contract, which were then sent to POLYVAC or delivered to site by the Experts themselves.

In 2013, the first year, mainly equipment for starting up of pathological laboratory was procured at a total cost of 13,567,000JPY.

In fiscal year 2014 and fiscal 2015 during the second phase, Total Organic Carbon Tester (TOC tester) and Refrigerated Centrifuge used in the Quality Control Department, Formaldehyde Fumigator and neutralization device, etc. were procured with a total cost of 9,524,000JPY.

In fiscal year 2016 and fiscal 2017 during the third phase, electronic scales, sensors for validation, maintenance equipment and other devices related to adoption to single dose MR vaccine production and breeding SPF rabbits at POLYVAC were procured with a total cost of 3,191,000JPY.

Total cost over all 5years was approximately 26,282,000JPY. For details, refer to the Appendix (4) attached hereto.

8. General Operational Cost

8.1 Outline of General Operational Cost

General Operational Costs are contained within the Services Contract and the contract sum for fiscal year 2013(the first year) was 17,921,000JPY for the 11month period from the commencement of the Project in May 2013 to March 2014 and the adjusted cost was 17,943,000JPY, roughly in line with originally scheduled costs.

The contract sum for the second term from fiscal year 2014 (the second year) and fiscal year 2015 (third year) was 22,783,000JPY for the 24 month period from April 2014 to March 2016 and the adjusted cost was 22,308,000JPY, roughly in line with originally scheduled costs.

The contract sum for the third term from fiscal year 2016 (the fourth year) and fiscal year 2017 (fifth year) was 29,184,000JPY for the 24 month period from April 2016 to March 2018 and the adjusted cost at the end of the term was approximately 29,625,000JPY, roughly in line with originally scheduled costs. However, the determination of the final cost will be confirmed at the time the Contract Costs Adjustment Report is confirmed.

8.2 Actual General Operational Cost

Refer to the Appendix (5) for detailed outlays by fiscal year.

9. Ideas and Lessons Learned in Implementing the Project

9.1 Ideas in Implementing the Project

Output1: “POLYVAC has proper technical capabilities as a manufacturer of MR vaccine.” and Output2: “POLYVAC can produce MR vaccine properly complying with WHO-cGMP.” are the two essential components for “acquiring capability to produce WHO-GMP compliant MR vaccine”. To Project objectives of accomplishing the necessary upgrading of facilities, building systems and procurement of new equipment and their validation, establishment of the GMP documentation system and education/training of the staff in its operation, technology transfer for SOP of the entire production process, establishment of the quality assurance system, conduction of clinical trials (Vietnamese side operations), and acquire the production capacity to meet domestic demand in Vietnam within the 5 year Project period was an extremely ambitions target.

Since the Project was a Service contract based technological cooperation project, taking responsibility and self-reliance was also a requirement and in addition, all experts were dispatched as short term experts on one to two or maximum 4 weeks schedules, the following items were given priority in the operation of the Project.

(1) To deal timely with any problems arising from all the stakeholders without dividing them into the internal and the external groups in this Project. Especially, Internet conferencing was utilized to deal with emergency situations such aberrations or deviations and allow thorough discussions between KDS experts and POLYVAC staff to arrive at decisions.

(2) To carry out steady management of the entire Project (formulation and sure execution of the detailed plans, monitoring and appropriate evaluation of progress of daily works, timely execution of countermeasures, etc.), since the limits of available time and budget were clearly defined.

(3) To nurture ownership and independence among the counterpart staff by provisioning for weekly meetings and 8 self-governed working groups.

(4) Establishment of a technical transfer scheme via which the counterparts can acquire the technology accurately and efficiently and the current state of progress is visible to a third party (Implementation of Transparency). Specifically, preparation by the experts of a “Table of Technology Transfer Management Results”, as shown in the Appendix (10), in order to define the technology transfer items and the attained technical competency level. In addition, technical instructions began with the preparation and translation into the Vietnamese language of the training materials necessary for each item in the technology transfer, after which repeated classroom guidance and on-the-job training were conducted. Furthermore, a Certificate is issued to counterparts who reach a given level in the final evaluation of the technical instruction by each Expert in the field and submitted to the QA of POLYVAC. It is then confirmed by the KDSV experts and POLYVAC that the technology transfer has been completed successfully.

9.2 Lessons Learned

(1) Importance of communications between Japanese experts and Counterparts

The Japanese experts and POLYVAC staff members encountered some difficulties in communication due to the difficulty of finding corresponding specialized technical terms in each others languages, since both sides were technical people, not linguists. Especial difficulties were

encountered in conducting technology transfer in English. To meet this challenge, highly capable interpreters/translators have been employed as local staff since the "previous phase" for translation between Japanese-Vietnamese. These staff members have, through their Project activities, acquired knowledge not only of the equivalent technical terms, but also their meanings, allowing for extremely accurate translations and interpretations. This has been beneficial, not only for the transfer of technology by the Experts, but also from the view point of Project management, contributing to increased efficiency of the Project.

The translators/interpreters have cooperated in the creation of a Japanese/Vietnamese Special Technical Term Dictionary, which updated regularly and shared with all members and external translators. Also, POLYVAC staff have conducted Japanese and English language classes on their own initiative, further contributing to smooth communications.

(2) Building of Accurate Progress Control System

In this Project, many meetings have been held from the start of the Project, including daily experts coordination meetings, morning briefing assemblies and regular weekly meetings with POLYVAC members (235 weekly meetings have been held between May 2013 to end of March 2018), and monthly experts meetings in Japan. These meetings have contributed greatly to the progress management of the Project, sharing of outputs and information and decision making. The weekly meeting and morning briefing assemblies were continued by POLYVAC staffs independently and effectively even when no experts were present. Thus, organizational capacity has been transferred with lasting effects even after the end of this Project.

In concrete terms, transfer of technology for 325 processes necessary for MR vaccine have been completed through implementing their primary activities as MR vaccine manufacturers by both KDSV experts and POLYVAC staff. The Project has recognized the importance of schedule management of technology transfer and monitoring of output achievements in order to dispatch experts for on-site guidance and carry out training in Japan effectively and efficiently under these conditions and has carried out their careful planning and implementation. As a result, POLYVAC staff capable of independently carrying out and instructing other staff have been trained in all processes and the technology for manufacturing vaccine compliant with WHO-cGMP has been established at POLYVAC.

Appropriate implementation of project schedule management and administration management are common to all projects, but especially under exceptional circumstances, such as when the length and timing for expert dispatches is limited, or when the number of technology transfer items is immense, the importance of careful schedule management is increased. In this regard, this Project stands as an exemplar case for other projects.

(3) Activity Organization to promote ownership and independence

POLYVAC launched 8 working groups continued from the "previous phase", from the first year for this Project, activated as necessary according to the progress of the Project. In each activity, the leader and sub-leader of each working group were selected from POLYVAC staff members. The organization was structured so that the leader independently decided on timing of meetings, solving of problems and promoting the sharing of information among various related departments

keeping pace with the progress of the Project. The Japanese experts strictly adhered to limiting their activities to giving advice to the POLYVAC staffs in order to foster their spirit of ownership. As is manifest from the above, "precise management of the Project" is important in implementing any project, be it even in human resource development. The technologies that they have been acquired through the Project may be easily scattered and lost unless those technologies are sustainably maintained and developed.

9.3 Remaining Tasks

(1) Ministry of Health and Other Vietnam Agencies

- With respect to the certification of Vietnamese NRA by WHO, an important precondition for POLYVAC to acquire WHO Prequalification, the four agencies, namely Drug Authority Vietnam (DAV) MOH, Department of Science and Technology Training (DST) MOH, Vietnam Authority of Preventive Medicine (VAPM) MOH, and NICVB, divide the 6 functions, Marketing Authorization and Licensing Activities, Regulatory inspection, Authorization / Approval of clinical trials, Laboratory access, NRA lot release, and Post-marketing activities including surveillance of adverse events following immunization (AEFI), among themselves. The four agencies were first certified by WHO in April 2015. However, the review for renewal of certification is scheduled to be conducted this year and therefore, they must make all necessary preparations to ensure a certain renewal of certification.
- The Vietnamese government procurement cost of vaccines for government vaccination programs must be set appropriately by taking into account maintenance/operation and future renewal costs of facilities and equipment by POLYVAC, in order to a sustainably maintain a stable supply of high quality domestically produced vaccines.
- In view of the many benefits derived from domestic production of vaccines, the domestic organizational structure for long term utilization of domestically produced MR vaccine, made available through the Project, in domestic vaccination programs, must be continued to be reviewed and strengthened. In particular, vaccines are a vital component of Human Security and a legal framework to enable EPI to procure directly from POLYVAC, not by tender, must be established.
- A legal framework must be established to enable vaccination using Measles vaccine produced by POLYVAC in appropriate places at appropriate times, since their safety and effectiveness were confirmed through clinical trials on 6~8 month old infants conducted in 2017.

(2) POLYVAC

- In order for vaccines produced by POLYVAC to be exported, POLYVAC must acquire WHO Prequalification, and as a first step, they must make certain to apply this year for prequalification of their Measles vaccine, which is already domestically marketed.
- There are still many issues in order for POLYVAC to become a technically and financially independent, internationally competitive vaccine manufacturer. The issues that must be addressed by POLYVAC itself are the improvement of the capabilities of the QA staff, repeated internal training on GMP for the preparation and revision of GMP documentation in

a timely manner, the staff to produce greater volumes of vaccines in compliance with GMP and reduce production cost, improve response capabilities against aberrations and deviations, and to realize a stable supply of starting materials, all in compliance with GMP. Especially, it is necessary to procure SPF eggs, an important starting material for Measles vaccine bulk production, from multiple sources and to forwardly maintain the technology for breeding of SPF rabbits, an important starting material for Rubella vaccine bulk production.

- POLYVAC continues its efforts to reduce production cost of vaccine with respect to international competitiveness.
- With respect to the objective added to third term to develop a single dose MR vaccine, POLYVAC must finalize the prescription (composition) for the vaccine, based on studies and analysis of the results of the quality tests conducted of the past two years and implement the required validation as soon as possible. In addition, GMP documentation required for justification of clinical trials and application for marketing license must also be prepared and submitted expeditiously.
- Since POLYVAC has acquired the capability to produce SPF rabbits, the main starting material for Rubella vaccine bulk, in order to ensure a stable supply and lower production costs, POLYVAC must maintain the technologies and proceed quickly to conclude SPF rabbit technology transfer contracts to enable marketing of SPF rabbits to other research and education agencies, etc.
- Continuous technology transfer was conducted for the Pathological Department, because it is essential that it accumulate experience. However, since the time was limited, the efforts focused on effective transfer of basic technology that POLYVAC staff would be able to build on in the future. Furthermore, in order to maintain these specialized technologies in the future, it is necessary for POLYVAC to strive on its own to earn commissions to carry out these test services for external agencies at the earliest possible date.
- As a result of the continued priority attention devoted to Working Groups WG-3 (Rat and Insect Prevention) and WG-5 (Procurement), it is now possible for POLYVAC to respond independently in most cases, but some very specialized materials are still beyond their capabilities at present, they must make proactive efforts to provide solutions.
- The improvement of the capabilities of the Quality Assurance Department staff responsible for drug administration is necessary in order to improve communications with DAV, etc.
- Since the clinical trial for 10 dose MR vaccine were conducted on children 12months old and over, it will be necessary to investigate and implement the conduction of clinical trials on 9 months old children in view of implementing two time vaccination of MR vaccine in the future.

10. Revision of PDM

10.1 Outline of PDM Revision

The first edition of PDM (Project Design Matrix) was revised and the second edition officially issued at the first meeting of the Joint Coordination Committee (JCC) held in November 2013 based on proposals from Vietnamese side. Additionally, the second edition was revised at the third JCC meeting held on the occasion of the Mid-term review held in November 2015 and the third edition was officially issued. The third edition is the final edition.

10.2 Details of PDM Revision

The main items of revision are summarized below. For the details, refer to the Appendix (6) attached hereto.

(1) Details of revisions for Second Edition

1) Production numbers 200 was added to verifiable criteria for Output 1.
2) References to Vietnamese GMP (VN-GMP) were erased after it was pointed out by Ministry of Health that VN-GMP was the same as WHO-GMP.

(2) Details of revisions for Third Edition

1) Production numbers for verifiable criteria for Output 1 was revised from 200 to 325.
2) The phrase “using MR vaccine produced by POLYVAC” was added to verifiable criteria for Overall Goal.
3) The following two items were added to Important Assumption to Project Purpose.
   - 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.

11. Records of JCC Meetings

11.1 Outline of JCC

The JCC is outlined below.

(1) Functions

The JCC meeting was held at least once a year to make discussions on the following items:

1) Exchange of opinions on important items related to this Project
2) Monitoring and evaluation of the progress and achievement level of the Project
3) Approval of the work schedule and Implementation plans (for entire Project period and individual year plans) of the Project
4) Others

(2) Members

The Committee was chaired by the Director of POLYVAC and the following members participated in it:

1) Project Director (Director of POLYVAC)
2) Representative of Ministry of Health (preferably the Deputy Minister)
3) Representative of International Cooperation Department, Ministry of Health
4) Representative of Drug Administration Department, Ministry of Health
5) Representative of Preventive Medical Services Department, Ministry of Health
6) Representative of Science, Technology and Training Department, Ministry of Health
7) Representative of Planning and Finance Department, Ministry of Health
8) Representative of POLYVAC
9) Representative of NIHE
10) Representative NICVB
11) Representative of WHO Office in Vietnam
12) KDSV Project Manager and other JICA experts
13) Representative of JICA Vietnam Office

Note1: An official of the Japanese Embassy may attend the Committee meeting as an observer.
Note2: Staff from other related organizations may attend the Committee meeting as an observer.

11.2 Records of JCC Meetings

JCC was held once every year, including during the Mid-term Review Study (2015) and Terminal Evaluation Study (2017) for a total 5 times. The achievements for 5 years are shown in Table 11.1 below. For the details, refer to the Appendix (7) attached hereto.

Table 11.1 Record of JCC Meetings

No.	Fiscal Year	Date of Meeting	Main Participants
1	2013 (First year)	October 22, 2013	Senior Representative of JICA Vietnam Office, Official of the Japanese Embassy, Assistant Director of International Corporation Department, Ministry of Health, Deputy Director of DAV, Deputy Director of NICVB, Official in charge of EPI, WHO Vietnam Office, Project Manager of KDSV, etc.
2	2014 (Second year)	October 8, 2014	Senior Representative of JICA Vietnam Office, Official of the Japanese Embassy, Director of International Corporation Department, Ministry of Health, Representative of Military Medical College responsible for Clinical Trials, Official in charge of EPI - WHO Vietnam Office, Project Manager of KDSV, etc.
3	2015 (Third year)	November 27, 2015	Mid-term Review Study Team, Senior Representative of JICA Vietnam Office, Official of the Japanese Embassy, Official in charge of EPI, WHO Vietnam Office, Project Manager of KDSV, etc..
4	2016 (Fourth year)	November11, 2016	Mr. Yoshida, Director, JICA Headquarters, Senior Representative of JICA Vietnam Office, Official of the Japanese Embassy, Policy Advisor, Ministry of Health (JICA Expert), Director of International Corporation Department, Ministry of Health, Deputy Director of Medical Prevention Department, Director of Vietnam EPI Program (Director of NIHE), Director of NICVB, Director of IVAC, Official in charge of EPI - WHO Vietnam Office, Project Manager of KDSV, etc.
5	2017 (Fifth year)	September 29, 2017	Terminal Evaluation Study Team, Senior Representative of JICA Vietnam Office, Director of International Cooperation Department, Ministry of Health, Official in charge of EPI - WHO Vietnam Office, Project Manager of KDSV, etc.
	Total 5 times		

Appendices

(1) Dispatch of Experts (FY2013-FY2017)
(2) Counterpart Training (FY2013-FY2017)
(3) List of Provided Equipment (FY2013-FY2017)
(4) List of Equipment for Experts (FY2013-FY2017)
(5) List of General Operational Cost in Vietnam (FY2013-FY2017)
(6) PDM Revised Edition (2nd and 3rd Editions)
(7) JCC Minutes of Meetings (1st-5th meetings)
(8) List of Products
(9) List of Counterparts
(10) Achievement of Education/Training and Certificate (Abstract)

(1) Dispatch of Experts
(FY2013 – FY2017)

Technical Cooperation Project for Strengthening Capacity for MR Combined Vaccine Production

Dispatch Record of Experts in FY2013 (1st Year)

Legend; ; Confirmed Schedule ; This application ; Plan Rev.; 9 Date; 28-Feb-14

No.	Category	Description		PIC	Class	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
1	General Schedule/ Event	General	Commencement of the Project (19 May) / New Year / TE 1/28–2/5												
			Contract between JICA and KDSV / 24 Apr.												
			Technology Transfer Agreement / 17 May												
			Hanoi Project Office Setting up												
			Rectification of issues on operations / JCC No.1												
			WHO Prequalification												
		GMP/QA	Validation Master Plan for MR												
		Rubella Bulk Production	Documentation												
			Training on site by experts												
			Case Study on site												SPF Rabbit 12/27
		MR Final Production	-												
		QC	Documentation and Transfer Validation												
		Measles Vaccine Production	Bulk Production												
			Final Production												
			Calibration/Periodical Validation												
		Facilities and Equipment	Modification of Production and Animal Lab. buildings and procurement of additional equipment												Detailed / Tender Documents and Tender Close / Contract / Manufacturing, Installation and Commissioning / IQ/OQ by POLYVAC
2	Management	総括 岡部正博	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	26	31	5	6	8	2	
			Engineering, Project Coordination/Management	Shuzo Ishikawa	3	147	141	-6	26	29	3	6	7	1	
			QC Mger	Kenichi Baba	3	70	64	-6	46	40	-6	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	
			C/P training admi.	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	6	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	
						29.27	100.2%		20.00	99.3%			98.4%		Man-Month, %

Dispatch of Experts

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 (2nd Year)

No.		Category	Description		PIC	Class	Schedule (Apr 2014 – Mar 2015)	Total days Vietnam Plan	Vietnam Actual	Vietnam Balance	Japan Plan	Japan Actual	Japan Balance	Total Trips Plan	Total Trips Actual	Total Trips Balance	Remarks
4	Dispatch of Experts	Management					New Year (late Dec 2014); TET (Feb 2015, 3W)										
			総括 荒井 節夫	PJ Manager	Setsuo Arai	2	10/5 7 10/11	11	7	-4	7	7	0	1	1	0	
			副総括 李 富雄	Deputy PJ Mger/Production	Tomio Lee	3	5/14 18 7 6/7; 7/9 11 7/19; 7/30 2 10 8/10; 8/20 6 8/25; 9/14 7 9/20; 10/5 14 10/18; 11/23 8 16 12/16; 2/4 8 2/11; 3/1 21 3/21	126	128	2	19	27	8	6	9	3	
				QC Mger	Kenichi Baba	3	9/7 14 9/20	56	14	-42	30	21	-9	4	1	-3	Coordination on CPs
				Administration Mger	Yasuhiro Tsuchida	3	10/5 7 10/11	7	7	0	2	2	0	1	1	0	
				Deputy Administration Mger	Miki Tamura	3	4/20 11 4/30; 9/28 3 11 10/11	36	25	-11	6	4	-2	3	2	-1	
				Administration for C/P Training	Miki Tamura	5					36	36	0				
5		QA/GMP/ Validation		GMP/Validation (1)	Shigemitsu Hirayama	3	6/1 11 6/11	22	11	-11	20	26	6	2	1	-1	Preparation of GMP Doc. in Japan
				Quality Assurance (1) /GMP/Validation (2)	Takanori Nakashima	3		28	0	-28	20	0	-20	2	0	-2	Ditto
				GMP/Validation (3)	Mika Mizuta	3	6/8 11 6/18; 9/8 12 9/19; 8 5 12/5; 3/2 13 3/14	22	49	27	30	41	11	2	4	2	Ditto
				Quality Assurance (2)	Tetsuo Nakayama	3	9/8 6 9/13; 12/9 5 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	6/22 9 5 7/5; 1/18 14 1/31	28	28	0	6	6	0	2	2	0	
6		BP	Rubella	Bulk Production	Hiroki Katsuda	4	5/20 12 3 6/3; 8/10 14 8/23; 9/7 14 9/20; 11/11 15 11/25; 3/1 14 3/14	56	72	16	12	15	3	4	5	1	
7		FP	MR Vaccine	Final Production(1)	Shuichi Baba	3	6/1 14 6/14; 12/14 14 12/27	28	28	0	6	6	0	2	2	0	
				Final Production(2)	Kunihiko Komuro	3	11/16 7 11/22	7	7	0	3	3	0	1	1	0	
8		QC	Pathology	Quality Control (1)	Manabu Ikeda	3	4/13 7 4/19; 7/13 14 7/26; 8/3 14 8/16; 11/30 1 20 12/20; 3/1 14 3/14	70	70	0	15	15	0	5	5	0	
			Biological	Quality Control (2)	Yoshihisa Takeda	3	4/20 7 4/26; 5/11 7 5/17; 9/14 7 9/20	35	21	-14	15	9	-6	5	3	-2	
			Animal Test	Quality Control (3)	Toshio Kosugi	3	4/13 7 4/19; 5/18 7 5/24; 10/12 11 10/22	35	25	-10	15	9	-6	5	3	-2	
			Animal Breeding	Quality Control (4)	Kuniji Ito	3	5/13 7 5/19; 8/31 1 6 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	4/10 21 4/30; 6/22 9 12 7/12; 8/17 14 8/30; 9/17 14 11 10/11; 10/26 6 5 11/5; 12/21 11 17 1/17; 3/15 14 3/28	126	134	8	18	21	3	6	7	1	
10		Facilities Validation / Engineering	Facilities/Equipment General	Facilities/Equipment Validation	Shuzo Ishikawa	3	2/1 13 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	10/26 6 1 11/1	7	7	0	2	2	0	1	1	0	
			Autoclave	Equip Validation (2)	Kaoru Tomiyama	3	6/29 2 5 7/5	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	6/1 14 6/14	7	14	7	2	2	0	1	1	0	
			Freeze Dryer	Equip Validation (6)	Shigeru Iwami	3	6/1 14 6/14; 10/26 6 1 11/1	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	3/23 6 3/28	7	6	-1	2	2	0	1	1	0	
			Filling and Capping Machines	Equip Validation (9)	Yoshikazu Takahashi	5	11/30 1 6 12/6	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 (May 2014); △ PR/R (Oct 2014); △ F/R (Mar 2015)										

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

Detailed Plan in FY2015 (3rd Year)

Dispatch Record of Experts in FY2015 (3rd Year)

Legend; ; Confirmed Schedule ; This application ; Plan

rev-20 Date; 01 April 2016

No.	Category	Description		PIC	Class	Total days Vietnam Plan	Vietnam Actual	Vietnam Balance	Japan Plan	Japan Actual	Japan Balance	Total Trips Plan	Total Trips Actual	Total Trips Balance	Remarks
1	Management														
		総括 荒井 節夫	PJ Manager	Setsuo Arai	2	11	8	-3	11	11	0	1	1	0	
		副総括 李 富雄	Deputy PJ M'ger/Production	Tomio Lee	3	163	127	-36	22	22	0	7	6	-1	
			QC M'ger	Kenichi Baba	3	14	14	0	12	13	1	1	1	0	Coordination on CPs
			Administration M'ger	Yasuhiro Tsuchida	3	7	8	1	2	3	1	1	1	0	
			Administration	Miki Tamura	3	36	31	-5	6	7	1	3	3	0	
			Administration for C/P Training	Miki Tamura	5		0		43	40	-3				
2	QA/GMP/ Validation		GMP/Validation (1)	Shigemitsu Hirayama	3	11	0	-11	12	12	0	1	0	-1	Preparation of GMP Doc. in Japan
			Quality Assurance (1) /GMP/Validation (2)	Mika Mizuta	3	33	39	6	10	13	3	3	3	0	Ditto
			Quality Assurance (2)	Tetsuo Nakayama	3	14	6	-8	6	3	-3	2	1	-1	
		Antibody Test	Quality Assurance (3)	to be informed	3	14	4	-10	6	3	-3	2	1	-1	
		Total Adviser	WHO-GMP	Tsuguo Sasaki	3	28	28	0	6	8	2	2	2	0	
3	BP	Rubella vaccine bulk	Rubella Vaccine Bulk Production	Hiroki Katsuda	4	14	0	-14	2	1	-1	1	0	-1	
4	FP	MR Vaccine	Final Production(1)	Shuichi Baba	3	28	14	-14	4	3	-1	2	1	-1	
		MR Vaccine	Final Production(2)	Kunihiko Komuro	3	14	14	0	4	5	1	2	2	0	
5	QC	Pathology	Quality Control (1)	Manabu Ikeda	3	70	81	11	10	11	1	5	5	0	
		Biological	Quality Control (2)	Yoshihisa Takeda	3	21	21	0	6	7	1	3	3	0	
		Animal Test	Quality Control (3)	Toshio Kosugi	3	21	14	-7	6	4	-2	3	2	-1	
		Animal Breeding	Quality Control (4)	Kuniji Ito	3	0	7	7	0	4	4	0	1	1	
6	MP	Facilities/Equipment General	Medium Preparation		3										
7	Management/ Engineering		Project Management and Engineering	Shuzo Ishikawa	3	126	140	14	18	22	4	6	7	1	
8	Facilities and Equipment Validations	Facilities/Equipment General	Facilities/Equipment Validation		3	21	21	0	3	5	2	1	1	0	
		HVAC(1)	Facilities Validation (1)	Yasushi Matsumoto	3	7	7	0	1	2	1	1	1	0	
		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	12	5	2	2	0	1	1	0	
		Vial Washing (Electrical)	Equip Validation (4)	Atsushi Kobayashi	3	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)	Yukihiro Motoki	3	0	7	7	0	2	2	0	1	1	
		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	0	7	7	0	2	2	0	1	1	
		Vial Washing Machine (Total)	Equip Validation (10) Additional	Takeshi Yamaguchi	3	0	12	12	0	2	2	0	1	1	
		Laminar/Clean bench/Safety cabinet	Equip Validation (11) Additional	Hayato Hirai	3	0	7	7	0	2	2	0	1	1	
9		Summary				667	641	-26	194	211	17	49	48	-1	Original Contract in FY2015; 581days, 178days, 43trips Revised Contract in FY2015; 667days, 194days, 49trips
						22.23	96.1%		9.70	108.8%			98.0%		

Technical Cooperation Project for Strengthening Capacity for MR Combined Vaccine Production(Term 3)

Detailed Plan in FY2016 (4th Year)

Dispatch Record of Experts in FY2016 (4th Year)

Legend; ——— ; Confirmed Schedule ——— ; This application - - - - - ; Plan

rev-9 Date; 30 Mar. 2017

No.	Category		Description		PIC	Class	Schedule (Apr 2016 – Mar 2017)	Total days Vietnam Plan	Vietnam Actual	Vietnam Balance	Japan Plan	Japan Actual	Japan Balance	Total Trips Plan	Actual	Balance	Remarks
4	Dispatch of Expert	Management					JCC No.4/11 Nov.; New Year; TET										
			総括 荒井 節夫	PJ Director	Setsuo Arai	2	8: 11/6–11/13	7	8	1	4	4	0	1	1	0	
			副総括 李 富雄	Deputy PJ Mger/Production	Tomio Lee	3	11: 4/20–4/30; 12: 5/17–5/28; 18, 1: 7/14–8/1; 7: 9/4–9/10; 14, 7: 9/18–10/8; 8: 11/6–11/13; 12: 1/15–1/26	84	90	6	18	18	0	6	7	1	
				QC Mger	Kenichi Baba	3		0	0	0	8	8	0	0	0	0	Coordination on CPs
				Administration Mger	Yasuhiro Tsuchida	3	4: 9/4–9/8; 12: 11/2–11/13	7	12	5	2	2	0	1	1	0	
				Administration	Miki Tamura	3		25	0	-25	6	6	0	3	0	-3	
				Administration for C/PTraining	Miki Tamura	5		0	0	0	22	22	0	0	0	0	
5		QA/GMP/ Validation		GMP/Validation (1)	Shigemitsu Hirayama	3		11	0	-11	10	9	-1	1	0	-1	Preparation of GMP Doc. in Japan
				GMP/Validation (2)	Mika Mizuta	3	14: 7/10–7/23; 14: 10/9–10/22; 11: 12/14–12/24; 3, 8: 2/26–3/8	39	50	11	30	31	1	3	4	1	Ditto
				Quality Assurance (1)	Tetsuo Nakayama	3	7: 7/6–7/12; 5: 10/3–10/7	14	12	-2	3	3	0	2	2	0	
			Antibody Test	Quality Assurance (2)	Yoshie Motegi	3		0	0	0	0	0	0	0	0	0	
				Quality Assurance (3)	Takashi Ito	3	7: 7/6–7/12; 5: 10/3–10/7	14	12	-2	3	3	0	2	2	0	
				Quality Assurance (4)	Teiichiro Koga	3	4: 9/4–9/7; 2: 9/15–9/16; 7: 11/6–11/12	7	6	-1	2	2	0	1	1	0	
			Total Adviser	WHO-GMP	Tsuguo Sasaki	3	4, 10: 8/28–9/10; 14: 3/12–3/25	28	28	0	6	6	0	2	2	0	
6		BP	Rubella	Bulk Production	Hiroki Katsuda	4	14: 8/7–8/20	14	14	0	2	2	0	1	1	0	
7		FP	MR Vaccine	Final Production(1)	Shuichi Baba	3	7: 7/24–7/30	7	7	0	2	2	0	1	1	0	
			MR Vaccine	Final Production(2)	Kuniaki Komuro	3	7: 9/4–9/10	7	7	0	2	2	0	1	1	0	
8		QC	Pathology	Quality Control (1)	Manabu Ikeda	3	12, 2: 6/19–7/2; 14: 10/16–10/29; 14: 12/11–12/24; 14: 2/5–2/18; 14: 3/12–3/25	70	70	0	8	8	0	5	5	0	
			Biological	Quality Control (2)	Yoshihisa Takeda	3	7: 8/21–8/27; 14: 2/12–2/25	14	21	7	4	4	0	2	2	0	
			Animal Test	Quality Control (3)	Toshio Kosugi	3	7: 8/21–8/27	7	7	0	2	2	0	1	1	0	
			Animal Breeding(1)	Quality Control (4)	Kuniji Ito	3	7: 7/3–7/9; 7: 2/19–2/25	28	14	-14	3	3	0	3	2	-1	
			Animal Breeding(2)	Quality Control (5)	Fumikazu Sakai	3	7: 2/19–2/25	14	7	-7	2	2	0	1	1	0	
			Animal Breeding(3)	Quality Control (6)	Yatsuka Horii	4		14	0	-14	2	0	-2	1	0	-1	
9		MP	Facilities/Equipment General	Medium Preparation		3		0	0	0	0	0		0	0	0	
10		Management/ Engineering	Project Management and Engineering	Engineering/Coordination	Shuzo Ishikawa	3	11: 4/20–4/30; 9, 4: 5/23–6/4; 21: 7/3–7/23; 7: 9/4–9/10; 13, 14: 12/19–1/14; 21: 3/8–3/28	105	100	-5	18	18	0	6	6	0	
11		Facilities and Equipment Validations	Facilities/Equipment (General)	Facilities/Equipment Validation	Shuzo Ishikawa	3	9, 13: 10/23–11/13	21	22	1	5	5	0	1	1	0	
			HVAC(1)	Facilities Validation (1)	Yasushi Matsumoto	3		0	0	0	0	0	0	0	0	0	
			HVAC(2)	Facilities Validation (2)	Atsushi Shibata	3		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		7	0	-7	1	0	-1	1	0	-1	
			Vial Washing (Mechanical)	Equip Validation (3)	Hiroki Takahashi	4		0	0	0	0	0	0	0	0	0	
			Vial Washing (Electrical)	Equip Validation (4)	Atsushi Kobayashi	3		0	0	0	0	0	0	0	0	0	
			Filling Machine	Equip Validation (5)	Yoshihiko Kasuya	3	1, 5: 7/31–8/5	0	6	6	0	1	1	0	1	1	
			Freeze Dryer	Equip Validation (6)	Shigeru Iwami	3	8, 5: 7/24–8/5	7	13	6	1	1	0	1	1	0	
			Laminar/Clean bench/Safety cabinet	Equip Validation (7)	Masayuki Kitano	3		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)	Yoshikazu Takahashi	4		0	0	0	0	0	0	0	0	0	
			Vial Washing Machine (Total)	Equip Validation (10)	Takeshi Yamaguchi	3		0	0	0	0	0	0	0	0	0	
			Laminar/Clean bench/Safety cabinet	Equip Validation (11)	Hayato Hirai	3		0	0	0	0	0	0	0	0	0	
12			Summary					551	506	-45	166	164	-2	47	43	-4	Original Contract in FY2016; 551days, 166days, 47trips
								18.37	91.8%		8.30	98.8%			91.5%		

Technical Cooperation Project for Strengthening Capacity for MR Combined Vaccine Production(Term 3)

Detailed Plan in FY2017 (5th Year)

Dispatch Record of Exoerts in FY2017 (5th Year)

Legend; ; Dispatched schedule ; This application ; Plan ; by Others

rev-18, Date; 16 April 2018

No.	Category		Description	PIC	Class	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
1	Dispatch of Experts	Management	総括 荒井 節夫	Project Director	Setsuo Arai	2	16	16	0	4	4	0	2	2	0	
			副総括 李 富雄	Deputy PJ Mgr./ Production	Tomio Lee	3	100	100	0	21	21	0	7	7	0	
				QC Mgr.	Kenichi Baba	3	0	0	0	5	4	-1	0	0	0	Coordination on CPs
				Administration Mgr.	Yasuhiro Tsuchida	3	20	21	1	4	4	0	3	2	-1	
				Administration	Miki Tamura	3	17	0	-17	6	6	0	2	0	-2	
				Administration for C/P Training	Miki Tamura	5		0		10	10	0				
2		QA/GMP/ Validation		GMP/Validation (1)	Shigemitsu Hirayama	3	0	0	0	3	0	-3	0	0	0	Preparation of GMP Doc. in Japan
				GMP/Validation (2)	Mika Mizuta	3	22	22	0	3	6	3	2	2	0	Ditto
				Quality Assurance (1)	Tetsuo Nakayama	3	7	5	-2	1	1	0	1	1	0	
			Antibody Test	Quality Assurance (2)	Yoshie Motegi	3	0	0	0	0	0	0	0	0	0	
				Quality Assurance (3)	Takashi Ito	3	0	5	5	1	1	0	0	1	1	
				Quality Assurance (4)	Teiichiro Koga	3	15	0	-15	2	0	-2	2	0	-2	
			Total Adviser	WHO-GMP	Tsuguo Sasaki	3	14	14	0	3	3	0	1	1	0	
3		BP	Rubella	Bulk Production	Hiroki Katsuda	4	14	18	4	2	2	0	1	1	0	
4		FP	MR Vaccine	Final Production(1)	Shuichi Baba	3	7	7	0	2	2	0	1	1	0	
			MR Vaccine	Final Production(2)	Kunihiko Komuro	3	14	17	3	4	4	0	2	2	0	
5		QC	Pathology	Quality Control (1)	Manabu Ikeda	3	49	56	7	6	6	0	3	4	1	
			Biological	Quality Control (2)	Yoshihisa Takeda	3	14	14	0	4	2	-2	2	1	-1	
			Animal Test	Quality Control (3)	Toshio Kosugi	3	7	7	0	2	2	0	1	1	0	
			Animal Breeding(1)	Quality Control (4)	Kuniji Ito	3	22	36	14	3	5	2	3	5	2	
			Animal Breeding(2)	Quality Control (5)	Fumikazu Sakai	3	7	0	-7	3	0	-3	1	0	-1	
			Animal Breeding(3)	Quality Control (6)	Yatsuka Horii	4	28	28	0	3	4	1	3	4	1	
			Animal Breeding(4)	Quality Control (7)	Toshikazu Kurogochi	3	15	8	-7	0	2	2	2	1	-1	
6		MP	Rubella/MR Vaccine	Medium Preparation		3		0								
7		Management/ Engineering	Project Management and Engineering	Engineering/ Coordination	Shuzo Ishikawa	3	124	138	14	21	19	-2	7	8	1	
8		Facilities and Equipment Validations	Facilities/Equipment (General)	Facilities/Equipment Validation		3	14	7	-7	3	3	0	1	1	0	
			HVAC(1)	Facilities Validation (1)	Yasushi Matsumoto	3	0	0	0	0	0	0	0	0	0	
			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	7	6	-1	1	1	0	1	1	0	
			Vial Washing (Mechanical)	Equip Validation (3)	Hiroki Takahashi	5	0	0	0	0	0	0	0	0	0	
			Vial Washing (Electrical)	Equip Validation (4)	Atsuo Kobayashi	3	0	0	0	0	0	0	0	0	0	
			Filling Machine	Equip Validation (5)	Yoshihiko Kasuya	3	0	7	7	0	1	1	0	1	1	
			Freeze Dryer	Equip Validation (6)	Shigeru Iwami	3	7	14	7	0	2	2	1	2	1	
			Laminar/Clean bench/Safety cabinet	Equip Validation (7)	Yukihiro Motoki	3	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	0	0	0	0	0	0	0	0	0	
			Vial Washing Machine (Total)	Equip Validation (10) Additional	Takeshi Yamaguchi	3	0	0	0	0	0	0	0	0	0	
			Laminar/Clean bench/Safety cabinet	Equip Validation (11) Additional	Hayato Hirai	3	0	0	0	0	0	0	0	0	0	
9			Summary				540	546	6	117	115	-2	49	49	0	
							18.00	101.1%		5.85	98.3%			100.0%		Man-Month
						Term3 Total		1,052			278			92		

(2) Counterpart Training
(FY2013 – FY2017)

Counterpart Training (FY2013-FY2017)

1. FY2013 (First Year)

Description	Objective	Desired result	Timing	No. of Trainees.
Rubella Bulk Production (Lecture, Observation, OJT)	Lectures and OTJ on methods and processes used in the manufacture of rubella stock solution.	Understand and acquire technology used in methods and processes used in the manufacture of rubella stock solution. (Primarily removal of kidneys from SPF rabbits, digestion, and culturing of rabbit kidney cells)	From 23rd Jun. to 21st Aug. 2013 Total: 60 days	2
Quality Control (Pathology) (Lecture, Observation, OJT)	Lectures and OTJ on pathology and pathological examination of SPF rabbits.	Understand and acquire technology for pathology and pathological examination of SPF rabbits necessary in the manufacture of rubella stock solution. (necropsy, specimen preparation {removal, fixing, embedding, slicing, and staining} and examination with microscope)	From 23rd June to 21st August 2013 Total: 60 days	1
			From 16th Sep. to 9th Nov. 2013 Total: 55 days	1
Quality Control (Biology) (Lecture, Observation, OJT)	Lectures and OTJ on biological tests used in the manufacture of rubella stock solution.	Understand and acquire technology for biological test methods used in the manufacture of rubella stock solution. (Culture observation, Hemadsorption virus detection test, cultured rabbit kidney cell inoculation test, Nosema cuniculi detection test, and virus content test)	From 23rd June to 21st August 2013 Total: 60 days	1
			From 16th Sep. to 9th Nov. 2013 Total: 55 days	1
Quality Control (Animal Testing) (Lecture, Observation, OJT)	Lectures and OTJ on animal tests used in the manufacture of rubella stock solution.	Understand and acquire technology for animal tests used in the manufacture of rubella stock solution. (rabbit inoculation tests, marker tests)	From 16th Sep. to 9th Nov. 2013 Total: 55 days	2
SPF rabbit Breeding Management (Lecture, OJT)	Lectures and OTJ on management of SPF rabbits.	Acquire basic knowledge for the raising and health management of SPF rabbits.	From 14th Oct. to 9th Nov. 2013 Total: 27 days	2
Final Production (Lecture, Observation)	Lectures and OTJ on the final manufacturing of MR vaccine.	Understand and acquire technology used in methods and processes for the final manufacturing of MR vaccine. (final bulk, filling, freeze drying, sealing)	From 17 Nov. to 14th Dec. 2013 Total: 28 days	2
Medium Preparation (Lecture, Observation)	Lectures and OTJ on culture media preparation.	Understand and acquire technology for culture media preparation necessary to the manufacture of rubella stock solution and MR vaccine.	From 17 Nov. to 14th Dec. 2013 Total: 28 days	1
Quality Assurance (Lecture, Observation, OJT)	Acquire comprehensive knowledge of MR vaccine.	Acquire basic knowledge of final manufacturing and quality testing used for MR vaccines necessary to be capable of performing QA activities.	From 17 Nov. to 14th Dec. 2013 Total: 28 days	2
Total			15 persons, 654 days	

2. FY2014 (Second Year)

Description	Objective	Desired result	Timing	No. of Trainees.
Rubella Vaccine Bulk Production (Lecture, Observation, OJT)	Lectures and OTJ on methods and processes used in the manufacture of rubella stock solution.	Understand and acquire technology used in methods and processes used in the manufacture of rubella vaccine bulk. (Primarily removal of kidneys from SPF rabbits, digestion, and culturing of rabbit kidney cells)	From 6th Apr. to 03rd May 2014 Total: 28 days	2
Quality Control (Pathology) (Lecture, Observation, OJT)	Lectures and OTJ on pathology and pathological examination of SPF rabbits.	Understand and acquire technology for pathology and pathological examination of SPF rabbits necessary in the manufacture of rubella vaccine bulk. (necropsy, specimen preparation {removal, fixing, embedding, slicing, and staining} and examination with microscope)	From 6th Apr. to 31st May 2014 Total: 56 days	1
Quality Control (Biology) (Lecture, Observation, OJT)	Lectures and OTJ on biological tests used in the manufacture of rubella vaccine bulk.	Understand and acquire technology for biological test methods used in the manufacture of rubella vaccine bulk. (Culture observation, Hemadsorption virus detection test, cultured rabbit kidney cell inoculation test, Nosema cuniculi detection test, and virus content test), and preparation of antiserum of rubella.	From 6th Apr. to 31st May 2014 Total: 56 days	1
Quality Assurance (Lecture, Observation, OJT)	Acquire comprehensive knowledge of MR vaccine.	Acquire basic knowledge of quality testing used for MR vaccines necessary to be capable of performing QA activities.	From 6th May to 31st May 2014 Total: 26 days	2
SPF rabbit Breeding Management (Lecture, OJT)	Lectures and OTJ on management of SPF rabbits.	Acquire basic knowledge for the raising, health management, Microbiological test and breeding of SPF rabbits.	From 12th Oct. to 8th Nov. 2014 Total: 27 days	1
Quality Control (Animal Testing) (Lecture, Observation, OJT)	Lectures and OTJ on animal tests used in the manufacture of rubella stock solution.	Understand and acquire technology for animal tests used in the manufacture of rubella vaccine bulk. (Rabbit inoculation tests, Marker tests), and preparation of antiserum of rubella.	From 24th Nov. to 20th Dec. 2014 Total: 27 days	1
Final Production (Lecture, Observation)	Lectures and OTJ on the final manufacturing of MR vaccine.	Understand and acquire technology used in methods and processes for the final manufacturing of MR vaccine. (Final bulk, Filling, Freeze drying, sealing)	From 24th Nov. to 20th Dec. 2014 Total: 27 days	1
Medium Preparation (Lecture, Observation)	Lectures and OTJ on culture media preparation.	Understand and acquire technology for culture media preparation necessary to the manufacture of rubella stock solution and MR vaccine.	From 24th Nov. to 20th Dec. 2014 Total: 27 days	1
Total			10 persons, 328 days	

3. FY2015 (Third Year)

Description	Objective	Desired result	Timing	No. of Trainees.
Rubella Vaccine Bulk Production (Lecture, Observation, OJT)	Lectures and OTJ on methods and processes used in the manufacture of rubella stock solution.	Understand and acquire technology used in methods and processes used in the manufacture of rubella vaccine bulk. (Primarily removal of kidneys from SPF rabbits, digestion, and culturing of rabbit kidney cells)	From 5th July to 01st Aug. 2015 Total: 28 days	1
Quality Control (Biology) (Lecture, Observation, OJT)	Lectures and OTJ on biological tests used in the manufacture of rubella vaccine bulk.	Understand and acquire technology for biological test methods used in the manufacture of rubella vaccine bulk. (Culture observation, cultured rabbit kidney cell inoculation test and virus titer test), and viable cell number on process water, identification of microorganism and cleaning validation.	From 5th July to 01st Aug. 2015 Total: 28 days	1
Quality Assurance (Lecture, Observation, OJT)	Acquire comprehensive knowledge of MR vaccine.	Acquire basic knowledge of quality testing used for MR vaccines necessary to be capable of performing QA activities.	From 5th July to 01st Aug. 2015 Total: 28 days	2
SPF rabbit Breeding Management (Lecture, OJT)	Lectures and OTJ on management of SPF rabbits.	Acquire basic knowledge for the raising, health management, microbiological test and breeding of SPF rabbits.	From 12th Oct. to 07th Nov. 2015 Total: 27 days	1
Final Production (Lecture, Observation)	Lectures and OTJ on the final manufacturing of MR vaccine.	Understand and acquire technology used in methods and processes for the final manufacturing of MR vaccine. (final bulk, filling, freeze drying, sealing)	From 29th Nov. to 19th Dec. 2015 Total: 21 days	1
Facilities Maintenance (Lecture, Observation)	Lectures and Observation at Factories for Calibration/Validation and Maintenance	Understand and acquire technology for facilities and equipment operation and maintenance including calibration/validation	From 29th Nov. to 19th Dec. 2015 Total: 21 days	2
Total			Total; 8 persons, 202 days	

4. FY2016 (Fourth Year)

Description	Objective	Desired result	Timing	No. of Trainees.
Quality Control (Pathology) (Lecture, Observation, OJT)	Lectures and OTJ on pathology and pathological examination of SPF rabbits.	Understand and acquire technology for pathology and pathological examination of SPF rabbits necessary in the manufacture of rubella vaccine bulk. (necropsy, specimen preparation, removal, fixing, embedding, slicing, and staining and examination with microscope)	From 3rd July to 30th July 2016 Total: 28 days	1
SPF rabbit Breeding Management (Lecture, OJT)	Lectures and OTJ on management of SPF rabbits.	Acquire basic knowledge for the raising, health management, microbiological test and breeding of SPF rabbits.	From 2nd Oct. to 22nd Oct. 2016 Total: 21 days	2
Facilities Maintenance (Lecture, Observation)	Lectures and Observation at Factories for Calibration/Validation and Maintenance	Understand and acquire technology for facilities and equipment operation and maintenance including calibration/validation	From 20th Nov. to 3rd Dec. 2016 Total: 14 days	2
Final Production (Lecture, Observation)	Lectures and OTJ on the final production of MR vaccine.	Understand and acquire technology used in methods and processes for the final production of MR vaccine. (final bulk, filling, freeze drying, capping)	From 20th Nov. to 17th Dec. 2016 Total: 28 days	2
Total			Total; 7 persons, 154 days	

5. FY2017 (Fifth Year)

Description	Objective	Desired result	Timing	No. of Trainees.
Quality Control (Pathology) (Lecture, Observation, OJT)	Lectures and OTJ on pathology and pathological examination of SPF rabbits.	Understand and acquire technology for pathology and pathological examination of SPF rabbits necessary in the manufacture of rubella vaccine bulk. (Immunostaining, Disease Diagnosis and examination with microscope)	From 14th May to 10th June 2017 Total: 28 days	1
Rubella Vaccine Bulk Production (Lecture, Observation, OJT)	Lectures and OTJ on methods and processes used in the manufacture of rubella stock solution.	Understand and acquire technology used in methods and processes used in the manufacture of rubella vaccine bulk. (Primarily removal of kidneys from SPF rabbits, digestion, and culturing of rabbit kidney cells) And Understanding of supplemental technologies for the Final production for MR vaccine and Quality control.	From 11th June to 8th July 2017 Total: 28 days	3
SPF rabbit Breeding Management (Lecture, Observation, OJT)	Lectures and OTJ on management of SPF rabbits.	Acquire basic knowledge for the raising, health management, microbiological test and breeding of SPF rabbits.	From 9th Oct. to 28th Oct. 2017 Total: 20 days	2
Total			Total; 6 persons, 152 days	

(3) List of Provided Equipment
(FY2013 – FY2017)

List of Provided Euipment (FY2013～FY2017)

As of 30 March 2018

No.	Fiscal Year	Code No.	Name of Equipment	Brand Name	Model No.	Q'ty	POLYVAC Dept.
1	FY2013	13A-1	Compressor for compressed air supply system	KOBELCO	FE200A-5 6A01P00202F3	2	Engineering
2		13B-1	Calibration Kit	METTLER TOLEDO	1885 Calibration system 5000 TOC System	1	Engineering
3		13C-1	Particle counter	HACH ULTRA	A2400	3	Bulk/QC
4		13C-2	Particle counter for Animal Lab	PMS	Lasair III-310B	1	Engineering
5		13C-3	Air sampler	SATORIUS	MD8	3	Bulk/Medium/QC
6		13D-1	Deep Freezer for BP	PANASONIC	MDF-U74V	4	Bulk
7		13D-2	Deep Freezer for QC	PANASONIC	MDF-U5386	1	QC
8		13D-3	Electronic Balance for Rabbit with Printer	SHIMADZU	BW12KH	2	QC (Animal)
9		13D-4	Rabbit breeding cage	Local manufacturer	Order made	3	QC (Animal)
10		13D-5	Stirrer	IKA	Eurostar 20 Digital	1	Medium
11		13D-6	Liquid nitrogen stocker	TAYLOR WHARTON	LS-3000	1	QC
12		13D-7	Refrigerator for wasted animals	TOSHIBA	GR-RG66FVDA	1	QC (Animal)
13		13D-8	Silicon tube for MP	COLE PARMER	HV96420-36	2	Medium
14		13E-1	Pooling tank SUS 10L for BP	NITTO KINZOKU	KITASATO Special SUS316L -10L	68	Bulk
15		13E-2	Gaskets for 70L Pooling tank	IKEMOTO	PL-70, AC40-6V	1	Bulk
16		13E-3	Sensors for Egg Incubator	SHOWA FURANKI	SHAB-11	1	Bulk
17		13E-4	Heat proof strings for Autoclave	MARUFUJI	Karauchi-himo	1	Medium
18		13E-5	Roux bottle for QC	SANWA RIKA	KITASATO Special	30	QC
19		13E-6	Rotor for Cooled centrifuges	KOKUSAN	RF-124T	1	QC
20		13E-7	Dispenser 100mL	TOYO RIKO	JH-1x2	1	Bulk
21		13E-8	Dispenser 10mL	TOYO RIKO	JA-1	1	Bulk
22		13F-1	Rubber stopper for Siphon	KOTOBUKI	No. 21	20	Final
23		13F-2	Silicon tube for Filling machine	AS ONE	6-586-14	5	Final
24		13F-3	Clean shoes	GOLDWIN	PA9680P + PA5600	60	Common
25		13F-4	Clean wear (Garment)	GOLDWIN	PP1940	10	Common
26		13F-5	Finn pipette	THEREMO SCIENTIFIC	8 Nos. of pipttes with Stepper	1	QC
27		13F-6	Recorder for Freezer (Chino)	CHINO	EH3D67-000	2	Bulk/QC
28		13F-7	Recorder for Freezer (Yokogawa)	YOKOGAWA	μR20000(437112) HC-100	1	Bulk
29		13F-8	Alcohol spray machine for hand washing	SARAYA	HDI - 2002	2	Common
30		13F-9	Digital single-lens reflex camera (pathology)	OLYMPUS	OM-D E-M5 with Accessories	1	QC (Pathology)
31		13F-10	Compressor	GAST	DOA-P504-BN	1	QC
32		13G-1	Silicon tube with SUS adaptor-1	ADVANTA PURE	APSH-P1000	1	Final
33		13G-2	Silicon tube with SUS adaptor-2	ADVANTA PURE	APSH-P1000	1	Final
34		13G-3	Silicon tube with SUS adaptor-3	ADVANTA PURE	APSH- P500	1	Final
35		13G-4	Silicon tube with SUS adaptor-4	ADVANTA PURE	APSH- P1000	1	Final
36		13G-5	Frame type working table set	LFS	Order made	1	QC (Pathology)
37		13G-6	Fluorescent type task lamp	PANASONIC	SQT652	2	QC (Pathology)
38		13G-7	Collection tank 20L (Pathology)	LFS	Order made	2	QC (Pathology)
39		13G-8	Digital timer	CONTROL	Traceable	1	QC (Pathology)
40		13G-9	Cart for transportation	LFS	Order made	1	QC (Animal)

No.	Fiscal Year	Code No.	Name of Equipment	Brand Name	Model No.	Q'ty	POLYVAC Dept.
41		13G-10	Disinfectant Vat	LFS	Order made	6	QC (Animal)
42		13G-11	Circulation pump for WFI production system	ALFA LAVAL	LKH-25/175	1	Engineering
43		13H-1	Vacuum cleaner with HEPA filter for Clean room	PHILIP	FC9228	1	Bulk
44		13H-2	Automated plate preparation system	SYATEC	Media fill	1	QC
45		13H-3	Pipette aid	CORNING	Stripettor Plus Code; 4091	4	QC
46		13H-4	Filtration and Sterilization system for drinking water for animal	KANGAROO	Order made	2	QC (Animal)
47	FY2016	16A-1	Renewal of Building Management System	AZBIL	Savic-net FX Step2	1	Engineering
48		16B-1	Safety cabinet	AIRTECH	BSC-1300 IIA2	1	QC (Animal)
49		16B-2	Pass box	AIRTECH	APB-545	1	QC (Animal)
50		16C-1	Autoclave, Steam Boiler	SUKURA SI	SNI-O15DW OSG-1200T	1	QC (Animal)
51		16D-1	Micropipette-1	THEREMO	10-100µl	2	QC (Animal)
52		16D-2	Micropipette-2	THEREMO	100-1000µl	2	QC (Animal)
53		16D-3	Multi micropipette 8 channel	THEREMO	30-300µl	1	QC (Animal)
54		16D-4	Centrifugal separator	HETTICH	EBA-280	1	QC (Animal)
55		16D-5	Incubator	CONTHERM	1400CP	1	QC (Animal)
56		16D-6	Refrigerator	PANASONIC	MPR-S313	2	QC (Animal)
57		16D-7	Vortex mixer	STUART	SA8	1	QC (Animal)
58		16D-8	Plate Vortex	IKA	MS3 Digital	1	QC (Animal)
59		16D-9	Water bath	JULABO	PURA10	1	QC (Animal)
60		16D-10	Labo Autoclave	HIRAYAMA	HVA-110	1	QC (Animal)
61		16D-11	Microscope	OLYMPUS	CX-23	1	QC (Animal)
62		16D-12	Freezer	PANASONIC	MDF-C8V1	1	QC (Animal)
60		16D-13	Spectrodensitometer for VVM	X-RITE	X-rite 504	1	QC
61		16D-14	Air sampler	LIGHTHOUSE	ActiveCount 100	2	QC /Medium
62		16D-15	Particle counter	HACH ULTRA	3413	1	QC
66		16D-16	Air conditioners	DAIKIN	RZQ71LV1, etc.	6	QC (Animal)
67		16D-17	Packaged Type Air Handling Unit	TRANE	CLCPeuro25mm	1	QC (Animal)
68		16D-18	Exhaust Fan Unit	AAF	RPT-11-P-1-N-N, etc.	1	QC (Animal)
69		16D-19	Ammoniac Gas Meter	SENKO	SP2nd	1	QC (Animal)
70		16D-20	Sound Level Meter	RION	NL-42	1	QC (Animal)
71		16D-21	Digital illumination meter	KYORITSU	5201	1	QC (Animal)
72		16D-22	Air Velocity Meter	KIMO	LV110	1	QC (Animal)
73		16D-23	Filtration and Sterilization system for drinking water for animal	Local	Order made	2	QC (Animal)
	FY2017	17A-1	Modification of Final Produciton Line				
74		17A-1- 17A-7	Attachments for Vial Washing and Sterilization Machine of Single dose	BOSCH PACKAGING TECHNOLOGY	8-112-113-106 8-112-113-107 8-112-113-108, etc.	1	Final
75		17B-1- 17B-25	Attachments for Filling Machine of Single dose	SUZUKI ENGINEERING	2906S1-2000-2 2906S1-1200-2 2906S1-900-2, etc.	1	Final
76		17C-1- 17C-12	Attachments for Capping Machine of Single dose flip off cap	SUZUKI ENGINEERING	2906S3-600-2 2906S3-400-2 2906S3-300-2, etc.	1	Final
77		17D-1- 17D-3	Attachments for Capping Machine of 10 dose flip off cap	SUZUKI ENGINEERING	2906S3-510-3 EP-9979 2906S3-240-3	1	Final

(4) List of Equipment for Experts
(FY2013 – FY2017)

List of Equipment for Experts (FY2013～FY2017)

As of 30 March 2018

No.	Fiscal Year	Code No.	Name of Equipment	Brand Name	Model No.	Q'ty	POLYVAC Dept.
1	FY2013	CE-1301	Autopsy Tool Set	AS ONE	Various combinations	1	Bulk
2		CE-1302	Surgical Set-BP	AS-ONE	Ditto	1	Bulk
3		CE-1303	Printing Thermometer	ANRITSU	AP-800ES	1	Bulk
4		CE-1304	Pooling Tank for Bulk 10L	NA	KDSV Special	12	Bulk
5		CE-1305	CO2 Incubator	PANASONIC	MCO-19AIC-PE	1	QC
6		CE-1306	Tissue Embedding System	SAKURA FINETEK	Tissue-Tek TEC5	1	QC (Pathology)
7		CE-1307	Automatic Tissue Processor	SAKURA FINETEK	Tissue-Tek VIP 5 Jr	1	QC (Pathology)
8		CE-1308	Paraffin Oven	SAKURA FINETEK	PM-401-II	1	QC (Pathology)
9		CE-1309	Microtome	THERMO SCIENTIFIC	HM430	1	QC (Pathology)
10		CE-1310	Tissue Floating Water Bath	SAKURA FINETEK	PS-110WH	1	QC (Pathology)
11		CE-1311	Slide Warmer	SAKURA FINETEK	PS-53	1	QC (Pathology)
12		CE-1312	Camera System for the Microscope, BX-53	NA	DP 73 etc.	1	QC (Pathology)
13		CE-1313	Surgical Set-PT	SANSHO, AS-ONE, THERMO SCIENTIFIC, SANPLATEK	Various combinations	1	QC (Pathology)
14		CE-1314	Rabbit Breeding Rack	ORIENTAL YEAST	NIH Standard	1	QC (Animal)
15		CE-1315	Clinical Thermometer	TATEYAMA KAGAKU	D717	1	QC (Animal)
16		CE-1316	Hair Clipper	OSTER	Golden A5	1	QC (Animal)
17		CE-1317	Fixing Board	NA	KDSV Special	1	QC (Animal)
18		CE-1318	Surgical Sets-AL	AS-ONE	Various combinations	1	QC (Animal)
19	FY2014	CE-1401	Cooled Centrifuge	KOKUSAN Corporation	H-60R	1	QC
20		CE-1402	Hybrid Memory Recorder	CHINO Corporation	AH4706-N0A-NNN	1	Bulk
21		CE-1403/ 04	Metal-sheathed resistance thermometer sensor flor Recorder /Traceability certificate	CHINO Corporation	NRHS1-0	6	Bulk
22		CE-1405	pH Meter and Printer	HORIBA, Ltd.	LAQUAact D-713 CMB910-24RJ100-A	1	QC
23	FY2015	CE-1501	Formalin Fumigator	Parma Biotech JAPAN	MH-20	1	Common
24		CE-1502	Formalin Neutralizer	Parma Biotech JAPAN	FOT2000	1	Common
25		CE-1503	TOC Analyzer	GE USA	M9 Laboratory Analyzer	1	QC
26		CE-1504	Mist Generator	AIRTECH JAPAN	ACV-500	1	Common
27		CE-1505	Hot Stirrer	AS ONE	1-5477-02	2	QC/Medium
28	FY2017	CE-1701	Electronics Balance and Printer	SARTORIUS	TE214S YDP20-OCE	1	Final
29		CE-1702	Gas Leakage Detector	BBK TECHNOLOGIES	SRL-2K7	1	Final
30		CE-1703	Electronics Balance and Printer	SHIMAZU	BW12KH EP-110	1	QC (Animal)
31		CE-1704	Thermocouple	OKAZAKI	T type, Class 1, 0.32mmΦ、12mL	40	Common
32		CE-1705	Tool set	KYOTO TOOL	SK3561W	3	Engineering
33		CE-1706	SUS Bellows for Freeze Dryer	IMA LIFE JAPAN	LYOFAST18	1	Final

(5) List of Operational Cost in Vietnam
(FY2013 – FY2017)

List of Operation Cost in Vietnam (FY2013-FY2017)

1. Term 1 (FY2013 (First Year))

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)－(B)
1. Personnel Cost	6,047,818	6,025,947	21,871
2. Rental Fee	1,358,210	1,515,925	▲ 157,715
3. Maintenance/Management for Equipment Cost	141,285	27,594	113,691
4. Consumables Cost	7,808,935	7,762,890	46,045
5. Transportion Fee for C/P traing	0	0	0
6. Communication Cost	767,878	555,463	212,415
7. Document Fee	0	0	0
8. Miscellaneous Cost	1,797,673	1,606,149	191,524
Sub Total	17,921,799	17,493,968	427,831
Adjustment	▲ 799	▲ 968	
Total	**17,921,000**	**17,493,000**	**428,000**

2. Term 2 (FY2014 (Second Year)/FY2015 (Third Year))

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)－(B)
1. Personnel Cost	16,058,302	14,200,834	1,857,468
2. Rental Fee	3,320,556	3,580,630	▲ 260,074
3. Maintenance/Management for Equipment Cost	122,952	7,840	115,112
4. Consumables Cost	2,391,125	3,677,210	▲ 1,286,085
5. Transportion Fee for C/P traing	0	124,101	▲ 124,101
6. Communication Cost	806,050	300,465	505,585
7. Document Fee	0	17,160	▲ 17,160
8. Miscellaneous Cost	84,600	400,261	▲ 315,661
Sub Total	22,783,585	22,308,501	475,084
Adjustment	▲ 585	▲ 501	
Total	**22,783,000**	**22,308,000**	**475,000**

3. Term 3 (FY2016 (Fourth Year)/FY2017 (Fifth Year))

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)－(B)
1. Personnel Cost	23,118,761	19,403,456	3,715,305
2. Rental Fee	3,567,912	3,352,969	214,943
3. Maintenance/Management for Equipment Cost	136,812	79,418	57,394
4. Consumables Cost	880,000	5,308,998	▲ 4,428,998
5. Transportion Fee for C/P traing	413,280	312,155	101,125
6. Communication Cost	838,950	287,952	550,998
7. Document Fee	0	19,953	▲ 19,953
8. Miscellaneous Cost	228,480	860,305	▲ 631,825
Sub Total	29,184,195	29,625,206	▲ 441,011
Adjustment	▲ 195	▲ 206	
Total	**29,184,000**	**29,625,000**	**▲ 441,000**

(6) PDM Revised Edition
(2nd and 3rd Editions)

PDM (Project Design Matrix) (Version 2)

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: October 22, 2013

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 with MR vaccine in Viet Nam is at or above 95%.	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.
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 200 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

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

(7) JCC Minutes of Meetings
(1st-5th meetings)

MINUTES OF MEETING

1st JOINT COORDINATING COMMITTEE (JCC) FOR THE JAPANESE TECHNICAL COOPERATION FOR THE PROJECT FOR STRENGTHENING CAPACITY FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION

In accordance with the Record of Discussion (RD) signed on April 17th, 2013 for the Project, the first JCC meeting was held on October 22nd, 2013 attended by the Vietnamese and Japanese members.

In the meeting the Deputy Project Director of Kitasato Daiichi Sankyo Vaccine Co., Ltd (KDSV) presented the inception report; another Deputy Project Director of KDSV presented the overall project schedule and project design matrix; Project Manager of Center for Research and Production of Vaccines and Biologicals (POLYVAC) presented the progress of the project. Further, participants made comments and discussion. The discussion was summarized by Associate Professor, Dr. Nguyen Dang Hien, Chairman of the meeting.

As a result of the discussions, both Vietnamese side and Japanese side agreed upon the items in the document attached hereto:

Hanoi, November 22nd, 2013

Mr. Okiura Fumihiko
Deputy Chief Representative
Viet Nam Office
Japan International Cooperation Agency

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

Dr. Setsuo Arai
Deputy Project Director
Vice President of Kitasato Daiichi Sankyo Vaccine Co., Ltd

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

Minute of Joint Coordinating Committee (JCC)
The First Conference

- **Time and Date:** 9h30-12h15, 22nd October 2013.
- **Location:** Conference Room, Measles vaccine production facilities- Center for Research and Production of Vaccines and Biologicals (POLYVAC) - No.418 Vinh Hung, Thanh Tri, Ha Noi.
- **Attendant:** (Refer to Name list attached)

Agenda & Discussion

1. Dr. Nguyen Dang Hien opened the meeting and introduced the guests and agenda of the meeting.

2. Mr. Fumihiko Okiura, Senior Deputy Resident Representative of JICA Vietnam office congratulated the team for the progress made in project implementation and also assured that JICA would continue its enthusiastic support for the success of the project. He stressed the importance of Rubella disease control as the disease had recent breakouts in Vietnam in 2011 and also in Japan in late 2012 and 2013. He expressed his hope that with the assistance of Vietnamese Ministry of Health (MOH), as well as the efforts of Center for Research and Production of Vaccines and Biologicals (POLYVAC) and Kitasato Daiichi Sankyo Vaccine Co., Ltd (KDSV), the project would be successful.

3. MA. Nguyen Thi Minh Chau, Deputy Director of International Cooperation Department of MOH had a speech. The Deputy Director affirmed that the project would contribute significantly help the Vietnamese health sector to achieve the goal of supplying Measles-Rubella combined vaccine for Expanded Program on Immunization (EPI). On behalf of MOH, the Deputy Director thanked the Government of Japan (GOJ) for its assistance in the health sector and also thanked Japanese International Cooperation Agency (JICA) and KDSV for implementing of the project. Additionally, the Deputy Director committed to facilitate the implementation of the project efficiently and on schedule.

4. Dr. Setsuo Arai, Deputy Project Director, KDSV presented the inception report.

5. Dr. Tomio Lee, Deputy Project Director, KDSV presented the overall project schedule and project design matrix.

6. Dr. Nguyen Thuy Huong, Deputy Director of POLYVAC presented the progress of the project.

7. Opinions of attendants of JCC meeting:

7.1. Mr. Nguyen Viet Hung, Deputy Director of Drug Administration of Vietnam, expressed his pleasure to attend the first JCC meeting of Technical Cooperation Project for Strengthening Capacity for Measles - Rubella combined Vaccine Production. He said that the Vietnamese MOH was extremely interested in the project as it was consistent with MOH policy on providing adequate and quality drugs at reasonable prices combined with their safe and effective usage. Deputy Director also expressed 3 related projects that were being implemented by the Government of Vietnam (GOV) and MOH relating to the production and usage of vaccines.

(1) GOV is implementing the national product program concerning the production and usage of vaccines relating to the health sector. According to the Plan effective to 2020 and future vision to 2030, MOH has set a target of providing adequate vaccines for EPI to vaccinate Vietnamese children. Measles, Rubella vaccines are included in the plan.

(2) MOH has also set up the plan for usage and production of vaccine up to 2020 based on EPI evaluation on effective vaccines usage, as well as strengthening the capacity of domestic vaccine manufacturers and improving disease prediction. Measles and Rubella vaccines were in this plan, also.

(3) MOH had improved the NRA functions in order to upgrade the quality of vaccines, to allow for export. It was expected that, Vietnamese NRA would be assessed and recognized by WHO in first quarter 2014.

The Deputy Director expressed the commitment of the Drug Administration of Vietnam would coordinate with POLYVAC and relevant organizations to implement necessary works to assure that the project would be implemented on schedule and achieve the target. He kindly requested POLYVAC to revise the project goal in project design matrix from "to

produce vaccines achieving Vietnamese GMP" to "to produce vaccines achieving WHO GMP assessed and recognized by MOH of Vietnam".

7.2. Dr. Kohei Toda- Medical Officer of WHO in Vietnam: Thanked Vietnamese MOH, Embassy of Japan, JICA, and KDSV for their assistance in implementation of this project. He also highly appreciated MOH efforts to improve the functions of the NRA in assessment capabilities that are projected to be recognized by WHO. He expressed the hope that with the cooperation of all parties, POLYVAC would quickly produce Measles-Rubella combined vaccine with safety, effectiveness and high quality for inoculation of children in Vietnam and worldwide.

7.3. Mr. Nguyen Van Quang- Officer of Department of Planning and Finance, MOH of Vietnam: Informed that MOH had approved the counterpart fund of GOV for this project. The sum was 28.5 billion VND to be disbursed over 5 years at the average annual rate of approximately 5-6 billions VND. The fund represented a significant proportion of the total domestic capital that MOH was provided yearly. This showed the great interest of MOH for the project. He kindly requested JICA Vietnam to quickly send the equipment list to be provided for project to MOH for approval and do necessary procedures for aid confirmation and tax exemption with the Ministry of Finance. In order to receive counterpart fund for following year in time, he further kindly requested POLYVAC to send the Application for providing counterpart fund to Department of Planning and Finance in September or October of the previous year. He also reminded POLYVAC to follow strictly the reporting regulation applied for grant aid project every quarter. Finally, he thanked GOJ for supporting Vietnam to produce Measles and Rubella combined vaccine, hoped the project would be successful.

Mr. Nguyen Van Quang also proposed that Department of Planning and Finance should be mentioned in the members list of project coordinating committee in order to facilitate better cooperation with relevant agencies.

7.4. Mr. Dao Huu Thien- Deputy Director of National Institute for Control of Vaccine and Biologicals (NICVB): In concert with the MOH interests, NICVB was also trying to improve the functions of NRA. Recently, MOH and NICVB had organized the inspection to evaluate NRA functions of the Institute. The results showed that most criteria had been achieved. Relating to vaccine testing function, NICVB was also in the process of updating with new techniques in response to requirements of domestic vaccine manufacturers. The Deputy Director also suggested WHO to support NICVB for training in the new techniques.

7.5. Prof. Nguyen Van Man- Former Director of POLYVAC: expressed his pleasure in participating in the First JCC meeting of Technical Cooperation Project for Strengthening Capacity for Measles-Rubella combined Vaccine Production as well as knowing the project was being implemented. He thanked GOJ, WHO, Vietnamese MOH and related agencies for the great contribution in implementation of the project. The production of measles and rubella vaccine would play an important role in disease elimination for Vietnamese children. However, in order to eliminate measles disease, it should have a plentiful source of vaccines and inoculate following the immunization program. Vaccine production facilities of POLYVAC had been designed to produce 7.5 million measles vaccines doses, but currently it only produces 2.5 million vaccine doses annually according to EPI demand. He expressed hope that Vietnamese MOH and relevant authorities would make the appropriate plan for vaccine utilization in order that POLYVAC could produce the vaccine with maximum capacity as originally designed.

8. Conclusion:

Dr. Nguyen Dang Hien summarized the discussions of the meeting and agreed with the opinions of all attendants as follows: (1) VN-GMP in the all official documents will be deleted. (2) Planning and Finance Department of MOH will be added in the member of JCC. (3) The inception report was confirmed. POLYVAC reiterated its commitment to strive to complete the project and he also requested the relevant organizations for their assistance. The first JCC meeting has been closed successfully. Finally, Dr. Nguyen Dang Hien thanked the participants and declared that the meeting finished.

Annex I : Agenda

Annex II : List of Participants

Annex III : Project Design Matrix (Version 2) and Plan of Operation(PO)

Annex IV : List of JCC Members (Revised)

Annex I

THE PROJECT FOR STRENGTHENING CAPACITY FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION

1st JCC Meeting

- Date and Time : (Tue) 22nd October 2013, 09:30-12:00
- Place : 3F Conference Room, Administration building of Measles facilities, 418 Vinh Hung Street, Hoang Mai District, Hanoi
- Language : Vietnamese-Japanese with Interpreters

PROGRAM

No	Time	Description	
1	09:30-09:50	Opening Address Introduction of all attendances Introduction of Program of Meeting	Dr. Hien, Director of POLYVAC, Project Director
2	09:50-10:00	Speech	Mr. Fumihiko OKIURA, Senior Representative of JICA Vietnam Office
3	10:00-10:10	Speech	Representative from MOH
4	10:10-10:30	Speech/Explanation of Inception Report	Dr. Setsuo ARAI, Vice President and Vice Project Director of KDSV
5	10:30-10:45	Coffee break	
6	10:45-11:00	Explanation of Overall Schedule and PDM	Dr. Tomio Lee, Vice Project Director of KDSV
7	11:00-11:20	Presentation on Progress of the Project	Dr. Huong, Vice Director of POLYVAC, Project Manager
8	11:20-12:00	Q&A, Comments and Discussions on the revision of PDM, etc.	Dr. Hien, Director of POLYVAC, Project Director
9	12:00	Closing Address	Dr. Hien, Director of POLYVAC, Project Director

Annex II

Participants for the 1st Joint Coordinating Committee meeting
Technical Cooperation Project for Strengthening Capacity for Measles – Rubella Combined Vaccine Production in Vietnam (October 22nd 2013)

No	Name in Full	Position	Remarks
	Ministry of Health (MOH)		
	International Cooperation Department		
1	MA. Nguyen Thi Minh Chau	Deputy Director	
2	Mrs. Vu Ha Thu	Specialist	
	Planning and Finance Dept		
3	Mr. Nguyen Van Quang	Specialist	
	Drug Administration of Vietnam		
4	Mr. Nguyen Viet Hung	Deputy Director	
5	Mrs. Nguyen Hong Nhung	Specialist	
	NICVB		
6	Mr. Doan Huu Thien	Deputy Director	
7	Mrs. Nguyen Thi Mai Huong	Specialist	
	POLYVAC		
8	Prof. Nguyen Van Man	Senior Advisor	
9	Assoc. Prof. Nguyen Dang Hien	Director	
10	Assoc. Prof. Le Thi Luan	Deputy Director	
11	Dr. Nguyen Thuy Huong	Deputy Director	
12	Mr. Le Quoc Hung	Manager of Final Production Dept	
13	Mrs. Nguyen Thanh Van	Deputy Manager of Final Production Dept	
14	Mr. Nguyen Dang Quynh	Final Production Dept	
15	Mr. Nguyen Duy Chuc	Final Production Dept	
16	Mr. Nguyen Xuan Hoa	Manager of Bulk Production Dept	
17	Mr. Le Tuan Anh	Manager of Medium Production Dept 2	
18	MA. Pham Anh Thu	Deputy Manager of QC Dept 2	
19	Nguyen Mai Huong	QC Dept 2	
20	Mrs. Le Thu Nga	Deputy Manager of QA Dept	
21	Mrs. Tran Thi Phuong	Deputy Manager of QA Dept	
22	Ms. Nguyen Thi Phuong Thao	QA Dept	
23	Mr. Thai Hung	QA Dept	
24	Ms. Hoang Thi Lan	QA Dept	
25	Mrs. Nguyen Thi Hai Thanh	Manager of Administration Dept	
26	Mrs. Cao Hai Anh	Administration Dept	
27	Ms. Nguyen Thi Thuy	Administration Dept	
28	Mr. Nguyen Huu Thang	Administration Dept	
29	Mrs. Nguyen Thi Thanh Mai	Deputy Manager of Accounting Dept	
30	Mr. Nguyen Manh Khue	Deputy Manager of	

		Procurement Dept	
31	Mr. Nguyen Dang Anh	Manager of Engineering Dept	
32	Mr. Tran Trong Hai	Procurement Dept	
33	MA. Dang Mai Dung	Manager of QC Dept 1	
34	Mrs. Tran Thi Bich Hanh	Deputy Manager of QC Dept 1	
35	Mr. Nguyen Nghia Vu	Manager of Medium Production Dept 1	
36	Mr.Trinh Van Quang	Manager of Bulk Dept 1	
	JICA		
37	Mr. Fumihiko Okiura	Senior Deputy Resident Representative	
38	Ms. Ai Miura	Senior Project Formulation Advisor	
39	Mrs. Dao Thi Khanh	Program Officer	
	EOJ		
40	Ms. Yoko Tsuruya	First Secretary	
	WHO		
41	Dr. Kohei Toda	Medical Officer, EPI	
	Kitasato Daiichi Sankyo Vaccine Co.,Ltd		
42	Dr. Setsuo Arai	Deputy Project Manager	
43	Dr. Tomio Lee	Deputy Project Manager	
44	Dr. Yasuhiro Tsuchida	Administration 1	
45	Dr. Miki Tamura	Administration 2	
46	Mr. Shuzo Ishikawa	Project Coordinator/Engineer	
47	Mrs. Dinh Thi Van Chi	Hanoi Project Office	
48	Mrs. Le Thi Ly	Hanoi Project Office	
49	Mrs. Nguyen Huong Giang	Hanoi Project Office	
50	Ms. Vu Thanh Hoa	Hanoi Project Office	

Annex III

PDM (Project Design Matrix) (Version 2)

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 22, 2013

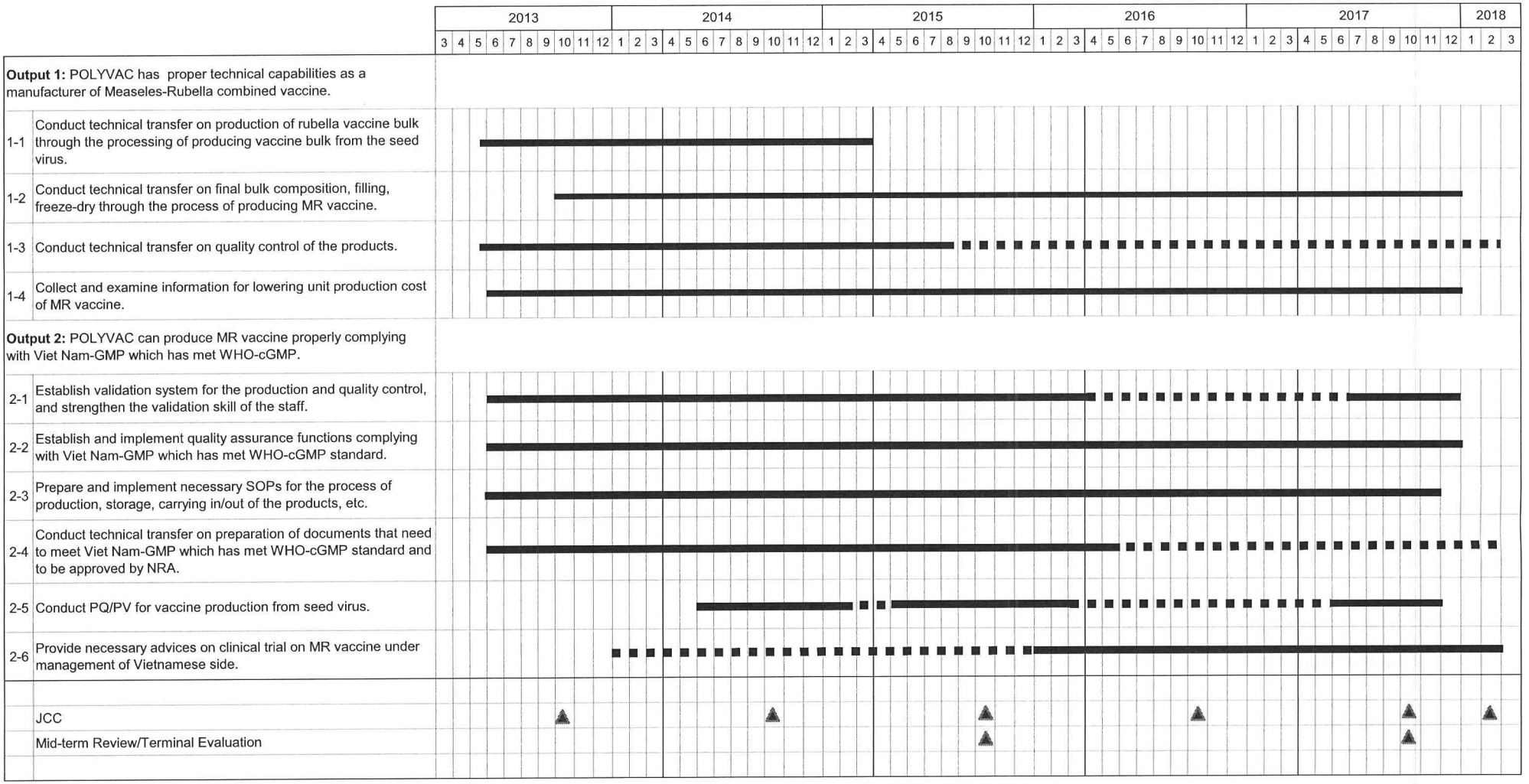
Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumptions
Overall Goal Spread of measles and rubella in Viet Nam is decreased.	1. Number of case of children infected with measles and rubella in Viet Nam is decreased compared with the average between 2009 and 2012. (Measles: 2, 107 cases, Rubella: 3,710 cases)[1] 2. Coverage rate of children immunized with MR vaccine in Viet Nam is at or above 95%.	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.
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 200 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

PO (Plan of Operation)



Annex IV

List of JCC Members (Revised)

(1) Chairperson

The chairperson shall be the Director of POLYVAC, who is also the Project Director.

(2) Members

1) Project Director
2) Representatives of MOH (Vice Minister is preferred)
3) Representative of the International Cooperation Department of MOH
4) Representative of the Drug Administration of Vietnam of MOH
5) Representative of the Preventive Medicine Department of MOH
6) Representative of the Science, Technology and Training Department of MOH
7) Representative of the Planning and Finance Department of MOH
8) Representatives of POLYVAC
9) Representative of National Institute of Hygiene and Epidemiology (NIHE)
10) Representative of National Institute for Control of Vaccine and Biologicals (NICVB)
11) Representative of WHO Vietnam Office
12) JICA Experts
13) Representative of JICA Vietnam Office

MINUTES OF MEETING

2nd JOINT COORDINATING COMMITTEE (JCC) FOR THE JAPANESE TECHNICAL COOPERATION FOR THE PROJECT FOR STRENGTHENING CAPACITY FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION

In accordance with the Record of Discussion (RD) signed on April 17th, 2013 for the Project, the second JCC meeting was held on October 8th, 2014 attended by the Vietnamese and Japanese members.

In the meeting the Project Director of Kitasato Daiichi Sankyo Vaccine Co., Ltd (KDSV) presented the general progress; Deputy Project Director of KDSV presented the overall project schedule and issues; Project Manager of Center for Research and Production of Vaccines and Biologicals (POLYVAC) presented the progress of the project. Further, participants made comments and discussion. The discussion was summarized by Associate Professor, Dr. Nguyen Dang Hien, Chairman of the meeting.

As a result of the discussions, both Vietnamese side and Japanese side agreed upon the items in the document attached hereto:

Hanoi, October 23rd, 2014

Mr. Chikahiro Masuda
Senior Representative
Viet Nam Office
Japan International Cooperation Agency

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

Dr. Setsuo Arai
Project Director
Vice President of Kitasato Daiichi Sankyo Vaccine Co., Ltd.

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

Minutes of Joint Coordinating Committee (JCC)

The Second Conference

- **Time and Date:** 9h30-12h30, Wednesday, 08th October 2014
- **Location:** Conference Room, Measles vaccine production facilities - Center for Research and Production of Vaccines and Biologicals (POLYVAC) - No.418 Vinh Hung, Thanh Tri, Ha Noi.
- **Attendant:** (Name list attached)

Agenda & Discussion

1. **Dr. Nguyen Dang Hien** opened the meeting and introduced the guests and agenda of meeting.

2. **Mr. Chikahiro Masuda, Senior Representative, JICA Vietnam office** :

   Mr. Masuda expressed his pleasure in attending the conference and thanked POLYVAC, KDSV company for making the effort to implement the project during the past year. He directed attention to the two issues that should be considered for the successful and efficient implementation of the project. The first issue was that POLYVAC should be self sufficient in supplying SPF rabbit used for rubella vaccine production; these animals were currently imported from Japan. This would help POLYVAC to be both self sufficient in vaccine production and reduce the production cost. Therefore he hoped that the Vietnamese Ministry of Health (MOH) would provide financial support to POLYVAC for building the SPF rabbit breeding facilities. The second issue was that clinical trials for measles-rubella combined vaccine would be time commsuming. Therefore he requested POLYVAC to quickly prepare the clinical trial application dossier and submit to MOH to promote the implementation of the clinical trials. He also stressed the importance of measles and rubella vaccines for preventing the outbreak of the diseases and expressed the intent of JICA to maintain close communications with relevant agencies to support implementing the project successfully.

3. **Dr. Tran Thi Giang Huong, Director of International Cooperation Department of MOH** spoke next. She emphasized the importance of the collaborative relationship between Vietnam and Japan during the past 40 years, and affirmed the strategic

partnership between Japan and Vietnam. The Government of Japan had assisted Vietnam in general and the preventive health sector in particular to implement many projects successfully and efficiently. Regarding the measles outbreak in 2014, the measles vaccine production project, implemented from 2006 with assistance from Japan, had played a very significant role in eliminating the disease by providing approximately 6 million doses of measles vaccine. 2014 was also the year which showed the remarkable effort of POLYVAC in both the timely supply of sufficient vaccines to prevent the measles epidemic and implementing sucessfully the project of measles- rubella combined vaccine production. The project has the important mission to provide the vaccines for EPI of Vietnam and also in supporting Vietnamese officials to develop the vaccine production, production administration and quality testing skills that meet the GMP requirement of WHO. On behalf of the Vietnamese government, the Director expressed her deep gratitude to the Government of Japan, JICA, and KDSV for the assistance of enhancing the vaccine production capacity and promoting the development of preventive health sector in Vietnam. She expressed her commitment to providing the favorable conditions to facilitate the successful implementation of the project.

4. **Dr. Setsuo Arai, Excutive Vice President of Kitasato Daiichi Sankyo Co., Ltd.- Project Manager** stated that the project had been implemented on schedule in the past year, and thanked the Vietnamese MOH, JICA, other related agencies and individuals for their assistance. If the project progresses according to schedule, clinical trial application dossiers could be submitted to Vietnamese MOH by the end of 2014, the clinical trials could be commenced in 2015, and the measles-rubella combined vaccines could be expected to get the marketing license in March 2018. In other words, it is possible that the project could be completed 6 months earlier compared with the original plan. The Director also committed to strive to obtain the vaccine license in the shortest possible time. He expressed his pleasure and admiration in POLYVAC for the emergency provision measles vaccine to extinguish the measles epidemic while implementing successfully the project in 2014. In order to produce vaccines conveniently in routine production, he said that POLYVAC should be supported in building the SPF rabbit breeding facilities to enable self procurement of the material source and reduction of the production cost. SPF rabbit was the specific-pathogen free rabbit whose breeding required special conditions but no facilities in Vietnam could meet the requirements at present. The import of SPF rabbits from Japan currently was only suitable for the duration of the project, but not in mass production. It is important that POLYVAC identify facilities capable of domestic breeding of SPF rabbits. POLYVAC is presently developing plans for facilites capable of domestic breeding of SPF rabbits, and it is hoped that Vietnamese MOH and relevant authorities would

consider and strongly support POLYVAC to build the facilities. Finally, he committed the Japanese side to work closely with POLYVAC to implement the project successfully and also hoped to receive the assistance from relevant agencies and individuals.

5. **Dr. Nguyen Thuy Huong-Deputy Director of Center for Research and Production of Vaccine and Biologicals (POLYVAC)** presented the progress of the project. During the past year, all project working items were implemented according to the set goals. As scheduled, the project works for the past year were mostly related to technology transfer, case study and validation of rubella bulk production process. Up to now POLYVAC has successfully implemented the case study, PQ (performance qualification) and PST (process simulation test) of bulk production process. The PV (process validation) is scheduled to be completed in the middle of January 2015. In addition, POLYVAC has implemented the processes of IQ (installation qualification), OQ (operational qualification), CAL (calibration) and PQ for most of the new equipment; the remaining equipment should be completed by the end of this year. The technical training programs were also conducted as planned including on-site training by experts and counterpart training in Japan. In order to enhance communications, the KDSV experts and POLYVAC officials have held many meetings including daily meeting, weekly meeting, briefing and debriefing meetings with experts, working group meetings.

6. **Dr. Tomio Lee - Deputy Project Manager, Kitasato Daiichi Sankyo Co., Ltd. and Dr. Nguyen Thuy Huong-Deputy Director of POLYVAC Duand Project Manager** presented the overall project schedule, project design matrix and project issues. Dr. Lee presented the revised project plan in which the progress would be accelerated by 6 months compared with the original plan. In the revised plan, the clinical trial application dossier would be submitted to MOH by the end of 2014 year and implemented in 2015. He reported the measures taken to reduce production costs including converting FBS (fetal bovine serum) to NBCS (new born calf serum), and validation performed by POLYVAC- self calibration using devices provided by JICA. In addition, the project was considering other measures such as domestic rabbit supply for testing, and SPF rabbit breeding facilities in POLYVAC for production. Moreover, the presentation also emphasized the need of vaccine export during mass production to achieve financial independence of POLYVAC and that therefore the vaccine must achieve the GMP standard of WHO.

7. **Dr. Nguyen Dang Hien** raised 2 issues to consult the opinion of the delegates. The issues are about the SPF rabbit breeding facilities and the clinical trial of measles-rubella combined vaccine.

8. **Opinions of attendants of JCC meeting:**

(1) **Prof. Nguyen Van Man- Former Director of POLYVAC:** expressed the pleasure of attending the 2nd conference as well as knowing the projects was implemented successfully last year. Currently Vietnam must import measles-rubella combined vaccines from India for EPI, therefore he hoped that the project would be implemented successfully and promptly to provide vaccines for Vietnamese children. Professor Man agreed with Dr. Arai about the need to accelerate the implementation of the project to provide vaccines in the shortest possible time. He believed that the vaccines produced by Japanese technology to be transferred by Japanese experts would be safe and have the required quality. According to his experience, the clinical trial would be the time-consuming process (about 18 months). Therefore he hoped Vietnamese MOH and other relevant agencies would provide support for the smooth and succesful implemention of the project.

(2) **Dr. Tran Thi Giang Huong, Director of International Cooperation Department of MOH:** The Director expressed agreement on the need for building SPF rabbit breeding facility in POLYVAC to realize the domestic production of vaccines and their export abroad as a future target and also the need for making efforts to implement clinical trial on schedule. The Director said that the team of KDSV, JICA, WHO would visit Dr. Nguyen Thanh Long, Deputy Minister in the afternoon today. Therefore she suggested the team should present the issues to the Deputy Minister and other related agencies to seek assistance. Also in the afternoon, Dr. Nguyen Thanh Long would have a meeting with relevant agencies on investment for domestic vaccine production. The Director would raise the issue of SPF rabbit breeding facilities at these meetings for consideration.

(3) **Dr. Kohei Toda- Medical Officer of WHO in Vietnam:** stated that currently WHO was supporting Vietnam in evaluating the functions of NRA for achieving the international criteria. This would be an opportunity for Vietnamese vaccines to comply with international standards. Recently, WHO had recommended vaccinating the rubella vaccine for the children from 9 months old. Therefore, POLYVAC should pay attention to the age of children participating in the clinical trial. He hoped that Vietnamese MOH would support the project by investing to fullfill facilities of POLYVAC in order to implement the project smoothly and successfully. In addition, he hoped that the project would continue receiving the technical assistance from Japan,

JICA, KDSV Company. There will still be be much hard work, but he firmly believed that with cooperation of relevant parties the project would be implemented successfully.

(4) **Mr. Nguyen Van Quang- Officer of Department of Planning and Finance, MOH of Vietnam:** stated that currently the Vietnamese MOH was concentrating on domestic vaccine production. In 2014, MOH provided to POLYVAC the corresponding fund of 6.2 billion VND. It was an attempt of MOH at supporting the project, therefore he kindly requested POLYVAC to use the fund effectively. About the issue of clinical trial, he recommended POLYVAC to submit the application dossier in time, set up the due date for each working item, and work closely with relevant agencies to control the progress. For MOH side, he committed to make the effort to review and approve the dossiers. Regarding SPF rabbit breeding facilities, he said that the importing of rabbits was expensive and required complicated procedures. Therefore, he agreed about the need of building the SPF rabbit breeding facilities in POLYVAC and hoped Japanese side would support POLYVAC on this matter. He kindly requested POLYVAC to submit the proposal of funding to Vietnamese MOH for the consideration.

(5) **Ms. Dao Thi Khanh, Officer of JICA office in Vietnam,** raised a question to POLYVAC about SPF rabbit breeding facility. She wondered that the facility would be a new one or be improved from existing animal facilities.

(6) **Dr. Nguyen Dang Hien:** answered the question of Ms. Dao Thi Khanh. POLYVAC planned to use existing facilities for SPF rabbit breeding and building new facility for normal animals used for testing. Vietnamese MOH had approved the fund of building the new facilities. Currently, POLYVAC was preparing the detail design plan, detailed cost estimate, and breeding plan to submit to the Vietnamese MOH. The technology for breeding SPF rabbits is important for the successful operations of the facilities. Therefore, POLYVAC has addded it to the proposal for consideration as a component of the assistance from the Vietnamese MOH and JICA.

9. **Conclusion:**

Dr. Nguyen Dang Hien summarized the discussions of the meeting and agreed with the opinions of the attendants. Representative of POLYVAC expressed his committment to strive for the smooth implemention of the project and he also requested the relevant offices for their assistance. He declared the meeting successful. Finally, Dr. Nguyen Dang Hien thanked the participants and declared the meeting closed.

THE PROJECT FOR STRENGTHENING CAPACITY FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION

2nd JCC Meeting

-Date and Time : Wednesday 8th October 2014, 09:30-12:00
-Place : 3F Conference Room, Administration building of Measles facilities,
418 Vinh Hung, Thanh Tri, Hoang Mai, Hanoi
- Language : Vietnamese-Japanese with Interpreters

PROGRAM

No	Time	Description	
1	09:30-09:50	Opening Address Introduction of all attendances Introduction of Program of Meeting	Dr. Nguyen Dang Hien, Director of POLYVAC, Project Director
2	09:50-10:00	Speech	Mr. Chikahiro MASUDA, Senior Representative of JICA Vietnam Office
3	10:00-10:10	Speech	Dr. Tran Thi Giang Huong Director of International Cooperation Department, MOH
4	10:10-10:20	Speech	Dr. Setsuo ARAI, Vice President and Project Director of KDSV
5	10:20-10:35	Presentation on Progress of the Project	Dr. Nguyen Thuy Huong, Vice Director of POLYVAC, Project Manager
6	10:35-10:50	Coffee break	
7	10:50-11:10	Explanation of Overall Schedule, PDM and Issues	- Dr. Tomio LEE, Vice Project Director of KDSV - Dr. Nguyen Thuy Huong, Vice Director of POLYVAC, Project Manager
8	11:10-12:00	Q&A, Comments and Discussions	Dr. Nguyen Dang Hien, Director of POLYVAC, Project Director
9	12:00	Closing Address	Dr. Nguyen Dang Hien, Director of POLYVAC, Project Director

LIST OF PARTICIPANTS TO THE 2nd JCC MEETING

"THE PROJECT FOR STRENGTHENING CAPACITY FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION"

No	Name in full	Position	Remarks
	Ministry of Health		
	Department of International Cooperation		
1	Dr. Tran Thi Giang Huong	Director	
2	Mrs. Vu Ha Thu	Officer	
	Department of Planning and Finance		
3	Mr. Nguyen Van Quang	Officer	
	Drug Administration of Vietnam		
4	Mr. Phan Cong Chien	Officer	
	Department of Preventive Medicine		
5	Mrs. Nguyen Thi My Hanh	Officer	
	Military Institute		
6	Mr. Dinh Hong Duong	Officer	
	POLYVAC		
7	Prof. Nguyen Van Man	Senior Advisor	
8	Assoc. Prof. Nguyen Dang Hien	Director	
9	Assoc. Prof. Le Thi Luan	Deputy Director	
10	Dr. Nguyen Thuy Huong	Deputy Director	
11	Mr. Le Quoc Hung	Manager of Final Production Dept.	
12	Mrs. Nguyen Thanh Van	Deputy Manager of Final Production Dept.	
13	Mr. Nguyen Dang Quynh	Final Production Dept.	
14	Mr. Nguyen Xuan Hoa	Manager of Measles Bulk Production Dept.	
15	Mr. Pham Thanh Truong	Bulk Production Dept.	
16	Mr. Le Tuan Anh	Manager of Medium Production Dept. 2	
17	Mrs. Ngo Thu Huong	Manager of QC No. 2	
18	Mr. Pham Huu Tien	QC Dept. No. 2	
19	Mrs. Tran Thi Phuong	Deputy Manager of QA Dept.	
20	Ms. Nguyen Thi Phuong Thao	QA Dept.	
21	Mr. Thai Hung	QA Dept.	
22	Ms. Hoang Thi Lan	QA Dept.	
23	Mrs. Nguyen Thi Hai Thanh	Manager of Administration Dept.	
24	Mr. Nguyen Duc Thang	Administration Dept.	
25	Ms. Ly Bich Thuy	Administration Dept.	
26	Mrs. Nguyen Thi Thanh Mai	Deputy Manager of Accounting Dept.	
27	Mr. Nguyen Manh Khue	Deputy Manager of Procurement Dept.	

29	Mr. Nguyen Dang Anh	Manager of Engineering Dept.	
30	Mr. Le Hoang Nam	Deputy Manager of Engineering Dept.	
31	Mr. Tran Trong Hai	Procurement Dept.	
32	MA. Dang Mai Dung	Manager of QC Dept. 1	
33	Mrs. Tran Thi Bich Hanh	Deputy Manager of QC Dept. 1	
34	Mr. Nguyen Nghia Vu	Manager of Medium Production Dept. 1	
35	Mr. Trinh Van Quang	Manager of Polio Bulk Dept.	
36	Mrs. Nguyen Anh Tuyet	Deputy Manager of Polio Bulk Dept.	
	JICA		
37	Mr. Chikahiro MASUDA	Senior Representative	
38	Mrs. Dao Thi Khanh	Program Officer	
	EOJ		
39	Ms. Yoko TSURUYA	First Secretary	
	WHO		
40	Dr. Kohei TODA	Medical Officer, EPI	
41	Dr. Makiko IIJIMA	Medical Officer, WHO	
	Kitasato Daiichi Sankyo Vaccine Co., Ltd		
42	Dr. Setsuo ARAI	Project Manager	
43	Dr. Tomio LEE	Deputy Project Manager	
44	Mr. Yasuhiro TSUCHIDA	Administration 1	
45	Dr. Miki TAMURA	Administration 2	
46	Mr. Shuzo ISHIKAWA	Project Coordinator/Engineer	
47	Mrs. Dinh Thi Van Chi	Hanoi Project Office	
48	Mrs. Nguyen Huong Giang	Hanoi Project Office	
49	Ms. Vu Thanh Hoa	Hanoi Project Office	
50	Ms. Nguyen Ngoc Tram	Hanoi Project Office	

MINUTES OF MEETING

THE 3rd JOINT COORDINATING COMMITTEE (JCC) FOR THE JAPANESE TECHNICAL COOPERATION FOR THE PROJECT FOR STRENGTHENING CAPACITY FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION

In accordance with the Record of Discussion (RD) signed on April 17th, 2013 for the Project, the third JCC meeting was held on November 27th, 2015 attended by the Vietnamese and Japanese members.

In the meeting, Project Director of Kitasato Daiichi Sankyo Vaccine Co., Ltd (KDSV) presented the general progress; Project Manager of Center for Research and Production of Vaccines and Biologicals (POLYVAC) presented the progress of the project and the overall project schedule; Mid-term review team of JICA Headquarter presented the results of Project Mid-term review and some recommendations. Further, participants made comments and discussion. The discussion was summarized by Associate Professor, Dr. Nguyen Dang Hien, Chairman of the meeting.

As a result of the discussions, both Vietnamese side and Japanese side agreed upon the items in the document attached hereto:

Hanoi, December 21st, 2015

Mr. Chikahiro Masuda
Senior Representative
Viet Nam Office
Japan International Cooperation Agency

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

Dr. Setsuo Arai
Project Director
Vice President of Kitasato Daiichi Sankyo Vaccine Co., Ltd

(Technical Cooperation Project for Strengthening Capacity for Measles-Rubella combined Vaccine Production)

Minutes of Joint Coordinating Committee (JCC)

The Third Conference

- **Time and Date:** 9h30-12h30, 27th November 2015
- **Location:** Conference Room, Vaccine production facilities - Center for Research and Production of Vaccines and Biologicals (POLYVAC) - No.418 Vinh Hung, Thanh Tri, Ha Noi.
- **Attendant:** (Name list attached)

Agenda & Discussion

1. **Dr. Nguyen Dang Hien - Director of Center for Research and Production of Vaccines and Biologicals (POLYVAC)** opened the meeting and introduced the guests and agenda of meeting. Project for strengthening capacity for measles-rubella combined vaccine production with funding from the Japanese government was one of the key tasks of the health sector in Vietnam. The project would be implemented during a 5year period (from 2013 to 2018). 2015 was the time of the project mid-term review. During the project year for 2015, POLYVAC had successfully implemented PV for production of three consecutive lots of rubella bulk vaccine with high quality; successfully produced PV-1 of measles-rubella combined vaccine (MR vaccine) and was in progress of producing 2 remaining PV lots. The coming year 2016 will play a decisive role for the project; the critical clinical trials for measles-rubella combined vaccine are scheduled for this year. Hopefully in this conference, the concerned parties will present their recommendations to help the smooth implementation of the project and achieving the planned-outputs.

2. **Mr. Chikahiro Masuda, Senior Deputy Resident Representative of JICA Vietnam** expressed his pleasure in attending the 3rd JCC conference and satisfaction for the project being implemented smoothly over the past 2.5 years. He raised some issues for making the project successful and efficient. The first issue concerned the price of measles and MR vaccine. At present, Vietnam Ministry of Health (MOH) has decided the domestic vaccine price based on a comparison with the price of imported vaccines. Consequently, POLYVAC was obliged to sell measles vaccine to EPI at low price and had not achieved any profit for a

long time. He hoped MOH would consider making appropriate price based on production costs such as materials, equipment, consumables etc., so that POLYVAC could maintain long-term production. The second issue concerned the cost of importing rabbits. POLYVAC should take the initiative in production of SPF rabbit for rubella vaccine. It was very important to help in reducing the vaccine cost and stabilizing vaccine production. If MOH could support POLYVAC in conventional animal laboratory building, JICA would consider supporting POLYVAC on equipment and technology transfer. In addition, he was looking forward to receiving further support from MOH in accelerating the implementation of clinical trial in order to avoid affecting the project schedule. He also emphasized the-importance of the project in helping Vietnam to actively provide vaccine against measles, rubella disease and hoped that the relevant authorities would support the project for successful implementation.

3. **Ts. Setsuo Arai - Vice President of Kitasato Daiichi Sankyo Co., Ltd., Project Manager:** addressed the conference. He was delighted to announce that the project had been implemented almost as scheduled, and expressed his deepest gratitude to MOH, Embassy of Japan, JICA, WHO representative office in Vietnam, the relevant authorities and individuals for their support during project implementation. As scheduled, the clinical trial for MR vaccine would start in March 2016. If the clinical trial and long-term stability test were carried out smoothly, POLYVAC could get marketing licenses in 2018 at the end of the project. However, after getting the marketing license and implementing mass production, some issues could be encountered. These issues would be mentioned in the report of project mid-term review. He pledged to make the best efforts to collaborate closely with POLYVAC to solve these issues, as well as to complete the project goal in the remaining 2 years. He also expected to continue receiving the support of relevant organizations and individuals.

4. **Dr. Nguyen Thuy Huong - Deputy Director of Center for Research and Production of Vaccines and Biologicals (POLYVAC), Project manager**: made a presentation on the progress of the project. The project working items during the past 2.5 years were implemented as scheduled. The works in 2015 were mainly related to performance qualification (PQ), process validation (PV) for rubella bulk vaccine and MR vaccine. POLYVAC has completed PV for producing three consecutive lots of rubella bulk vaccine in Oct. 2015, 10 months behind schedule, due to the problems with not reaching the defined temperature in incubation room, but the overall project schedule has not been affected. Up to now, POLYVAC has implemented PV-1 for production of MR vaccine and successfully

completed several important tests with good results, including potency test, thermal stability test, residual moisture test, sterility test and pH test. The remaining tests such as general safety test, mycoplasma test are being implemented. PV-2 is in progress and PV-3 will be implemented as scheduled on 2nd Dec. 2015. POLYVAC has completed the processes of IQ (installation qualification), OQ (operation qualification), CAL (calibration) and PQ (performance qualification) for all new equipment. The technical transfer training was also carried out as planned including on-site training by experts and counterpart training in Japan. Moreover, in order to enhance communications, KDSV experts and POLYVAC has held a series of meetings, such as daily meetings, weekly meetings, briefing and debriefing of experts and working group meetings. Dr. Nguyen Thuy Huong also informed the committee of some plans for upcoming events as below:

(1) To continue implementing PV-3 for production of MR vaccine.

(2) To finish QC tests for all 3 lots of PV of MR vaccine.

(3) To prepare and submit the dossier to Drug Administration of Vietnam (DAV) to get GMP license for MR vaccine production line.

(4) To prepare and submit summary protocol of PV-1 for MR vaccine to National Institute for Control of Vaccine and Biologicals (NICVB) for quality certificate.

(5) To prepare and submit Clinical trial protocol for MR vaccine to MOH for approval.

(6) To carry out clinical trial phase III for MR vaccine.

(7) To prepare and submit the dossier to MOH for marketing license of MR vaccine.

(8) To continue counterpart training for POLYVAC staffs in Japan and dispatching of KDSV experts and GMP experts to POLYVAC for training on site.

(9) To implement the long-term stability study to determine the shelf-life of MR vaccine.

At present, the technology transfer period of the project has been completed. In the coming time, POLYVAC will implement the works related to clinical trial and registration. Therefore, it hopes for continual support from MOH and relevant agencies to implement the works smoothly and successfully.

5. Mr. Tomoya Yoshida - Leader of Mid-term Review team of JICA Headquarter, Mr. Naoki Take - Consultant for JICA Headquarter, Ms. Haruka Nomura - Cooperation Planning of JICA Headquarter: Presented the results of project mid-term review and some recommendations. The evaluation was based on five criteria such as

relevance, effectiveness, efficiency, impact and sustainability. In general evaluation, it was noted that the project was being implemented on schedule and was expected to be completed and achieve the outputs as planned. The Team also made high evaluations for relevance, effectiveness, efficiency and impact. Sustainability of the project was affirmed with some recommendations to related parties as below:

❖ Recommendations to POLYVAC and Japanese experts:

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

❖ Recommendations to Vietnam MOH:

- To approve the application for marketing licence 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 valorise the appropriate purchasing price of MR vaccine produced by POLYVAC to cover the cost of production
- To achieve and maintain at least 95% coverage of MR vaccine with vaccine produced by POLYVAC after the completion of the Project
- Not to change the policy to prioritise vaccines produced in Viet Nam

In addition, on behalf of the evaluation team, Mr. Tomoya Yoshida also gave out some issues not covered in the project framework but was essential for POLYVAC to maintain long-term production.

1) POLYVAC should prepare a plan to export vaccines to reduce production cost and have long-term financial stability.

2) At present, Vietnam plans to replace the second dose of measles vaccine with MR vaccine. In the future, if the first dose of measles vaccine is also be replaced by MR vaccine, it is hoped that MOH will continue to use the vaccine manufactured by POLYVAC as the replacement.

3) It is hoped that in the future POLYVAC will produce monovalent rubella vaccine to vaccinate women of reproductive age in order to reduce birth defects caused by rubella disease in pregnant woman.

Finally, the JICA evaluation team leader pledged to make the efforts to cooperate with POLYVAC to implement the project successfully and hoped to receive support from all relevant parties.

6. Opinions of attendants of JCC meeting:

(1) Dr. Makiko Iijima- Medical Officer of WHO Representative Office in Vietnam: Expressed her pleasure in the knowledge that the project was being implemented on schedule, and highly appreciated the contribution of JICA, KDSV and POLYVAC in implementing the project. POLYVAC had over 20 years experience in the production of OPV vaccine, in addition to its new experience with MR vaccine. This was very important in providing vaccine in Vietnam. Currently Vietnam and the majority of countries in the region used MR vaccine from India. If POLYVAC could produce MR vaccine and export the vaccine to other countries in the future, it would be a great contribution not only for Vietnam but also globally. She raised two questions: 1) As reported, would POLYVAC apply for WHO prequalification in Jan. 2016? (2) How long will it take to breed SPF rabbits and the difficulties encountered with breeding SPF rabbit in Vietnam? Finally, she expressed confidence that the project would be completed as scheduled and kindly requested all parties to continue supporting POLYVAC.

(2) Dr. Nguyen Dang Hien: answered the question by Dr. Makiko Iijima. In 01/2016, POLYVAC would not apply for WHO Prequalification but only for the GMP licenses from Vietnam NRA for MR vaccine. This was a very important item necessary to be done before implementing clinical trial. Currently, POLYVAC has almost completed preparing the application dossiers and was waiting for the PV results of MR vaccine. Additionally, the measles vaccine production line has already received GMP licenses; and therefore the GMP application for MR vaccine production line would be more

favorable. He also hoped the breeding of SPF rabbits could be completed during the project period.

(3) **Dr. Tomio Lee - Deputy Project Manager of Kitasato Daiichi Sankyo Co., Ltd.:** Further commenting on the question by Dr. Makiko Iijima, he observed that SPF rabbit breeding was a difficult issue. Firstly, it was necessary to build a new animal facility to breed SPF rabbits separately from conventional animals to avoid cross contamination. In addition, the import of rabbit breeding species, breeding technology and prevention technology against cross contamination were also very complicated. Therefore, he was not prepared to estimate exact time required for breeding SPF rabbits in Vietnam.

(4) **Prof. Nguyen Van Man- Senior Advisor of POLYVAC:** expressed his pleasure at attending the conference and to know that the project was implemented successfully in the past year. The Professor said that it was necessary to have a GMP facility for breeding SPF rabbits used for vaccine production and expected that the relevant parties would support POLYVAC to establish the facility as well as for the transfer SPF rabbit breeding technique. Regarding the vaccine price, he noted that POLYVAC had not received the appropriate price due to annual production yields for EPI being significantly less than the actual capacity (only 2 ~ 3 million doses/year were provided compared to actual capacity of 7.5 million doses/year). Hopefully, Dr. Tran Thi Giang Huong would make proposal to MOH on appropriate price for measles vaccine and MR vaccine.

(5) **Dr. Tran Thi Giang Huong, Director of International Cooperation Department of MOH:** expressed her pleasure in attending the 3rd JCC conference as well as the awarding ceremony of the memorabilia "For people's health" of Vietnam MOH to Japanese experts. On behalf of the Vietnam MOH, she congratulated the Japanese experts awarded the People's Health Medals, and affirmed that it was the evidence of good collaborative relationship between Vietnam and Japan. The Director shared that recently the death rate of mothers and children in Vietnam had been reduced dramatically thanks to the successful implementation of EPI (Expanded Program on Immunization) with over 95% coverage. To ensure the sustainability of EPI, MOH had a strategy of being active in vaccine sourcing through promotion of domestic vaccine production. The Director expressed gratitude to the Japanese government for its assistance in establishing a modern production facility for measles and MR vaccines; thereby which Vietnam could be proactive in domestic vaccine sourcing. The Director also acknowledged the recommendations concerning actions to make the project

implementation effective and sustainable, provided in the project mid-term review by JICA and Vietnam Team, and would report it to leaders of Vietnam MOH for consideration. The Director also stated that she would report to the executive board (Minister, Vice Minister) of MOH on the concerns regarding the vaccine price for review and decide on an appropriate price to ensure the long-term production sustainability of POLYVAC. In addition, she requested POLYVAC to be more active in process of applying for WHO Prequalification for exporting measles vaccines, as well as produce monovalent rubella vaccine, in order to increase production capacity and reduce the vaccine cost. Related to the issue of SPF rabbits, she suggested the Japanese government to support POLYVAC in the required technologies and Vietnamese government would support POLYVAC in building a new animal house. Finally, the Director thanked the Japanese government, the Japanese Embassy, JICA and KDSV for their support in effectively and successfully implementing the project.

7. Signing the MOM of project mid-term review among the parties:

Mr. Tomoya Yoshida (Leader of mid-term review team of JICA Headquarter); Dr. Tran Thi Giang Huong (Representative of MOH) and Dr. Nguyen Dang Hien (Representative of POLYVAC) signed the minutes of meeting and report of JICA mid-term review.

8. Conclusion:

Dr. Nguyen Dang Hien summarized the discussions of the meeting and agreed with the opinions of the attendants. As Representative of POLYVAC, he committed to make the effort to implement the project and he also requested the relevant agencies for their assistance. He declared the 3rd JCC meeting successfully concluded. Finally, Dr. Nguyen Dang Hien thanked the participants and declared the meeting closed.

MINUTES OF MEETING

THE 4th JOINT COORDINATING COMMITTEE (JCC) FOR THE JAPANESE TECHNICAL COOPERATION FOR THE PROJECT FOR STRENGTHENING CAPACITY FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION

In accordance with the Record of Discussion (RD) signed on April 17th, 2013 for the Project, the fourth JCC meeting was held on November 11th, 2016 attended by the Vietnamese and Japanese members.

In the meeting, Project Director of Kitasato Daiichi Sankyo Vaccine Co., Ltd (KDSV) presented the general progress; Deputy Project Director of KDSV presented the overall project schedule; Project Manager of Center for Research and Production of Vaccines and Biologicals (POLYVAC) presented the progress of the project and the next action plan. Further, participants made comments and discussion. The discussion was summarized by Professor, Dr. Nguyen Dang Hien, Chairman of the meeting.

As a result of the discussions, both Vietnamese and Japanese sides agreed upon the items in the document attached hereto:

Hanoi, December 23rd, 2016

Mr. Chikahiro Masuda
Senior Representative
Viet Nam Office
Japan International Cooperation Agency (JICA)

Prof., Dr. Nguyen Dang Hien
Director of Center for Research and Production of Vaccines and Biologicals
Ministry of Health

Dr. Setsuo Arai
Project Director
Kitasato Daiichi Sankyo Vaccine Co., Ltd.

(Technical Cooperation Project for Strengthening Capacity for Measles-Rubella combined Vaccine Production)

Minutes of Joint Coordinating Committee (JCC)

The Forth Conference

- **Time and Date:** 9h00 - 12h30, 11th November 2016.
- **Location:** Conference Room, Vaccine production facilities - Center for Research and Production of Vaccines and Biologicals (POLYVAC) - No.418 Vinh Hung, Thanh Tri, Ha Noi.
- **Attendant:** (Name list attached)

Agenda & Discussion

1. **Dr. Nguyen Thuy Huong-Deputy Director of Center for Research and Production of Vaccines and Biologicals (POLYVAC), Project Manager:** introduced the guests and the agenda of meeting.

2. **Prof. Nguyen Dang Hien-POLYVAC:** had an opening speech. In 2016, POLYVAC had successfully produced three consecutive lots of measles-rubella combined vaccine (Commercial name: MRVAC), and implemented the clinical trial. On 2nd Nov. 2016, Administration of Science, Technology and Training of Vietnam Ministry of Health (MOH) had issued the certificate for the clinical trial result. These were decisive factors to apply for a marketing license for MRVAC, helping Vietnamese health sector to be proactive in vaccination. Hopefully in this conference, the related parties would give out the recommendations to help the smooth implementation of the project and the achievement of the planned outputs.

3. **Mrs. Nguyen Minh Hang-Deputy Director of General Department of Preventive Medicine of MOH:** expressed her pleasure of attending the 4th JCC conference. She emphasized that the project would help Vietnamese health sector to quickly achieve the goal of supplying Measles-Rubella combined vaccine (MR vaccine) for Expanded Program on Immunization (EPI), as well as help to strengthen the capacity of POLYVAC staff for vaccine production and quality tests in order to meet GMP standards. After four years of

implementation, the project had the positive results, especially implemented the successful clinical trial in this year. On behalf of MOH, the Deputy Director of the department expressed gratitude for the Japanese Government, the Japanese Embassy, JICA and KDSV for their support in effectively and smoothly implementing the project. She committed to make the favorable conditions to facilitate the project successfully in one year remaining, with the hope that Vietnam would be proactive in providing high quality MR vaccine.

4. **Mr. Chikahiro Masuda-Senior Representative of JICA Vietnam office:** expressed his pleasure of attending the conference as well as knowing the project had successfully implemented the vaccine technology transfer, validation, and clinical trial. One year remaining of the project was the time of getting marketing license for MRVAC, as well as determining its price. There should be an appropriate price for the MRVAC so that POLYVAC can maintain production after finishing the project. He hoped that the related parties would support POLYVAC to determine the suitable prices. In addition, breeding SPF rabbits was essential for POLYVAC to be active in vaccine production. Recently, JICA had supported POLYVAC in training of technology transfer for SPF rabbit production, and providing necessary equipment. Hoped that POLYVAC would quickly complete the construction of animal laboratory to implement the work.

5. **Dr. Setsuo Arai-Kitasato Daiichi Sankyo Vaccine Co., Ltd. (KDSV), Project Director:** had a speech. He delightedly announced that the project had been smoothly implemented on schedule, and thanked MOH, JICA, other related agencies, and individuals for their assistance. The important items were done in 2016 including: clinical trial, long-term stability test, and process validation with the actual production scale. In the coming time, he hopes hoped that MOH would grant the marketing license to MRVAC in fast track program in order to quickly provide the vaccine to EPI. In the remaining time of the project, some measures would be implemented in order to reduce production cost such as: 1) Breeding SPF rabbit to be proactive in production material; 2) Production of single-dose vaccine in order to increase the effective use, and reduce the waste of vaccine. JICA's support in technology and equipment has been received for these 2 items. Hoped that MOH would assist POLYVAC to build the new laboratory for testing animal, and then the current animal laboratory will be used for breeding SPF rabbits. In addition, he expressed the pleasure and admiration for National Regulatory Authority of Vietnam (NRA) to gain WHO accreditation. Hopefully, the related parties will continue supporting POLYVAC to promote vaccine export.

6. **Dr. Dinh Hong Duong-Viet Nam Military Medical University:** presented the clinical trial result of MRVAC. According to the result, the vaccine had been proved to be safe and having good immunogenicity, non-inferiority compared to an Indian vaccine that was being used in EPI.

7. **Dr. Tomio Lee-KDSV, Deputy Project Director and Dr. Nguyen Thuy Huong-Deputy Director of POLYVAC:** presented the project progress, and revised the overall schedule. Up to now, the project had been implemented according to the original schedule. In 2016, POLYVAC had successfully produced three consecutive lots of measles - rubella combined vaccine, successfully implemented clinical trial, and gain the GMP certificate from Drug Administration of Vietnam (DAV). The clinical trial study had been shortened from 12 months to 7 months and had been completed before the initial schedule. Therefore, the license for marketing of MR vaccine was expected to be issued earlier than initial schedule in Mar. 2018. The next tasks in the remaining period of the project are including:

   1) Apply for the marketing license for MR vaccine in Vietnam.
   2) Set up the formula and filling line for MR vaccine single dose. (additional plan)
   3) Receive basic technology transfer of SPF rabbit breeding from Kitayama Labes Co., Ltd., Japan. (additional plan)
   4) Set up the laboratory for quality control of SPF rabbits and animal house for QC tests.
   5) Continue dispatching Japanese experts to POLYVAC and sending POLYVAC staff to Japan for training.
   6) Procure the equipment and the materials for 2017 by both JICA and Vietnamese government budgets.

8. **Opinions of the attendants of JCC meeting:**

   (1) Prof. Dang Duc Anh-Director of the National Institute of Hygiene and Epidemiology, Director of the Vietnam Expanded Program on Immunization: expressed the pleasure when knowing that POLYVAC had successfully produced MR vaccine as well as finished the clinical trial. Hope that POLYVAC will receive License for marketing of MRVAC soon in order to provide MRVAC for EPI. Hopefully, MRVAC will be in EPI to vaccinate Vietnamese children in 2017.

(2) Mr. Tomoya Yoshida-Director of Human Development Department, JICA Headquarter: stated that the MR vaccine production project was one of the projects to be implemented smoothly among projects funded by JICA, and he expressed his pleasure of coming back to POLYVAC during the terminal evaluation in Sep. 2017. He affirmed that MR vaccine was the high quality vaccine, and it could be used in EPI. In coming time, there were 2 issues needed to be resolved: SPF rabbit production and MR vaccine single dose production. He hoped to continue receiving the assistant from the related parties to overcome these 2 issues, as well as the support from WHO to promptly apply for pre-qualification for Measles and MR vaccines of POLYVAC.

(3) Mr. Nguyen Van Quang-Officer of Department of Planning and Finance, MOH of Vietnam: congratulated the success of the project in the past years. He stated that in order to support POLYVAC, MOH had granted big counterpart fund as 28 billion VND and the relevant departments had cooperated closely in distributing this fund. Regarding to SPF rabbit production, he hoped that related parties would continue to cooperate closely in order to implement the work.

(4) Dr. Doan Huu Thien-Director of National Institute for Control of Vaccine and Biologicals (NICVB): congratulated POLYVAC for the success of MR vaccine production. He stated that NICVB would assist POLYVAC in breeding animal for testing during the time of setting up the conventional animal laboratory. The Director affirmed that MR vaccine had the high quality, the safety and immunogenicity of MR vaccine was equivalent to imported vaccines. Hope that in coming time, POLYVAC will quickly provide MR vaccine to the Vietnamese market and export to the world.

(5) Dr. Makiko Iijima-Medical Officer of WHO in Vietnam: expressed the pleasure when knowing the project had successfully produced the MR vaccine and completed the clinical trial. Hopefully, in coming time POLYVAC can produce the MR vaccine by itself, and timely provide to EPI for routine vaccination as well as for outbreak. She expected that POLYVAC would receive the supports from NICVB, DAV, and JICA, and committed to continue supporting to implement the project successfully. Regarding to the clinical trial, she hoped the related parties would consider implementing the bridging clinical study in children aged 9 ~ 12 months. Currently, the measles vaccine was introduced to children aged 9 months and older. However, the measles outbreak in a few years ago was occurred in children under 9 months of age who still hadn't been vaccinated. Therefore, she expected to implement the bridging study in children aged 6 ~ 9 months to use vaccine for these subjects.

(6) Dr. Do Si Hien-Director of Public Health Research and Consultancy Centre: As an independent supervisor for the clinical trial study, he affirmed that the clinical trial had been taken seriously, objectively as well as complied with the regulations of MOH. The result had proved that the MR vaccine of POLYVAC had high immunogenicity and ensured its safety. As the former director of EPI, he stated that the Japanese Government had supported Vietnam a lot in researching and producing the vaccines. He also expressed his deep gratitude to the Japanese Government, JICA and the Japanese experts.

9. Conclusion:

Prof. Nguyen Dang Hien summarized the discussions of the meeting and agreed with the options of the attendants. As the representative of POLYVAC, he committed to make the effort to implement the project and he also requested the relevant agencies for their assistance. He declared the 4th JCC meeting successfully concluded. Finally, Prof. Nguyen Dang Hien thanked the participants and declared the meeting closed.

MINUTES OF MEETING

THE 5th JOINT COORDINATING COMMITTEE (JCC) FOR THE JAPANESE TECHNICAL COOPERATION FOR THE PROJECT FOR STRENGTHENING CAPACITY FOR MEASLES-RUBELLA COMBINED VACCINE PRODUCTION

In accordance with the Record of Discussion (RD) signed on April 17th, 2013 for the Project, the fifth JCC meeting was held on September 29th, 2017 attended by the Vietnamese and Japanese members.

In the meeting, JICA Terminal Evaluation Team presented Terminal Evaluation Report; Deputy Director and Managers of Center for Research and Production of Vaccines and Biologicals (POLYVAC) presented Progress and Issues of the Project. Further, participants made comments and discussion. The discussion was summarized by Professor, Dr. Nguyen Dang Hien, Chairman of the meeting.

As a result of the discussions, both Vietnamese and Japanese sides agreed upon the items in the document attached hereto:

Hanoi, October 10th, 2017

Ms. Nozomi Iwama
Senior Representative
Viet Nam Office
Japan International Cooperation Agency (JICA)

Prof. Dr. Nguyen Dang Hien
Director of Center for Research and Production of Vaccines and Biologicals
Ministry of Health

Dr. Setsuo Arai
Project Director
Kitasato Daiichi Sankyo Vaccine Co., Ltd

(Technical Cooperation Project for Strengthening Capacity for Measles-Rubella combined Vaccine Production)

Minutes of Joint Coordinating Committee (JCC)

The Fifth Conference

- **Time and Date:** 14h00-17h15, 29th September 2017.
- **Location:** Conference Room, Vaccine production facilities - Center for Research and Production of Vaccines and Biologicals (POLYVAC) - No.418 Vinh Hung, Thanh Tri, Ha Noi.
- **Attendant:** (Name list attached)

Agenda & Discussion

1. **Prof. Nguyen Dang Hien - Director of Center for Research and Production of Vaccine and Biologicals (POLYVAC):** opened the meeting, introduced the guests and agenda of the meeting. The Record of Discussion for the "Technical Cooperation Project for Strengthening Capacity for Measles-Rubella combined Vaccine Production" (hereinafter called "Project") was signed on 17th April 2013 between Japan International Cooperation Agency (JICA) and Ministry of Health of Vietnam (MOH). POLYVAC was implementing agency with technical transferred by KDSV of Japan. After more than 4 years of implementation, the Project had reached the final stage with almost objectives achieved. On 27th March 2017, the Ministry of Health (hereinafter called "MOH") officially granted the marketing license for the MR vaccine, one year earlier than scheduled. On behalf of POLYVAC, the Director expressed a deep thank to all organizations and individuals for the supports during the past time. Hopefully in this conference, the related parties would give out the evaluation on Project implementation as well as the recommendation on future orientations so that the Project's achievements could be widespread and sustainable.
2. **Dr. Setsuo Arai – Project Director, Kitasato Daiichi Sankyo Vaccine Co., Ltd.:** had a speech. The Project Director honoured to announce that on 08th Sep. 2017, KDSV had received the Certificate of Good Performance from the Minister of MOH for the great contribution to the implementation of the Project. The Project Director also was delighted to announce that POLYVAC had received a Marketing License for the MR vaccine in the past year; therefore, the key target of the Project had been fulfilled. Although the Project was going to final stage, some activities were still being implemented in order to build a solid foundation for the future development of POLYVAC such as: Technical transfer for

SPF rabbit breeding, MR single-dose vaccine production, and scale-up production for vaccines. The Project Director hoped that POLYVAC would soon receive Prequalification of WHO, and could export vaccines to international market. Hopefully in the future, KDSV and POLYVAC would maintain the good relationship for mutual development. Finally, he expressed a deep thank to relevant authorities and individuals for the supports so that the Project could be implemented smoothly and successfully.

3. **Dr. Nguyen Thuy Huong - Deputy Director of POLYVAC, Project Manager and Managers of Departments**: Presented the progress and issue of the Project. Up to now, POLYVAC had completed almost project objectives. POLYVAC had proper technical capabilities as a manufacturer of MR vaccine and could produce MR vaccine properly complying with Vietnamese GMP/ WHO-cGMP.

4. **Mr. Tomoya Yoshida-Leader of the Terminal evaluation team of JICA, Dr. Yoichi Inoue-Consultant for JICA, Ms. Chie Yoshizu-Cooperation planning, JICA Vietnam Office, Dr. Yoshikuni Sato-Technical advisor**: Presented the results of the terminal evaluation and some recommendations. The terminal evaluation was based on five criteria (relevance, effectiveness, efficiency, impact, sustainability). For general evaluation, the Project had achieved setting objectives at high level. The recommendations for related parties such as MOH, POLYVAC as below:

(1) Recommendation on full and long-term utilization of POLYVAC- made MR vaccine for the Expanded Program on Immunization in Vietnam (hereinafter called "EPI"): MOH and POLYVAC should establish a proper mechanism to set appropriate volume of production and effective vaccine supply.

(2) Recommendation on an appropriate purchase price of POLYVAC- made MR vaccine:

Vietnamese government should consider the various advantages of domestic vaccine production for its immunization program and decide the appropriate purchase price with consideration of cost for maintaining high-quality vaccine supply from the viewpoint of business sustainability of POLYVAC such as maintenance and improvement of facility and equipment, sustain and develop ability of staff with high skill. Meanwhile, POLYVAC should make further effort to set the price of vaccine, which could be competitive to imported vaccine price.

(3) Recommendation on POLYVAC's assiduous efforts in the future:

POLYVAC is recommended to continue the efforts for the establishment of single-dose MR vaccine product, the reproduction of SPF rabbits and acquisition of WHO Prequalification, as means for enhancing the sustainability of the Project.

(4) Recommendation on maintaining the functions of National Regulatory Authority (hereinafter called "NRA") in Vietnam:

It is necessary for the MOH and the NRA to maintain the functions of NRA fully, which was certificated by WHO in 2015 so that POLYVAC-made vaccines can be supplied to international organizations (GAVI, etc.). Therefore, it is recommended for the MOH and the NRA to make best effort to make appropriate preparation for the next assessment by WHO expected.

(5) Recommendation on common understanding of laws and regulations:

Regarding the timing and necessary procedure for the commencement of MR vaccine supply, there turned out to exit discrepancies in the understanding of the regulations among the MOH, the NRA and POLYVAC. To prevent similar misunderstanding, it was recommended to further improve communications among stakeholders for precise understanding of laws and regulations.

5. Opinion of attendants of JCC meeting:

(1)Assoc. Prof. Do Si Hien - Director of Public Health Research and Consultancy Centre: As the former Director of EPI, he said the Japanese Government had supported Vietnam a lot in researching, production of vaccine and also expressed his deep gratitude to the Japanese Government, JICA and Japanese experts. He fully agreed with the terminal evaluation results, as well as the recommendations given. Epidemiologically, the age of individuals infected with measles, rubella may be changed in the future, so it was necessary to consider and calculate carefully to prevent the diseases for these ages. Hoped that in the coming time, the relevant authorities, individuals would support POLYVAC so that POLYVAC-made vaccines would be able to be exported to the international market.

6. Ms. Nozomi Iwama - Senior Representative of JICA Vietnam Office: Expressed the pleasure when knowing that the Project had been implemented smoothly and highly appreciated by the Terminal evaluation team. In the recent 11 years since the time of transferring the technology to produce measles vaccine, KDSV experts had made their best effort to transfer high quality vaccine production technology as well as helped POLYVAC to reduce production cost, facility management, personnel training, etc. In addition, the Japanese government also supported for building facility as well as upgrading and renovating the facility in two Projects of measles vaccine and MR vaccine production. Through the terminal evaluation, the Project could fully achieve the setting objectives at the end of the Project. She kindly requested the stakeholders to consider for implementing the recommendations given by the Terminal evaluation team. In addition, Vietnam's NRA met international standards certified by WHO, that was thought to be a prerequisite for the

export of vaccines. Therefore, Vietnamese government and MOH should make the best effort to maintain the certification in the next assessment by WHO. Moreover, she hoped the MOH and the Ministry of Finance of Vietnam would make the right decision to determine reasonable price for MR vaccine of POLYVAC.

7. **Dr. Tran Thi Giang Huong- Director General of International Cooperation Department of MOH:** On behalf of the MOH, the Director expressed the pleasure to attend the 5th JCC conference as well as knowing that the Project would complete 1 year earlier than scheduled. In Oct. 2017, MR vaccine would be used in EPI in four provinces of Vietnam, and from Nov. 2017, it would be used nationwide. With the success of the Project, Vietnam was among four nations that could produce MR vaccine in Asia, following Japan, India and China. The successful production of MR vaccine was considered to be one of top 10 prominent medical events of health sector, and one of top 10 outstanding scientific and technological achievements of Vietnam in 2017. To recognize the contributions, MOH awarded the Certificate of Good Performance from Minister of MOH, and Memorabilia "For People's Health" to the experts of KDSV. POLYVAC also received the Certificate of Good Performance from the Prime Minister for having outstanding achievements in implementing the Project. On behalf of MOH, the Director expressed a deep thank to the Japanese government, JICA, KDSV for the assistance of enhancing the vaccine production capacity and promoting the development of preventive health sector in Vietnam. Hopefully in the future, the POLYVAC-made vaccines would be exported abroad soon to help to protect the health of children around the world. The Director committed to make the favourable conditions to maintain the Project's achievements to help Vietnam to be active in providing MR vaccine that meet the international quality.

8. **Signing the Minutes of Meeting on the terminal evaluation:**

   Mr. Tomoya Yoshida (representative of JICA); Dr. Tran Thi Giang Huong (representative of the Vietnam MOH) and Prof. Nguyen Dang Hien (representative of POLYVAC) signed the Minutes of Meeting on the terminal evaluation.

9. **Conclusion**

   Dr. Nguyen Dang Hien summarized the discussions of the meeting and agreed with the opinions of the attendants. Representative of POLYVAC committed to make the best effort to implement the recommendations from the Terminal evaluation team, and also requested the relevant organizations for their assistance. Finally, he thanked the participants and declared the 5th JCC meeting closed successfully.

-End-

(8) List of Products

List of Products

In this Project, the outputs listed in the Tables below were prepared as part of the technical guidance provided to the counterpart agency POLYVAC.

The outputs prepared in Japan consisted mainly of the guidance and training materials including GMP-related standards, other standards, teaching materials necessary for technical training for calibration/validation and for technologies in various departments (Final production, Medium preparation, Bulk production and Quality control departments), validation work plan, technology transfer plan for each year and scale-up work plan.

The outputs in Vietnam included the Table of Technical Guidance Achievements for the implementation of the technical guidance programs in various fields and management of the progress status, the Certificates issued to those counterparts who reached a given technical level, the PQ and PV work schedules and the review of the report of the work results, the regular calibration and validation-related documents, the yearly master schedule, the quarterly daily works schedule, the Inception Report and the minutes of various meetings including the weekly meetings.

Fiscal 2013 (First Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Service Plan (1st Year)	Japan	Japanese
2.	Technology Transfer Plan (1st Year)	Japan, Vietnam	Japanese, English
3.	Various training materials relating to Rubella vaccine bulk production	Japan	Japanese, Vietnamese
4.	Various training materials relating to Quality control	Japan	Japanese, Vietnamese
5.	Various training materials relating to SPF rabbit rearing management	Japan	Japanese, Vietnamese
6.	Various training materials for technology transfer in building the GMP implementation system	Japan	Japanese, Vietnamese
7.	GMP-related standards and other standards	Japan	Japanese, Vietnamese
8.	MR vaccine Validation Master Plan	Japan, Vietnam	Japanese, Vietnamese
9.	QC Validation Master Plan	Japan, Vietnam	Japanese, Vietnamese
10.	Validation and Calibration Implementation Plan (1st Year)	Vietnam	English, Vietnam
11.	The 1st Year Master Schedule	Vietnam	English
12.	The 1st Year Quarter Schedule	Vietnam	English
13.	Technical Cooperation Plan of Operation/ Inception Plan Report	Japan and Vietnam	Japanese, English
14.	Minutes of Meeting of 1st Joint Coordination Committee (JCC No. 1)	Vietnam	English
15.	Minutes of Weekly Meetings with POLYVAC	Vietnam	English
16.	Project Progress Report (1)	Japan, Vietnam	Japanese, English
17.	List of training materials for each department	Japan, Vietnam	Japanese/Vietnamese
18.	Table of Educational Guidance Achievements	Vietnam	Japanese/Vietnamese
19.	Education/Training Completion Report (Certificate)	Vietnam	Japanese/Vietnamese
20.	Project management materials (Schedule management, problem solution scheme, documentation rules, etc.)	Vietnam	English
21.	Materials for management of facilities and equipment	Vietnam	English
22.	Materials for procurement management	Vietnam	English

No.	Name of Output	Place of Preparation	Remarks
23.	Tender document for the facilities renovation and the procurement of equipment	Vietnam	English
24.	Daily Working Report by experts (1st Year)	Vietnam	Japanese, Vietnamese
25.	Progress Monitoring Table (1st Year)	Japan	Japanese, English
26.	Completion Report on the counterpart training in Japan (1st Year)	Japan	Japanese
27.	Completion Report (1st Year)	Japan and Vietnam	Japanese, English

Fiscal 2014 (Second Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Service Plan (2nd Year)	Japan	Japanese
2.	Technology Transfer Plan (2nd Year)	Japan, Vietnam	Japanese, English
3.	Various training materials relating to Rubella vaccine bulk production	Japan	Japanese, Vietnamese
4.	Various training materials relating to Quality control	Japan	Japanese, Vietnamese
5.	Various training materials relating to SPF rabbit rearing management	Japan	Japanese, Vietnamese
6.	Various training materials for technology transfer in building the GMP implementation system	Japan	Japanese, Vietnamese
7.	GMP-related standards and other standards	Japan	Japanese, Vietnamese
8.	Validation and Calibration Implementation Plan (2nd Year)	Vietnam	English, Vietnam
9.	The 2nd Year Master Schedule	Vietnam	English
10.	The 2nd Year Quarter Schedule	Vietnam	English
11.	Minutes of Meeting of 2nd Joint Coordination Committee (JCC No. 2)	Vietnam	English
12.	Minutes of Weekly Meetings with POLYVAC	Vietnam	English
13.	Project Progress Report (2)	Japan, Vietnam	Japanese, English
14.	List of training materials for each department	Japan, Vietnam	Japanese/Vietnamese
15.	Table of Educational Guidance Achievements	Vietnam	Japanese/Vietnamese
16.	Education/Training Completion Report (Certificate)	Vietnam	Japanese/Vietnamese
17.	Project management materials (Schedule management, problem solution scheme, documentation rules, etc.)	Vietnam	English
18.	Materials for management of facilities and equipment	Vietnam	English
19.	Materials for procurement management	Vietnam	English
20.	Tender document for the facilities renovation and the procurement of equipment	Vietnam	English
21.	Daily working report by experts (2nd Year)	Vietnam	Japanese, Vietnamese
22.	Progress Monitoring Table (2nd Year)	Japan	Japanese, English
23.	Completion Report on the counterpart training in Japan (2nd Year)	Japan	Japanese
24.	Completion Report (2nd Year)	Japan and Vietnam	Japanese, English

Fiscal 2015 (Third Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Service Plan (3rd Year)	Japan	Japanese
2.	Technology Transfer Plan (3rd Year)	Japan, Vietnam	Japanese, English
3.	Various training materials relating to Rubella vaccine bulk production	Japan	Japanese, Vietnamese
4.	Various training materials relating to Quality control	Japan	Japanese, Vietnamese
5.	Various training materials relating to SPF rabbit breeding and rearing managements	Japan	Japanese, Vietnamese
6.	Training materials for technical guidance to Final production process	Japan, Vietnam	Japanese, Vietnamese
7.	Various training materials for technology transfer in building the GMP implementation system	Japan	Japanese, Vietnamese
8.	GMP-related standards and other standards	Japan	Japanese, Vietnamese
9.	Validation and Calibration Implementation Plan (3rd Year)	Vietnam	English, Vietnam
10.	The 3rd Year Master Schedule	Vietnam	English
11.	The 3rd Year Quarter Schedule	Vietnam	English
12.	Minutes of Meeting of 3rd Joint Coordination Committee (JCC No. 3)	Vietnam	English
13.	Minutes of Weekly Meetings with POLYVAC	Vietnam	English
14.	Project Progress Report (3)	Japan, Vietnam	Japanese, English
15.	List of training materials for each department	Japan, Vietnam	Japanese/Vietnamese
16.	Table of Educational Guidance Achievements	Vietnam	Japanese/Vietnamese
17.	Education/Training Completion Report (Certificate)	Vietnam	Japanese/Vietnamese
18.	Project management materials (Schedule management, problem solution scheme, documentation rules, etc.)	Vietnam	English
19.	Materials for management of facilities and equipment	Vietnam	English
20.	Materials for procurement management	Vietnam	English
21.	Protocol and Final Report for the clinical trial of MR vaccine in Vietnam	Vietnam	English, Vietnamese
22.	Daily working report by experts (3rd Year)	Vietnam	Japanese, Vietnamese
23.	Report on the preparatory survey for the mid-term survey	Japan, Vietnam	Japanese, English
24.	Progress Monitoring Table (3rd Year)	Japan	Japanese, English
25.	Completion Report on the counterpart training in Japan (3rd Year)	Japan	Japanese
26.	Completion Report (3rd Year)	Japan and Vietnam	Japanese

Fiscal 2016 (Fourth Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Service Plan (4th Year)	Japan	Japanese
2.	Technology Transfer Plan (4th Year)	Japan, Vietnam	Japanese, English
3.	Various training materials relating to Measles vaccine bulk production scale up study	Japan,	Japanese, Vietnamese
4.	Various training materials relating to Quality control	Japan	Japanese, Vietnamese
5.	Various training materials relating to SPF rabbit breeding and rearing managements	Japan	Japanese, Vietnamese
6.	Various training materials relating to the confirmation of Single dose MR vaccine formulation	Japan, Vietnam	Japanese, Vietnamese
7.	Various training materials relating to the improvement of GMP skill	Japan, Vietnam	Japanese, Vietnamese
8.	GMP-related standards and other standards	Japan	Japanese, Vietnamese

No.	Name of Output	Place of Preparation	Remarks
9.	Validation and Calibration Implementation Plan (4th Year)	Vietnam	English, Vietnam
10.	The 4th Year Master Schedule	Vietnam	English
11.	The 4th Year Quarter Schedule	Vietnam	English
12.	Minutes of Meeting of 4th Joint Coordination Committee (JCC No. 4)	Vietnam	English
13.	Minutes of Weekly Meetings with POLYVAC	Vietnam	English
14.	Project Progress Report (4)	Japan, Vietnam	Japanese, English
15.	List of training materials for each department	Japan, Vietnam	Japanese/Vietnamese
16.	Table of Educational Guidance Achievements	Vietnam	Japanese/Vietnamese
17.	Education/Training Completion Report (Certificate)	Vietnam	Japanese/Vietnamese
18.	Project management materials (Schedule management, problem solution scheme, documentation rules, etc.)	Vietnam	English
19.	Materials for management of facilities and equipment	Vietnam	English
20.	Materials for procurement management	Vietnam	English
21.	Daily working report by experts (4th Year)	Vietnam	Japanese, Vietnamese
22.	Progress Monitoring Table (4th Year)	Japan	Japanese, English
23.	Completion Report on the counterpart training in Japan (4th Year)	Japan	Japanese
24.	Completion Report (4th Year)	Japan and Vietnam	Japanese

Fiscal 2017 (Fifth Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Service Plan (5th Year)	Japan	Japanese
2.	Technology Transfer Plan (5th Year)	Japan, Vietnam	Japanese, English
3.	Various training materials relating to Measles vaccine bulk production scale up study and the study for improvement of Rubella vaccine bulk yield	Japan, Vietnam	Japanese, Vietnamese
4.	Various training materials relating to Quality control	Japan	Japanese, Vietnamese
5.	Various training materials relating to SPF rabbit breeding and rearing managements	Japan	Japanese, Vietnamese
6.	Various training materials relating to the confirmation of Single dose MR vaccine formulation	Japan, Vietnam	Japanese, Vietnamese
7.	Tender documents for the modification of final production line for the single dose MR vaccine	Japan, Vietnam	English
8.	Various training materials relating to the improvement of GMP skill	Japan, Vietnam	Japanese, Vietnamese
9.	GMP-related standards and other standards	Japan	Japanese, Vietnamese
10.	Validation and Calibration Implementation Plan (5th Year)	Vietnam	English, Vietnam
11.	The 5th Year Master Schedule	Vietnam	English
12.	The 5th Year Quarter Schedule	Vietnam	English
13.	Minutes of Meeting of 5th Joint Coordination Committee (JCC No. 5)	Vietnam	English
14.	Minutes of Weekly Meetings with POLYVAC	Vietnam	English
15.	Project Progress Report (5)	Japan, Vietnam	Japanese, English
16.	List of training materials for each department	Japan, Vietnam	Japanese/Vietnamese
17.	Table of Educational Guidance Achievements	Vietnam	Japanese/Vietnamese
18.	Education/Training Completion Report (Certificate)	Vietnam	Japanese/Vietnamese
19.	Project management materials (Schedule management, problem solution scheme, documentation rules, etc.)	Vietnam	English

No.	Name of Output	Place of Preparation	Remarks
20.	Materials for management of facilities and equipment	Vietnam	English
21.	Materials for procurement management	Vietnam	English
22.	Report on the preparatory survey for the terminal evaluation survey	Japan, Vietnam	Japanese, English
23.	The paper on the animal pathology	Vietnam	English
24.	Daily working report by experts (5th Year)	Vietnam	Japanese, Vietnamese
25.	Progress Monitoring Table (5th Year)	Japan	Japanese, English
26.	Completion Report on the counterpart training in Japan	Japan	Japanese
27.	Lecture materials for the terminal seminar	Japan	English
28.	Completion Report (5th Year)	Japan and Vietnam	Japanese, English
29.	Project Completion Report	Japan and Vietnam	Japanese and English

To ensure that POLYVAC acquires the production technology, quality control testing technology and calibration/validation technology that comply with WHO-GMP standards, it is essential that these technologies be properly documented. In this sense, the products consisting of training materials, work plans, reports on results, technical guidance work schedules, progress control tables and minutes of meetings will serve as a repository of technologies for this Project as well as for POLYVAC.

(9) List of Counterparts

List of Counterparts

Updated: 19 March 2018

No.	Name in full	Position	Remarks
Bulk Production Department			
1	Nguyen Xuan Hoa	Manager	
2	Pham Thanh Truong	Deputy Manager	
3	Lai Quynh Mai	Cell culture Group	
4	Vu Thi Mai	Prepare tools & materials Group	
5	Pham Le Tuan	Washing & Sterilize Group	
6	Pham Van Khoi	Environment monitoring Group	
7	Hoang Vu Linh	Tools washing & Sterilize Group	
8	Le Bao Chung	Control documentation Group	
9	Tran Thi Hoa Ly	Support for main works Group	
10	Luong Thi Thu Huyen	Washing and drying clothes Group	
11	Ly Thi Binh	Prepare medium Group	
12	Tran Thi Anh Quyen	Support for main works Group	New staff
Final Production Department			
1	Le Quoc Hung	Manager/Production Manager	
2	Nguyen Thi Thanh Van	Deputy Manager	
3	Nguyen Dang Quynh	Deputy Manager	
4	Nguyen Luong Ngoc Thanh	Environmental monitoring group	
5	Nguyen Manh Hien	Capping group	
6	Nguyen Huy Truong	Filling and Freeze-Drying group	
7	Nguyen Thi Thu	Visual inspection group	
8	Nguyen Sy Ban	Labeling group	

No.	Name in full	Position	Remarks
9	Nguyen Trong Nghia	Vial washing and sterilizing group	
10	To Toan Bo	Vial washing and sterilizing group	
11	Vu Van Huy	Capping group	
12	Nguyen Dang Duy	Labeling group	
13	Nguyen Thi Huyen	Visual inspection group	
14	Nguyen Minh Hang	Visual inspection group	New staff
Medium Preparation Department			
1	Le Tuan Anh	Manager	
2	Nguyen Thi Phuong Lan	Medium Preparation Group	
3	Nguyen Quoc Thien	Medium Preparation Group	
4	Nguyen Thai Hoc	Medium Preparation Group	
5	Nguyen Thi Thu Huong	Medium Preparation Group	
6	Tran Duc Linh	Medium Preparation Group	
Quality Control Department			
1	Ngo Thu Huong	Manager	
2	Pham Anh Thu	Deputy manager	
3	Nguyen Thi Nguyet	Chemical group, Pathological group	
4	Tran Van Son	Chemical group	
5	Ngo Tien Tho	Biological group	
6	Ngo Thi Thanh Huong	Biological group	
7	Nguyen Thi Duong	Biological group	
8	Vu Thi Huong	Biological group	
9	Pham Huu Tien	Animal group	

No.	Name in full	Position	Remarks
10	Le Van Duy	Animal group	
11	Nguyen Van Anh	Animal group	
12	Pham Thi Thuoc	Pathological group	
13	Le Huyen Trang	Staff	
Quality Assurance Department			
1	Tran Thi Phuong	Manager/ Deviation & Self inspection group (Leader).	
2	Le Thu Nga	Deputy Manager/ Validation, Deviation & Self inspection group (Member).	
3	Nong Thi Thanh Van	Product release group (leader). Documentation (Member)	
4	Le Thi Hoa	Documentation, changing control group (Leader). Training, Product release group (Member).	
5	Hoang Thi Lan	Documentation group (Member).	
6	Nguyen Thi Mai Huong	Documentation; registration (Member), Education (leader).	
7	Pham Thi Phuong Thao	Registration (Leader) Documentation group (Member).	
8	Luong Phu Duan	Validation (Leader) Deviation & Self inspection group (Member).	
Engineering Department			
1	Nguyen Dang Anh	Manager	
2	Dang Anh Tuan	Head of Validation/Calibration equipment and Manufacturing machine group	
3	Nguyen Tuan Dung	Validation/Calibration equipment and Manufacturing machine group	
4	Vu Van Dung	Validation/Calibration equipment and Manufacturing machine group	
5	Nguyen Manh Dung	Head of HVAC system, Steam supply system and Air compressor system group	
6	Luu Van Chien	HVAC system, Steam supply system and Air compressor system group	
7	Nguyen Quoc Phong	Water supply system, Production Water Supply system and Waste water treatment system group	
8	Tran Cong Thang	Electrical system and Fire Fighting system group	
9	Cao Minh Duc	Head of Water supply system, Production Water Supply system and Waste water treatment system group	

No.	Name in full	Position	Remarks
GMP Supporting Group			
Administration and Personnel Department			
1	Nguyen Thi Hai Thanh	Manager	
2	Nguyen Duc Thang	Staff	
3	Cao Thi Hai Anh	Staff	
Accounting Department			
1	Nguyen Thi Thanh Mai	Manager	
2	Dao Thi Thuy	Staff	
Procurement Department			
1	Nguyen Manh Khue	Manager	
2	Tran Trong Hai	Staff	
3	Vu Thuy Duong	Staff	

(10) Achievement of Education/Training and Certificate (Abstract)

Table of Training Result Management for Bulk Production of POLYVAC
Bảng quản lý kết quả đào tạo cho sản xuất bán thành phẩm của POLYVAC

2013.5.20～2018.3.6

Department: Bulk Production　　Trainer: Hiroki Katsuda
Phòng ban: Sản xuất bán thành phẩm　　Người hướng dẫn: Hiroki Katsuda

Classificaton Phân loại		Items Hạng mục	Trainee of POLYVAC and level achieved Người được đào tạo của POLYVAC và trình độ đạt được					
			Mr. Nguyen Xuan Hoa	Mr. Pham Thanh Truong	Ms. Lai Quynh Mai	Mr. Pham Van Khoi	Ms. Vu Thi Mai	Mr. Le Bao Trung
1. 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.	A:4	A:4	A:4	A:4	A:4	A:4
	1－2	The process of rubella vaccine bulk production. Các công đoạn sản xuất bán thành phẩm vắc xin rubella.	A:4	A:4	A:4	A:4	A:4	A:4
2. Process of rabbit kidney extirpation/ rabbit kidney cell culture Công đoạn lấy thận thỏ / nuôi cấy tế bào thận thỏ	2－1	Preparation for tools Chuẩn bị dụng cụ	A:4	A:4	B:4	B:4	B:4	B:4
	2 - 2	Extirpation of rabbit kidney Lấy thận	A:4	A:4	B:3	B:3	B:3	－
	2 - 3	Splitting kidney into small parts Cắt nhỏ thận	A:4	A:3	B:3	B:3	B:3	－
	2 - 4	Preparation of cell culturing solution, cell dispensing Pha dung dịch nuôi cấy tế bào, chia chai tế bào	A:4	A:4	B:4	B:4	B:4	B:4
	2 - 5	Counting number of centrifugated cell Tính toán số tế bào ly tâm	A:4	A:4	－	－	－	－
	2 - 6	Cell culture / Nuôi cấy tế bào	A:4	A:4	B:4	B:4	B:4	B:4
	2 - 7	Writing Standard Operating Procedure (SOP) Viết tài liệu quy trình (SOP)	A:4	B:4	－	－	－	－
3. Process for virus innoculation Công đoạn gây nhiễm vi rút	3 - 1	Observating cell culturing bottle Quan sát chai nuôi cấy tế bào	A:4	B:1	－	－	－	－
	3 - 2	Preparation of culturing solution Pha dung dịch nuôi cấy	A:4	A:4	B:4	B:4	B:4	B:4
	3 - 3	Preparation for tools, confirming operations of process Chuẩn bị dụng cụ, xác nhận các thao tác trong công đoạn	A:4	A:4	B:4	B:4	B:4	B:4
	3 - 4	Writing Standard Operating Procedure (SOP) Viết tài liệu quy trình (SOP)	A:4	B:4	－	－	－	－
4. Processes: washing virus innoculating cell, keeping at 5oC, harvesting, fine filtration, bulk dispensing Các công đoạn: Rửa tế bào lây nhiễm vi rút, Giữ ở 5 độ C, Gặt, Lọc tinh, Chia bán thành phẩm	4 - 1	Observating virus culturing bottle Quan sát chai nuôi cấy vi rút	A:4	B:1	－	－	－	－
	4 - 2	Preparation of culturing solution Pha dung dịch nuôi cấy	A:4	A:4	B:4	B:4	B:4	B:4
	4 - 3	Preparation for tools, confirming operations of process Chuẩn bị dụng cụ, xác nhận các thao tác trong công đoạn	A:4	A:4	B:4	B:4	B:4	B:4
	4 - 4	Writing Standard Operating Procedure (SOP) Viết tài liệu quy trình (SOP)	A:4	B:4	－	－	－	－
5. PQ	5 - 1	Validation for confirming effect of rabbit disinfection Thẩm định xác nhận hiệu quả khử trùng thỏ	A:4	A:4	－	－	－	－
	5 - 2	Validation for tool sterilization Thẩm định tiệt trùng dụng cụ	A:4	A:4	－	B:4	－	－
	5 - 3	Validation for environmental monitoring Thẩm định giám sát môi trường	A:4	A:4	－	B:4	－	－
	5 - 4	Production PQ / PQ sản xuất	A:4	A:4	－	B:4	－	－
	5 - 5	Validation for anti-cross contamination Thẩm định chống nhiễm chéo	A:4	A:4	－	－	－	－
6. PST, PV	6 - 1	MFT implementation Thực hiện MFT	A:4	A:4	B:2	B:2	－	－
	6 - 2	PV implementation Thực hiện PV	A:4	A:4	B:2	B:2	－	－

Black letter: Actual achievement until FY2016 , Red letter: Actual achievement of FY2017
Chữ đen: kết quả đến năm 2016, chữ đỏ: kết quả năm 2017

Level 1: Completed basic training course and acquired practical knowledge.
Trình độ 1: Đã kết thúc khóa đào tạo cơ bản và lĩnh hội được kiến thức thực hành.

Level 2: Capable of performing assigned work under the instruction of supervisors.
Trình độ 2: Có thể thao tác dưới sự hướng dẫn của người khác và có kiến thức phần nào.

Level 3: Capable of performing his/her assigned work on his/her own but unable to provide training for other.
Trình độ 3: Có thể tự thao tác và có kiến thức tương đối nhưng chưa thể đào tạo lại cho người khác.

Level 4: Capable of performing his/her assigned work on his/her own actively and also provide training for other.
Trình độ 4: Có thể chủ động thao tác và đào tạo lại cho người khác.

A:Trainee who receiving technical transfer from KDSV expert (in charge of process): Target to achieve Level 4.
A: Đối tượng được hướng dẫn chuyển giao công nghệ bởi chuyên gia KDSV (phụ trách công đoạn): Mục tiêu đạt Trình độ 4.

B: Assistant of process proposed by KDSV (target to achieve Level 3 upward after to be trained at POLYVAC)
B: Người hỗ trợ trong công đoạn do KDSV đề xuất (mục tiêu đạt Trình độ 3 trở lên sau khi được đào tạo nội bộ tại POLYVAC).

C:Trainee proposed by Kitasato due to Kitasato estimated production of POLYVAC in the future (target to achieve Level 3 upward after to be trained at POLYVAC)
C: Đối tượng được đào tạo do Kitasato đề xuất vì Kitasato đã lường trước được việc sản xuất sau này của POLYVAC (mục tiêu đạt Trình độ 3 trở lên sau khi được đào tạo nội bộ tại POLYVAC).

－Depending on training structure of POLYVAC.
Tùy thuộc vào cơ cấu đào tạo của POLYVAC.

Table of Training Result Management for QC Dept. of POLYVAC
Bảng quản lý kết quả đào tạo cho Phòng quản lý chất lượng của POLYVAC
2013.5.20～2018.3.9

Department: Quality Control
Phòng ban: Quản lý chất lượng

Trainer: Kenichi Baba, Yoshihisa Takeda, Toshio Kosugi, Manabu Ikeda
Người hướng dẫn: Kenichi Baba, Yoshihisa Takeda, Toshio Kosugi, Manabu Ikeda

Classification Phân loại		Items Hạng mục	Trainee of POLYVAC and level achieved Người được đào tạo của POLYVAC và trình độ đạt được												
			Dr. Ngo Thu Huong	Ms. Ngo Thi Thanh Huong	Mr. Cao Xuan Ngoc	Mr. Ngo Tien Tho	Ms. Pham Thi Thuoc	Mr. Pham Huu Tien	Mr. Le Van Duy	Ms. Nguyen Thi Nguyet	Ms. Pham Anh Thu	Mr. Pham Thanh Truong	Ms. Lai Quynh Mai	Mr. Pham Van Khoi	Mr. Le Bao Trung
		Training time Thời gian đào tạo	2013.5.20～2018.3.9	2013.5.20～2018.3.9	2013.5.20～2018.3.9	2018.2.26～2018.3.9	2013.5.20～2018.3.9	2013.5.20～2018.3.9	2013.5.20～2018.3.9	2014.5.9～2018.3.9	2015.4.10～2018.3.9	2014.7.21	2014.7.21	2014.7.21	2014.7.21
1. Receiving SPF rabbit Thử nghiệm tiếp nhận thỏ SPF	1-1	Method of writing record / Cách thức ghi biên bản	A : 3	-	-	-	-	-	-	-	-	-	-	-	-
	1-2	Transporting and receiving / Vận chuyển và tiếp nhận	-	-	-	-	-	-	-	-	-	-	-	-	-
	1-3	Health control / Quản lý sức khỏe	-	-	-	-	-	-	-	-	-	-	-	-	-
	1-4	Cutting hair / Cắt lông	A : 4	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	1-5	Bleeding / Lấy máu	A : 4	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	1-6	Disinfection / Khử trùng	A : 4	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	1-7	Transporting and handing over / Vận chuyển và bàn giao	A : 3	-	-	-	-	-	-	-	-	-	-	-	-
	1-8	Visual check rabbit kidney (when extirpation of kidney) Quan sát thận bằng mắt thường (khi lấy thận)	-	-	-	-	-	-	-	-	-	A : 3	A : 3	A : 3	A : 3
	1-9	Visual check rabbit kidney (when spliting into small parts) Quan sát thận bằng mắt thường (khi cắt nhỏ thận)	A : 3	-	-	-	A : 4	A : 4	-	A : 4	A : 4	-	-	-	-
	1-10	Autopsy / Giải phẫu	-	-	-	-	A : 4	A : 4	-	-	-	-	-	-	-
2. Test on control cell culture Thử nghiệm tế bào nuôi cấy đối chứng	2-1	Observation of cell culture / Quan sát nuôi cấy	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	2-2	Test for haemadsorbing viruses Thử nghiệm phủ định vi rút hấp phụ hồng cầu	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	2-3	Inoculation of rabbit kidney cell culture Thử nghiệm gây nhiễm tế bào nuôi cấy thận thỏ	A : 3	-	-	-	-	-	-	-	-	-	-	-	-
	2-4	Inoculation of simian cell culture (VERO) Thử nghiệm gây nhiễm tế bào nuôi cấy khỉ (VERO)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	2-5	Inoculation of FL cell culture Thử nghiệm gây nhiễm tế bào nuôi cấy FL	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	2-6	Encephalitozoon Cuniculi test Thử nghiệm Encephalitozoon Cuniculi	A : 3	-	-	-	A : 3	-	-	-	-	-	-	-	-
3. Rubella virus potency test Thử nghiệm hiệu giá vi rút rubella	3-1	RK13 cell culture / Nuôi cấy tế bào RK13	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	3-2	Medium preparation / Chuẩn bị môi trường	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	3-3	Virus dilution / Pha loãng vi rút	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	3-4	Inoculation / Gây nhiễm	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	3-5	NR method / Phương pháp NR	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	3-6	Calculation / Tính toán	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	3-7	Evaluation / Đánh giá	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
4. MR vaccine virus titration test Thử nghiệm hiệu giá vi rút vắc xin MR	4-1	RK13 cell culture / Nuôi cấy tế bào RK13	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-2	VERO cell culture / Nuôi cấy tế bào VERO	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-3	Medium preparation / Chuẩn bị môi trường	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-4	Virus dilution (measles) / Pha loãng vi rút (sởi)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-5	Virus dilution (rubella) / Pha loãng vi rút (rubella)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-6	Inoculation / Gây nhiễm	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-7	ABC kit method / Phương pháp ABC Kit	A : 3	-	-	-	-	-	-	-	-	-	-	-	-
	4-8	Calculation (measles) / Tính toán (sởi)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-9	Calculation (rubella) / Tính toán (rubella)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-10	Evaluation (measles) / Đánh giá (sởi)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	4-11	Evaluation (rubella) / Đánh giá (rubella)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
5. Cell bank for RK13 cell passage Ngân hàng nuôi cấy cấy chuyền tế bào RK 13	5-1	RK13 cell culture / Nuôi cấy tế bào RK13	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	5-2	Medium preparation / Chuẩn bị môi trường	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	5-3	Frozen preservation of seed Bảo quản đông lạnh tế bào chủng	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	5-4	Seed culture / Nuôi cấy tế bào chủng (seed)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
6. Rubella virus Immune serum Huyết thanh miễn dịch vi rút rubella	6-1	BHK-21 cell culture / Nuôi cấy tế bào BHK-21	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	6-2	Antigen production / Sản xuất kháng nguyên	A : 3	-	-	-	-	-	-	-	-	-	-	-	-
	6-3	Pig immune serum production Sản xuất huyết thanh miễn dịch lợn	-	-	-	-	-	-	-	-	-	-	-	-	-
	6-4	Rabbit immune serum production Sản xuất huyết thanh miễn dịch thỏ	A : 3	-	-	-	-	-	-	-	-	-	-	-	-
	6-5	HI Test / Thử nghiệm HI	A : 3	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	6-6	Evaluation / Đánh giá	A : 3	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-

7. Rabbit inoculation test Thử nghiệm tiêm thỏ	7-1	Weighing / Cân trọng lượng	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	7-2	Cutting hair / Cắt lông	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	7-3	Fixing / Cố định	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	7-4	Innoculation (thigh subcutaneous) Tiêm (tiêm dưới da đùi)	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	7-5	Inoculation (intracutaneous) Tiêm (trong da)	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	7-6	Observation / Quan sát	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	7-7	Evaluation / Đánh giá	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
8. Marker test Thử nghiệm marker	8-1	Weighing / Cân trọng lượng	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	8-2	Fixing / Cố định	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	8-3	Bleeding / Lấy máu	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	8-4	Inoculation / Tiêm	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	8-5	Observation / Quan sát	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	8-6	HI test / Thử nghiệm HI	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
	8-7	Evaluation / Đánh giá	-	A : 3	A : 3	-	-	-	-	-	-	-	-	-	-
9. Others (Confirmation content) Nội dung khác (nội dung xác nhận)	9-1	Measles immune antibody neutralization test Thử nghiệm trung hòa kháng thể miễn dịch sởi	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	9-2	Total viable bacterial count (growth promotion test) Thử nghiệm đánh giá số lượng khuẩn sống (thử nghiệm tính năng)	A : 4	-	-	-	-	-	-	-	-	-	-	-	-
	9-3	Antibiotic protency test by microbiologycal assay Thử nghiệm đo hoạt lực kháng sinh bằng phương pháp hiệu giá vi sinh vật	A : 4	-	-	-	-	-	-	-	A : 4	-	-	-	-
	9-4	Production of positive control virus Sản xuất vi rút đối chứng chứng dương	A : 4	-	-	A : 4	-	-	-	-	A : 4	-	-	-	-

Black letter: Actual achievement until FY2016 , Red letter: Actual achievement of FY2017

Chữ đen: kết quả đến năm 2016, chữ đỏ: kết quả năm 2017

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.

A:Trainee who receiving technical transfer from KDSV expert (in charge of process): Target to achieve Level 4.

B: Assistant of process proposed by KDSV (target to achieve Level 3 upward after to be trained at POLYVAC)

C:Trainee proposed by Kitasato due to Kitasato estimated production of POLYVAC in the future (target to achieve Level 3 upward after to be trained at POLYVAC)

- Depending on training structure of POLYVAC.

Trình độ 1: Đã kết thúc khóa đào tạo cơ bản và lĩnh hội được kiến thức thực hành.

Trình độ 2: Có thể thao tác dưới sự hướng dẫn của người khác và có kiến thức phần nào.

Trình độ 3: Có thể tự thao tác và có kiến thức tương đối nhưng chưa thể đào tạo lại cho người khác.

Trình độ 4: Có thể chủ động thao tác và đào tạo lại cho người khác.

A: Đối tượng được hướng dẫn chuyển giao công nghệ bởi chuyên gia KDSV (phụ trách công đoạn): Mục tiêu đạt Trình độ 4.

B: Người hỗ trợ trong công đoạn do KDSV đề xuất (mục tiêu đạt Trình độ 3 trở lên sau khi được đào tạo nội bộ tại POLYVAC).

C: Đối tượng được đào tạo do Kitasato đề xuất vì Kitasato đã lường trước được việc sản xuất sau này của POLYVAC (mục tiêu đạt Trình độ 3 trở lên sau khi được đào tạo nội bộ tại POLYVAC).

- Tùy thuộc vào cơ cấu đào tạo của POLYVAC.

QA

Ref No.: _____

Biên bản số: _____

Report on Completion of Technical Transfer Training for Breeding Animal for Quality Control

Báo cáo kết thúc đào tạo chuyển giao công nghệ nuôi động vật dùng cho thử nghiệm chất lượng chất lượng

1. Process: Breeding, managing and microbiological examination for SPF rabbit
   Công đoạn: Quản lý, chăn nuôi và kiểm tra vi sinh vật cho thỏ SPF
2. Trainee: Pham Huu Tiep
   Người thực hiện thử nghiệm: _____
3. Training time: 2017/11/13 ~ 2017/12/01
   Thời gian đào tạo: _____
4. Training place: POLYVAC MVPF, Kitayama Labes Co., Ltd
   Địa điểm đào tạo: POLYVAC MVPF, Công ty cổ phần Kitayama Labes
5. Evaluator (Trainer): 伊藤邦次 Date 2017/12/01
   Người đánh giá (người đào tạo): 橋井一束 Ngày

General Evaluation	☑ **Pass**	□ **Fail**
Đánh giá tổng hợp	□ **Đạt**	□ **Không đạt**

Table of Results of Training Items

Danh mục kết quả các hạng mục đào tạo

No. STT.	Training Items Hạng mục đào tạo	Studying Attitude Thái độ học tập	Level Achieved Trình độ đạt được
1	Microbiological examination: Capable of preparing necessary materials for 8 items of microbiological examination in SPF rabbits Kiểm tra vi sinh vật: Có thể chuẩn bị nguyên liệu, vật tư cần thiết để thực hiện kiểm tra vi sinh vật 8 hạng mục trên thỏ SPF	(E) G A F	1 2 3 (4)
2	Microbiological examination: Capable of taking necessary samples for microbiological examination in SPF rabbits Kiểm tra vi sinh vật: Có thể lấy mẫu cần thiết để thực hiện kiểm tra vi sinh vật trên thỏ SPF	(E) G A F	1 2 3 (4)
3	Microbiological examination: Capable of performing examination and evaluating examination result for 8 items of microbiological examination in SPF rabbits Kiểm tra vi sinh vật: Có thể tiến hành kiểm tra và đánh giá kết quả kiểm tra vi sinh vật 8 hạng mục trên thỏ SPF	(E) G A F	1 2 3 (4)
4	Microbiological examination: Capable of preparing necessary materials for 21 items of microbiological examination in SPF rabbits Kiểm tra vi sinh vật: Có thể chuẩn bị nguyên liệu, vật tư cần thiết để thực hiện kiểm tra vi sinh vật 21 hạng mục trên thỏ SPF	(E) G A F	1 2 3 (4)
5	Microbiological examination: Capable of performing examination and evaluating examination result for 21 items of microbiological examination in SPF rabbits	(E) G A F	1 2 3 (4)

	Kiểm tra vi sinh vật: Có thể tiến hành kiểm tra và đánh giá kết quả kiểm tra vi sinh vật 21 hạng mục trên thỏ SPF		
6	Breeding and management: Capable of operating and measuring with environmental monitoring equipment Quản lý và chăn nuôi: Có thể sử dụng và tiến hành đo bằng thiết bị giám sát môi trường	(E) G A F	1 2 3 (4)
7	Breeding and management: Capable of breeding and managing rabbits from mating, reproduction to weaning process Quản lý và chăn nuôi: Có thể quản lý chăn nuôi từ công đoạn nhân giống, cho sinh sản đến khi cai sữa	(E) G A F	1 2 3 (4)
8	Breeding and management: Capable of setting up the SPF facility (eliminate pathogen out of breeding rooms) Quản lý và chăn nuôi: Có thể thiết lập nhà xưởng SPF (loại bỏ khuẩn mang tác nhân gây bệnh ra khỏi phòng nuôi)	(E) G A F	1 2 3 (4)
9	Breeding and management: Have knowledge on epidemic prevention and capable of implemeting works related to contamination prevention Quản lý và chăn nuôi: Có kiến thức liên quan đến phòng chống dịch bệnh và có thể tiến hành phòng chống dịch bệnh	(E) G A F	1 2 3 (4)

Studying attitude: E: Excellent G: Good A: Average F: Fail

Thái độ học tập: E: Rất tốt G: Tốt A: Bình thường F: Không tốt

Level to be achieved (Above level 3 achievement is required for training completion)

Trình độ đạt được (Trường hợp đạt trên level 3 sẽ được kết thúc đào tạo)

Level 1: Completed basic training course and acquired practical knowledge.

Trình độ 1: Đã kết thúc khóa đào tạo cơ bản và lĩnh hội được kiến thức thực hành.

Level 2: Capable of performing assigned work under the instruction of supervisors.

Trình độ 2: Có thể thao táo dưới sự hướng dẫn của người khác và có kiến thức phần nào.

Level 3: Capable of performing his/her assigned work on his/her own but unable to provide.

Trình độ 3: Có thể tự thao tác và có kiến thức tương đối nhưng chưa thể đào tạo lại cho người khác.

Level 4: Capable of performing his/her assigned work and also provide training for other.

Trình độ 4: Có thể chủ động thao tác và đào tạo lại cho người khác.

Reviewed by (QC Manager): _____ Date/Ngày: 04/12/2017

Approved by (QA Manager): _____ Date/Ngày: 04/12/2017