Ministry of Health
The Social Republic of Vietnam

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

March 2010

JAPAN INTERNATIONAL COOPERATION AGENCY

The Kitasato Institute

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CONTENTS

Abbreviations

EPI	Expanded Program on Immunization
GAVI	GAVI Alliance (Former name: The Global Alliance for Vaccines and Immunization)
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HPAI	Highly Pathogenic Avian Influenza
IQ	Installation Qualification
JCC	Joint Coordination Committee
JICA	Japan International Cooperation Agency
JPY	Japanese Yen
MFT	Media Fill Test
MR vaccine	Measles and Rubella vaccine
MVPF	Measles Vaccine Production Facility
NICVB	National Institute for Control of Vaccine and Biologicals, Viet Nam
NIHE	National Institute of Hygiene and Epidemiology, Viet Nam
NRA	National Regulatory Authority
OJT	On the Job Training
OQ	Operational Qualification
PDM	Project Design Matrix
POLYVAC	Center for Research and Production of Vaccines and Biologicals
PQ	Performance Qualification
PV	Process Validation
PVF	Primary Vaccine Failure
QA	Quality Assurance
QC	Quality Control
SIAs	Supplementary Immunization Activities
SOP	Standard Operating Procedure
SPF	Specific Pathogen Free
SVF	Secondary Vaccine Failure
VN	Viet Nam
VND	Vietnamese Dong
WHO	World Health Organization
WPRO	Western Pacific Regional Office, WHO

Location Map

Map of the Socialist Republic of Viet Nam

Map of Hanoi and Location of Site

Photos of Technology Transfer Scenes

Comment: Clinical Trial

Comment: Final Products of Measles Vaccine

Comment: Morning Briefing

Comment: Vice Minister of Health in JCC

Comment: Terminal Evaluation Team

Comment: JCC No. 5

1. Outline of the Project

1.1 Background and Outline

The Government of the Social Republic of Vietnam (hereinafter called "Vietnam") had been implementing the Expanded Program on Immunization (EPI) as one of the national programs since 1981 in order to provide an effective means of reducing the mortality rate of children of less than 5 years old and suppressing infectious diseases. This Program was aimed at a higher EPI immunization rate while the efforts to establish the self-supply system of EPI vaccines (for polio, measles, diphtheria, pertussis, tetanus and tuberculosis) had been made, enabling the domestic production of EPI vaccines except the measles vaccine.

In the Western Pacific Region, measles has a high morbidity rate of infants and it is one of the causes of death for complication and any other disease. The vaccination rate in Vietnam is keeping 93% or more for the primary vaccination since 1993. However, the Primary Vaccine Failure (PVF: No immunization is obtained because the vaccine effect is reduced by the insufficiency of the low temperature storage system) and the Secondary Vaccine Failure (SVF: If the measles infection is reduced, decreasing the opportunity of infection with the wild virus, the immunization effect of measles vaccination cannot be sustained, causing the contraction of measles more than 10 years after vaccination.) had increased, resulting in the increase of patients after 1997. 19,000 cases of measles occurred in 2000 and the infection had occurred every 7 to 8 years. This effect shows the limit of the primary vaccination effect. The WHO Western Pacific Regional Office (WPRO) had promoted the measles suppression after the polio eradication and had recommended to increase the vaccination from once to 2 times in the measles vaccination program in each country.
In accordance with this recommendation, the Government of Vietnam started the regular vaccination in 2 times since 2006. Therefore, it was predicted that the domestic demand for measles vaccines would increase. Internationally, it was predicted that vaccine manufacturers in developed countries would shift from the production of measles vaccines at low costs to the high-profit vaccine production. So it is concerned in Vietnam about whether measles vaccines can be imported in a stable quantity at a low price. Therefore, the domestic production of measles vaccines for stable supply was one of the important issues to maintain the independent financial development of the National Immunization Program (and the related organizations) for which more than 50% of the budget was expended by the national budget.

Under these circumstances, the Government of Vietnam formulated the Measles Vaccine Production Facilities Construction Project and request Japan for the grant aid for construction of such facilities and the technical cooperation for the production of vaccines which comply with the WHO-GMP (Good Manufacturing Practice: standard for appropriate manufacture of medicines). In response to this request, Japan decided to implement the project of constructing the measles vaccine production facilities under the grant aid as a part of the Poliomyelitis Vaccine Research and Production Center

(POLYVAC) in 2003, which was followed by the technical cooperation project for transfer of vaccine production technology.

The construction of facilities under the grant aid was started in September 2004 and completed in March 2006. In parallel with this project, the preliminary evaluation study was made in July 2005 to formulate the plan of the technical cooperation project. Based on the results of the study, this Project was started for the purpose that "POLYVAC would acquire the capacity of producing the necessary volume of measles vaccines in compliance with the Vietnam GMP (VN-GMP) established in accordance with the WHO (World Health Organization)-Good Manufacturing Practice (WHO-GMP standard) and the project was completed in March 2010. Implementation of this Project was entrusted to the Kitasato Institute, Research Center for Biologicals.

1.2 Contents of the Project

(1) Overall Goal

Measles Infection Rate in the Socialist Republic of Viet Nam will be decreased from the current level.

(2) Project purpose

POLYVAC will be capable to produce necessary amount of measles vaccines for use of measles control activities in the Socialist Republic of Viet Nam complying with the Viet Nam GMP (VN-GMP) which has met WHO-GMP standard.

(3) Outputs

1) Output 1: Staff of POLYVAC acquires appropriate technical skill to produce quality measles vaccine.
2) Output 2: Production and quality management meet Vietnam-GMP which has met WHO-GMP standard.

(4) Activities

1-1) Conduct technical transfer on bulk, filling, freeze-dry through the process of producing vaccine from the imported bulk.

1-2) Conduct technical transfer on production of bulk vaccine through the processing of producing bulk vaccine from the seed virus.

1-3) Conduct technical transfer on proper operation of mass production (7.5 million doses/year) of the measles vaccine.

1-4) Conduct technical transfer on quality control of the products.

2-1) Conduct PQ (Performance Qualification)/PV (Process Validation) for vaccine production from bulk vaccine.

2-2) Conduct PQ/PV for vaccine production from seed virus.

2-3) Establish validation system for the production and strengthen the validation skill of the staff.

2-4) Establish and implement quality assurance functions complying with Vietnam-GMP, which has met WHO-GMP standard.

2-5) Prepare and implement necessary SOP for the process of production, storage, carrying in/out of the products, etc.

2-6) Conduct technical transfer on preparation of documents that need to meet Vietnam-GMP, which has met WHO-GMP standard, and to be approved by NRA in the Socialist Republic of Viet Nam.

(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 4 years from March 2006 (though the actual start of work was July 2006) to March 2010.

2. Achievements of the Project

2.1 Achievement of Output 1

"Staff of POLYVAC acquires appropriate technical skill to produce quality measles 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. The results of clinical tests using the measles vaccines formulated from the imported bulk certified the high safety and validity of the vaccines. The transfer of the technology in the integrated production of measles vaccines from seed virus was completed as planned after the mid-term evaluation. The validity and safety of those vaccines was also certified at clinical tests and the measles vaccine production has been in a high level of completeness in the technical viewpoint.

Based on these results, POLYVAC has acquired the permit of selling vaccines from the authority of Vietnam twice and shipped approximately 1.3 million doses of vaccines in total for the EPI of Vietnam. Actually, the vaccination of children has started in Vietnam.

However, the practical experience of the measles vaccine production facilities is still absolutely insufficient and it is the future issue to foster the practical capacity of solving problems such as recognition of anomalies and deviations and response to those symptoms. POLYVAC has not reached the level in which the transferred technology can be sustained and improved and it is necessary to strengthen the capacity of data analysis.

2.2 Achievement of Output 2

"Production and quality management meet Vietnam-GMP, which has met WHO-GMP standard."

Similarly to Output 1, the activities for Output 2 was 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. The formulation of the GMP system in POLYVAC as the measles vaccine production facility made smooth progress. As a result, the measles vaccines were produced by the manufacturing process and quality control to comply with the VN-GMP and sold in the country of Vietnam.

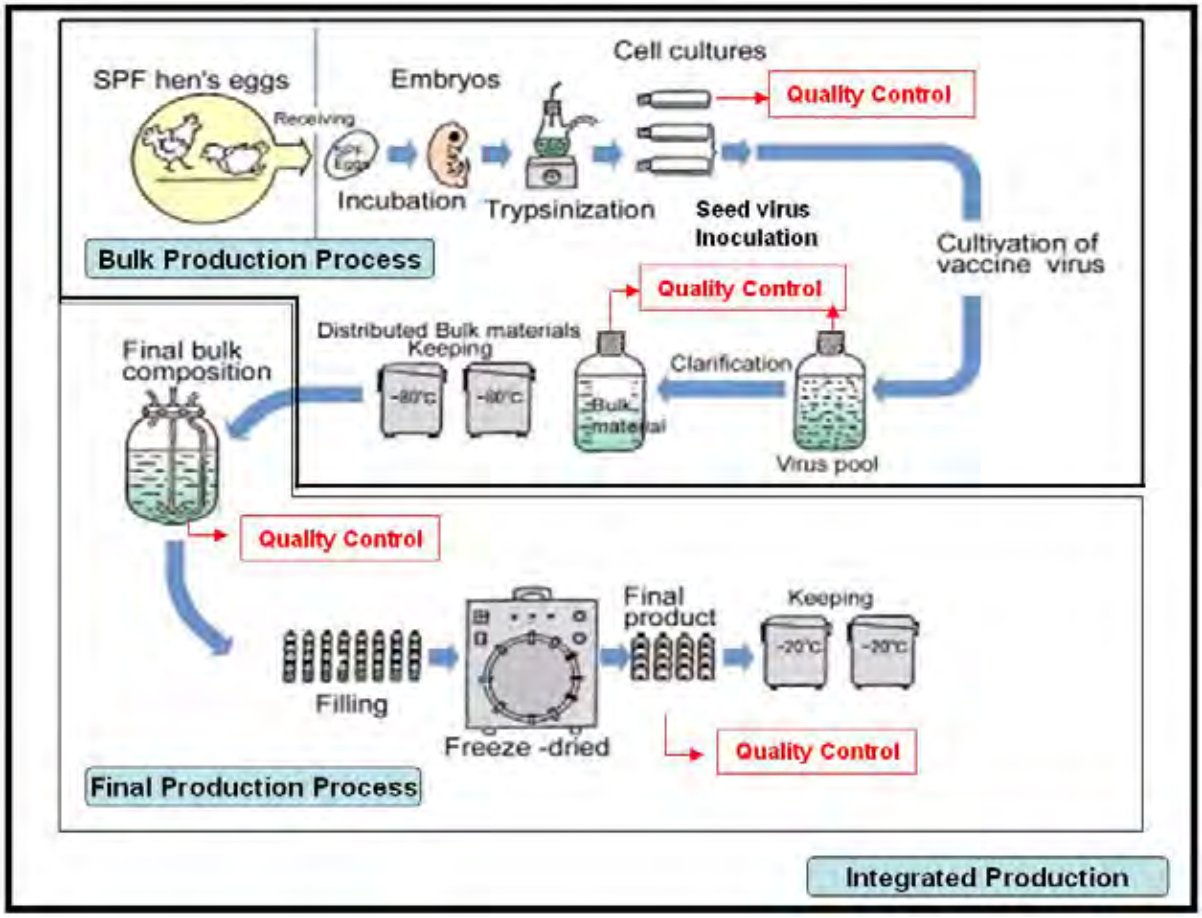
For starting the routine production and appropriate operation of the facility, it is necessary to follow up those activities and to furnish additional guidance to maintain the VN-GMP standard. It is also necessary to further improve the administration of various GMP-related documents for acquiring the prequalification by WHO in the future.

3. Schedule of Project Activities

3.1 Vaccine Production Process and Results of Activity

The measles vaccine production process is shown in Fig. 3-1. In this Project, vaccine bulk was imported, the technology for the formulation process (final production process) was transferred in the first stage, and the technology for the overall production process from the bulk production process to the formulation process was transferred in the second stage.

Fig. 3-1 Flowchart of measles vaccine production process



Further, the milestones from fiscal 2006 (first year) through the final year of 2009 (fourth year) are summarized by year below.

Milestones by Year	Status Achieved
(First year: July 2006 to March 2007) The measles vaccine production facilities are launched to ensure that the facilities and equipment are operated normally. POLYVAC staff acquires the technology for the formulation process to manufacture the final product (vaccine) from the imported vaccine bulk as well as the technology for related quality tests.	Completed successfully
(Second year: April 2007 to March 2008) The final product (vaccine) manufactured from vaccine bulk reaches a quality that	Completed successfully

Milestones by Year	Status Achieved
is in accordance with the WHO-GMP standard. Samples are available to be given to people in clinical tests. Further, POLYVAC staff acquires the technology for the bulk production process in which vaccine bulk is manufactured from seed virus, and the technology for vaccine bulk quality testing.	
(Third year: April 2008 to March 2009) The vaccine from full-scale integrated production (300,000 doses/batch) from seed virus to final product is of a quality that is in accordance with the WHO-GMP standard. Samples of measles vaccine manufactured 100% in Vietnam are available to be given to people in clinical tests.	Completed successfully
(Fourth year: April 2009 to March 2010) POLYVAC can produce 7.5 million doses of vaccines per year (300,000 doses/batch×25 batches) in the integrated production system from seed virus to final product. The NRA verifies that the vaccine produced satisfies the VN-GMP standard which is in accordance with the WHO-GMP standard.	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 bulk, filling, freeze-dry through the process of producing vaccine from the imported bulk.

The process validation (PV) in the scale of 1/3 (100 thousand doses per batch) of the official production was completed in 2007 (the second year). Through the first clinical test, the approval by the Ethics Committee, the approval by the Licensing Committee and the permit of sale, the shipments for the Vietnam EPI were completed in August 2009. After that, the following report was received: the vaccination of babies and infants was enforced in the Vietnam EPI. Therefore, it has been certified that this activity was completed successfully as originally planned. The formulation of 300K doses from the imported bulk which remained after the use in the PV was made in May 2009 and the shipments for the EPI has been completed by November 2009.

(2) Conduct technical transfer on production of bulk vaccine through the processing of producing bulk vaccine from the seed virus.

The PV of the bulk production processes was made in fiscal 2008 (the third year). After that, a series of 3 rounds of PV of the integrated production combined with the formulation technology established in 2007 (the second year) was made, resulting in the compliance of the processes.

Then, the transfer of the integrated production technology from seed virus to the final products was completed. Therefore, it is deemed that this technology transfer was completed successfully as originally planned. The second clinical tests using the vaccines manufactured in this integrated production were started in June 2009 and made smooth progress until they were completed in September 2009. As a result, the high safety and validity of the vaccines was verified and the second approval by the Ethics Committee and the approval by the Licensing Committee were acquired for the permit of sale. Then, the vaccines were shipped for the Vietnam EPI in January 2010.

(3) Conduct technical transfer on proper operation of mass production (7.5 million doses/year) of the measles vaccine.

To realize the increase of production from the 1/3 scale (100K doses per batch) to the final goal capacity of 7.5 million doses per year in this Project in 2008 (the third year), the scale-up test on 300K doses per batch was made and verified by the use of an actual machine using the bulk vaccine manufactured by POLYVAC. The test verified that the transfer of the production technology, the related works and the GMP technology made steady progress. As the result of this success, in 2009 (the forth year), the bulk production was started in a routine of about 2 weeks per batch from the middle of March, 2009 and 13 batches were manufactured until December 2009. In the calculation from the titer of the bulk produced by POLYVAC, the final products of approximately 700,000 doses can be produced in average. As a result, the bulk for about 9 million doses of final products could be manufactured. On the other hand, after having passed the MFT (Media Fill Test) which was conducted in September 2009, the routine production of a series of 5 batches was made for about 8 weeks from the middle of October, 2009 without any trouble and the result of the quality control test was good. Thus, it was verified that the transfer of the technology in mass production of vaccines was completed successfully.

(4) Conduct technical transfer on quality control of the products.

Basically, the transfer of all the technology was completed in the quality control department and the quality control tests necessary for the bulk process, formulation process and validation were made steadily in 2009. The avian leukemia negation test which is one of the WHO quality control requirements and a new item of technology transfer to this department was followed up. As the result of the examination and evaluation of the capacity and experience of the POLYVAC staffs, it was determined that the ELISA method using measuring instruments is the most adequate. Thus, POLYVAC decided to make the future tests by the ELISA method and prepared the standard operating procedure (SOP). In the future, it is also necessary to transfer the technology in animal tests in fixing the acquired technology among the counterparts.

3.3 Results of Activity for Output 2

(1) Conduct PQ/PV for vaccine production from bulk vaccine.

In the output up to 2007 (the second year), the organizational system and personnel assignments in related departments necessary for the processes of vaccine formulation from the vaccine bulk manufactured by Kitasato Institute, Japan were built and operated and various GMP-related documents were prepared in an appropriate way. As a result, the safety and validity of the manufactured vaccines was verified through PV in the clinical tests. The vaccines acquired the permit for sale from the National Regulatory Authority (NRA) of Vietnam in May 2009. Thus, it was certified that the GMP system configuration and operation was qualified.

(2) Conduct PQ/PV for vaccine production from seed virus.

As the output in 2008 (the third year), the various PQ and PV tests necessary for the integrated production processes from bulk manufacture by POLYVAC to formulation were made successfully, and the organizational system and personnel assignments in related departments necessary for the production processes were built and operated and various GMP-related documents were prepared in an appropriate way.

(3) Establish validation system for the production and strengthen the validation skill of the staff.

The PQ, MFT and PV tests necessary for the departments and processes were completed up to 2008 (the third year) as scheduled. In the final year, the training in preparing the additional protocols, the regular follow-up training for the trainees not to forget the acquired technologies and additional training were furnished to the counterparts. The regular calibration and regular validation which it is mandatory to make on a yearly basis was conducted as planned. Therefore, it was certified that the transfer of the minimum validation technology was completed successfully.

(4) Establish and implement quality assurance functions complying with Vietnam-GMP, which has met WHO-GMP standard.

The intensive training for the practical works including not only preparation of documents but also for the inspection method and the method of preparing the GMP-related documents was furnished to the staff and manager of QA (Quality Assurance) department. As the result, the transfer of the minimum technology was completed. In addition, the guidance of individual production managers (who are responsible for 4 departments, bulk production, formulation, preparation of media and technology) was continued to strengthen the production departments linking directly with product quality. As a result, the second clinical tests were made with the approval by the Ethics Committee that is one of the NRA functions and the high safety and validity of QA functions was verified. POLYVAC acquired the second approval for sale in December 2009 and the approval certified that the GMP system configuration and operation was qualified.

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

The SOP which is required for GMP at minimum was prepared in an appropriate manner, and reviewed and revised as necessary, and operated. However, the counterparts were guided to the method and concept of preparing the SOP which the expert made up as a sample in the work in Japan for better understanding of those. As the result of developing those method and concept, the SOP that was prepared by POLYVAC has increase to a bulky volume and it is necessary to examine its contents in detail from the viewpoint of quality assurance. POLYVAC is also making continuous efforts to standardize the description of the SOP and promote its common use. It is necessary to revise it by additions and corrections in referring to the SOP documents in the actual production field and enhance the perfectness of the SOP.

(6) Conduct technical transfer on preparation of documents that need to meet Vietnam-GMP, which has met WHO-GMP standard, and to be approved by NRA in the Socialist Republic of Vietnam.

Continued from the year of 2006 (the first year), the QA manual, the GMP standard documents (including GMP management rules, documentation control rules, production control, sanitation control and quality control) and the GMP procedures (including anomalies and deviations procedure, self-checking procedure, change control procedure, and education and training procedure) were prepared by QA department and the gaps between the descriptions and the actual works were checked through the simulated field inspection as a follow-up work, and the guidance to necessary revisions was provided until the transfer of the minimum technology was completed. After completion of this Project, it is necessary for POLYVAC to always improve these documents by reflecting its own experience and achievements on those in order to enhance the perfectness.

3.4 List of Products

The list of products from fiscal 2006 (first year) through 2009 (fourth year) is included in the Appendix.

4. Input

4.1 Summary of Input

The input outline includes the dispatch of experts, provision of equipment, acceptance of trainees 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 light and heat expenses, provision of land and facilities by the Vietnam side. The list of counterpart staff members is included in the Appendix.

4.2 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 vaccine production had high expertise in a wide rage. For example, the quality control test was divided into biology, chemistry, zoology and animal breeding, for which it was necessary to dispatch individual experts. The names of experts dispatched for 4 years in this Project and their works are listed in Table 5-1 below.

Table 5-1 List of Experts and Works

NO.	Name	Work Description	Description of Work
1	Setsuo ARAI	Project Manager	General management of the entire Project
2	Shuzo ISHIKAWA	Project Sub-Manager/Engineering	Sub-management of the Project/Guidance of Engineering
3	Tomio LEE	Project Sub-Manager/Vaccine Production Control (1)	General guidance of vaccine production
4	Keiko SASAKI	Vaccine Production Control (2)	General guidance of vaccine production
5	Shigemitsu HIRAYAMA	GMP/Validation	General guidance of GMP/validation
6	Hideo OKUMA	Organizational Management (1)	Dispatch control, personnel, general affairs and accounting
7	Miki TAMURA	Organizational Management (2)	Dispatch control, personnel, general affairs and accounting
8	Fumitoshi SATO	Bulk production (1)	General guidance of vaccine bulk production
9	Shinji NAKAJIMA	Bulk production (2)	Guidance of vaccine bulk production
10	Hiroki KATSUDA	Bulk production (3)	Guidance of validation and bulk production
11	Kazunori MIYAGAWA	Final production (1)	General guidance of final vaccine production
12	Shuuichi BABA	Final production (2)	Guidance of freezing and drying
13	Nobuyuki IHARA	Final production (3)	Guidance of calibration and validation
14	Kenichi BABA	Quality control (1)	Guidance of physicochemical experiments on vaccines and injection
15	Fumio YOSHIDA	Quality conrol (2)	Guidance of biological experiments on avian germ cells and virus suspension solution
16	Kazue SAIJO		
17	Rikio OIKAWA	Quality control (3)	Guidance of animal breeding control
18	Chiharu YOSHINO	Quality control (4)	Guidance of animal vaccination tests
19	Yukio HISASHIMA	Quality control (5)	Guidance of physicochemical experiments on vaccines and injection
20	Shigenobu URAYAMA	Quality control (6)	Guidance of animal vaccination tests
21	Mitsuo NAOI	Media preparation	Guidance of liquid medication and production water control
22	Takanori NAKASHIMA	Quality control (1)/ GMP/validation (2)	Guidance of quality control and GMP/validation
23	Tetsuo NAKAYAMA	Quality control (2))	Medical and clinical consultation on vaccines
24	Shuzo ISHIKAWA	Facility validation technology (1)	General guidance of validation of facilities
25	Yasuji MATSUMOTO	Facility validation technology (2)	Guidance of validation of air conditioning
26	Atsushi SHIBATA	Facilty validation technology (3)	Guidance of validation of air conditioning
27	Hirohisa KAJIOKA	Equipment validation technology (1)	Guidance of validation related to production water
28	Haruo HIROSE	Equipment validation technology (2)	Guidance of validation related to vial cleansing and sterilization equipment
29	Yasuo TAKAMORI		
30	Keisuke SUZUKI	Equipment validation technology (3)	Guidance of filling machine related validation
31	Toshiki YAMANOUCHI	Equipment validation technology (4)	Guidance of validation of freezing and drying equipment
32	Yoshihiko KASUYA		
33	Shigeru IWAMI		
34	Yukihiro MOTOKI	Equipment validation technology (5)	Guidance of validation related to laminar flow and clean bench
35	Kaoru TOMIYAMA	Equipment validation technology (6)	Guidance of validation related to sterilization equipment
36	Kaname HIROSE	Equipment calibration (1)	Guidance of calibration of all types of equipment
37	Takaya BAN	Equipment calibration (2)	Guidance of calibration of all types of equipment
38	Yasuaki TADA	Equipment calibration (3)	Guidance of calibration of all types of equipment

5.2 Dispatch of Experts

The achievements of dispatch of experts for 4 years are shown in Table 5-2 below. For the details, refer to the Appendix attached hereto.

Table 5-2 Dispatch Record of Experts

NO.	Fiscal Year	Number of Dispatches	Dispatched persons/day	Remarks
1	2006 (1st year)	55	1,486	Jul.2006-Mar.2007
2	2007 (2nd year)	70	1,573	Apr.2007-Mar.2008
3	2008 (3rd year)	49	862	Apr.2008-Mar.2009
4	2009 (4th year)	31	475	Apr.2009-Mar.2010
	Total	205	4,396 (147 persons/month)	

6. Counterpart Training

6.1 Outline of CP training

In the fiscal year of 2006, the training for the “anti-body titer measuring technology” was conducted to 2 members of Quality Control Department for a period of 2 months from January 2007 at the Kitasato Institute for Life Science.

In fiscal 2007, the training for “general GMP/valuation” and “general quality control” was conducted to one member of Quality Assurance Department and one member of Quality Control Department, two members in total for a period of one month from February 2008 at the Kitasato Institute, Research Center for Biologicals.

No training in Japan was conducted in fiscal 2008, but the training in the same level as the JICA training in Japan was conducted to 3 members of Engineering Department, one member of Procurement Department and 2 members of Administration Department, 6 members in total at the Kitasato Institute, Research Center for Biologicals under Vietnam’s own budget.

In fiscal 2009, a one-month training course starting September from 14 was conducted as a service contract by the Kitasato Institute, Research Center for Biologicals. In this training, the Deputy Managers of the Bulk Production Department and Final Production Department received training in the production technologies relevant to them respectively, in moth- and rat-proofing technology and in the management of their staff, equipment and materials.

Totally, 12 POLYVAC staff members were trained in Japan during the implementing period of this Project.

6.2 Participants of the Training

The list of participants stating participant names, details of training, training periods is attached hereto as Appendix.

7. Provision of Equipment and Equipment for Experts

7.1 Provision of Equipment

The equipment for this Project was provided once in 2006 as the calibration and validation equipment was procured by JICA Vietnam Office. The total equipment cost was approximately 21 million yen. For the details, refer to the Appendix attached hereto.

7.2 Equipment for Experts

For three years from 2006 to 2008, the equipment for calibration and validation was procured by the Kitasato Institute under the Work Outsourcing Agreement. The total equipment cost for 3 years amounted to approximately 12.5 million yen. In fiscal 2009, no equipment was carried to Vietnam. For the detail, refer to the Appendix attached hereto.

8. Operational Cost in Vietnam

8.1 Outline of Operational Cost in Vietnam

The contract amount for the fiscal year of 2006 (first year) amounted to 5,318,000 yen for the period of 8 months from the start of this Project in July 2006 to March 2007. The settled amount at the end of the fiscal year was 5,171,000 yen, approximate to the originally estimated amount.
The contract amount for the fiscal year of 2007 (second year) was 7,889,000 yen for the period of 11 months from April 2007 to March 2008. The settled amount at the year end was 7,031,000 yen, approximate to the originally estimated amount.
The contract amount for the fiscal year of 2008 (third year) was 6,668,000 yen for the period of 11 months from April 2008 to March 2009. The settled amount at the year end was 6,446,000 yen, approximate to the originally estimated amount.
The contract amount for the fiscal year of 2009 (fourth year) was 7,682,000 yen for the period of 11 months from April 2009 to March 2010. The settled amount at the year end was 6,367,000 yen due to the strong Japanese yen. The balance came to 1,315,000 yen. However, the final amount will be determined when the report on the contract amount settlement has been approved.

8.2 Operational Cost in Vietnam

The detailed operational costs in Vietnam are summarized in the List of Achievements by Fiscal Year as attached hereto.

8.3 Work-related Items

The approval and authorization services related to the measles vaccine produced in this Project were undertaken by the NRA. In Vietnam, 4 agencies: Drug Administration of Vietnam (DAV), Department of Science and Training (DST), Vietnamese Administration of Preventive Medicine (VAPM) and National Institute for Control of Vaccine and Biologicals (NICVB) are responsible for 6 approval and authorizations functions (marketing authorization and licensing activities, GMP regulatory inspection, authorization/approval of clinical trials, laboratory access, NRA lot release, and post-marketing activities including surveillance of adverse events following immunization (AEFI)). At this moment, it is reported that only 3 of these functions were operational. Authorization by 2 committees, the Ethics Committee and the Licensing Committee, is required by the NRA, but the problem of conflict of interests between the members of the two committees has been pointed out by WHO, and they are receiving guidance from WHO.
For the exportation of measles vaccines made by POLYVAC, it is necessary to acquire prequalification from WHO. However, it is an important requirement that the NRA acquire the

accreditation from WHO before POLYVAC makes the application to WHO for prequalification. Therefore, the Ministry of Health should strengthen the function of the NRA as quickly as possible in order to obtain the accreditation from WHO.

9. Ideas and Lessons Learned f in Implementing the Project

9.1 Ideas in Implementing the Project

The Output 1 “Improvement of Production Technology” and the Output 2 “Compliance with GMP Standard” were the most important issues for “measles vaccine production in compliance with the VN-GMP standard” like the two wheels of a car. It was a high goal line to be reached for 4 years to fully satisfy all the requirements for introduction of equipment, various validation works, building of GMP documentation system and education and training of related staff, transfer of operating technologies in all production processes, building of the quality assurance system, and conducting of clinical tests (out of the activity range of this Project), in order to acquire the production capacity to cover the domestic demand in Vietnam.

This Project was a technical cooperation project of work outsourcing type called for self-responsibility and self-completion, and all the study members were short-term experts without any work coordinator. Therefore, this Project was operated in giving the consideration to the following important points:

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.
2) To make the steady management of the entire Project (formulation and sure execution of the detailed plans, monitoring of progress of daily works, appropriate evaluation and timely execution of countermeasures, etc.)
3) To consider that the counterparts have the ownership and independent spirits as the weekly meetings and 8 working groups operated by them.
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. Specifically, preparation by the experts of a “Table of Technology Transfer Management Results” as shown in the Appendix, in order to define the technology transfer items and the technical level of the content of the technology. Also the preparation and translation into the Vietnamese language of the training materials necessary for each item in the technology transfer. Technical instruction is then given through repeated off-the-job and on-the-job training. In addition, a Certificate is issued to counterparts who reach a given level in the final evaluation of the technical instruction and submitted to the QA of POLYVAC. It is then confirmed by the Kitasato Institute and POLYVAC that the technology transfer has been completed successfully.

9.2 Lessons Learned

(1) Importance of communications between Japanese experts and Counterparts

In the communications between Japanese experts and PLYVAC staff members, there were surely some cases such as difficulty in understanding of technical terms due to difference in languages, but the textbooks in Vietnamese language were prepared on the initiative of Japanese experts later. In particular, these materials served for the technical guidance which was made without difficulty at the sites where no translator could enter. The POLYVAC staff side held the English and Japanese conversation courses independently for smooth communications between both sides.

(2) Building of Accurate Progress Control System

In this Project, many meetings were held from the start of the Project, including daily experts coordination meetings, morning and evening briefing assemblies and weekly meetings with POLYVAC members (183 weekly meetings were held until the end of February 2010), and monthly experts meetings in Japan. These meetings made great contribution to the smooth progress of the Project as well as common use of outputs and information and decision making. The weekly meeting and morning and evening briefing assemblies were continued by POLYVAC staffs independently and effectively even when no experts were present. Thus, the effect on building the system appeared after the end of this Project.

(3) Activity system considering ownership and independent spirits

In this Project, POLYVAC launched 8 working groups necessary to make the activities to meet the progress of the Project under the recommendations of the experts from the first year. The leader and sub-leader of each working group to make its activity were selected out of the POLYVAC staff members, and the leader had the initiative of holding meetings, solving problems and promoting the common use of information among various related departments keeping pace with the progress of the Project. The Japanese experts were absolutely keeping the standpoint of giving advice to the POLYVAC staffs to foster their spirit of ownership.

As described above, it is obviously important to “manage the Project accurately” in implementing the human development project. The technologies that they acquired in the Project may be easily scattered and lost unless those technologies are sustained and developed.

9.3 Tasks Remaining

POLYVAC is a young organization that has just been set up and is completely lacking in experience. Many tasks still remain for POLYVAC to become independent, technically and financially, as an internationally competitive vaccine manufacturer. What POLYVAC itself has to continue to tackle is the improvement of the capacity of its QA staff, providing them with repeated in-house training in GMP, preparing and revising GMP-related documents as and when necessary, producing volumes of

vaccines in accordance with the GMP through the efforts of all the staff members, and taking measures necessary for the reduction of production costs, for the improvement of the response to anomalies and deviations, and for the stable procurement of raw and other materials in accordance with GMP. In particular, it is important to hold discussions with the Ministry of Agriculture and Rural Development regarding multiple sources for the procurement of specific pathogen-free (SPF) eggs which is the most important raw material, and to work to make possible the importation of SPF eggs from countries even if it is reported that poultry in the countries are infected with the highly-pathogenic avian influenza (H5N1).

However, the inexperienced POLYVAC could not deal with these situations only through its own efforts. Without the assistance from Japan, it will be very hard to achieve such goals as the further improvement of the capacity of QA staff, changing validations to reduce costs, and acquisition of prequalification from WHO to ensure the export of vaccines.

On the other hand, it is necessary for the Vietnam Ministry of Health to continue the procurement of measles vaccine from POLYVAC. It is also desirable to enhance the procurement rate of domestically produced vaccines as far as is feasible. It is necessary for the Ministry of Health to continue to provide financial support until POLYVAC can cover operating costs, production facility and equipment maintenance costs and the cost of consumables from the income from sales of measles vaccine. It is also necessary to strengthen the ability of the NRA to acquire prequalification from WHO as quickly as possible in order to ensure that it will be possible in the future to export the measles vaccine produced by POLYVAC.

10. Revision of PDM

10.1 Outline of PDM Revision

The revision of the PDM (Project Design Matrix) was proposed by the Vietnamese side at the second meeting of the Joint Coordination Committee (JCC) which was held in September 2007 and the PDM was officially revised at the third JCC meeting held on the occasion of the mid-term evaluation in December 2007 and the second edition was issued officially.

10.2 Details of PDM Revision

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

(1) Addition and change of indicators for the Project purpose

1) The scale and frequency of vaccine production were indicated in numerical values.
2) The GMP did not specify the vaccine product itself, but related to all the production processes and quality control system. Therefore, it was described more accurately.

(2) Addition and change of indicators for outputs of the Project

1) To indicate it as clearly as possible that the technology transfer was made actually, the number of those main members of the staff selected by POLVAC who reached a given technical level in the technology transfer was adopted as the indicator.
2) The preparation of the SOP and other documents for equipment maintenance and control of raw materials and the appropriated management of those documents were added as indicators.
3) The indicator to show that the activities to attain the Output 2 complied with the GMP was also added.

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) Evaluation of the progress and achievement level of the Project
3) Approval of the work schedule and work plans (draft) of the Project
4) Others

(2) Members

The Committee was presided by the President of POLYVAC and the following members participated in it:

1) Project Director (POLYVAC President)
2) Project Manager from Kitasato Institute
3) Representative of Ministry of Public Health
4) Representative of Vietnam EPI
5) Representative in charge of NRA function
6) Representative of JICA Office in Vietnam
7) Representative of WHO Office in Vietnam
8) An official of the Japanese Embassy or staff members of related organization who may attend the Committee meeting as observers.

11.2 Records of JCC Meetings

JCC was held 5 times in total including once per year and once in the fiscal year of 2007 (the second year) when the mid-term evaluation was conducted. The achievements for 4 years are shown in Table 11.1 below. For the details, refer to the Appendix attached hereto.

Table 11.1 Record of JCC Meetings

No.	Fiscal Year	Date of Meeting	Main Participants
1	2006 (first year)	September 28, 2006	Deputy Resident Representative of JICA Office in Vietnam, Official of the Japanese Embassy, Assistant Director of International Corporation Department, Ministry of Health, Representative of Vietnam EPI, Vice President of NICVB, Official in charge of EPI - WHO Office in Vietnam, Project Manager of Kitasato Institute, etc.
2	2007 (second year)	September 20, 2007	Resident Representative of JICA Office in Vietnam, Official of the Japanese Embassy, Vice Minister of Ministry of Health, Director of International Cooperation Department, Director of Drug Administration Department, NICVB President, Project Manager of Kitasato Institute, etc.
3	2007 (second year)	December 19, 2007	Resident Representative of JICA Office in Vietnam, Mid-term Evaluation Study Team, Official of the Japanese Embassy, Assistant Director of International Cooperation Department of Ministry of Health, Representative of Vietnam EPI, Project Manager of Kitasato Institute, etc.
4	2008 (third year)	September 26, 2008	Deputy Resident Representative of JICA Office in Vietnam, Official of the Japanese Embassy, Vice Minister of Ministry of Health, Director of International Cooperation Department, Project Manager of Kitasato Institute, etc.
5	2009 (fourth year)	November 13, 2009	Resident Representative of JICA Office in Vietnam, Project Terminal Evaluation Study Team, Director of International Cooperation Department of Ministry of Public Health, Representative of WHO Office in Vietnam, Project Manager of Kitasato Institute, etc.
	Total 5 times		

Appendices

(1) Dispatch of Experts (F2006 – F2009)
(2) Counterpart Training (F2006 – F2009)
(3) List of Provided Equipment (F2006)
(4) List of Equipment for Experts (F2006 – F2008)
(5) List of Operational Cost in Vietnam (F2006 – F2009)
(6) PDM Revised Edition (2nd Edition)
(7) JCC Minutes of Meetings (1st – 5th meetings)
(8) List of Products
(9) List of Counterparts
(10) Table of Technology Transfer Management Results and List of Certificates Issued

(1) Dispatch of Experts
(F2006 – F2009)

Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production

DISPATCHED RECORD OF EXPERTS

Rev: 3 ***As of 20 Mar. 2007***

No.	Name of Expert	Responsibility	Total days Plan	Total days Actual
1.	Setsuo ARAI	Project Manager	10	10
2.	Shuzo ISHIKAWA	D. PM/Engineering	120	90
3.	Tomio LEE	D. PM/Product Manager-1	60	60
3-1.	Tomio LEE	Final Production	0	16
4.	Keiko SASAKI	Product Manager-2	30	30
5.	Shigemitsu HIRAYAMA	GMP/Validation-1	30	7
5-1.	Shigemitsu HIRAYAMA	Final Production	0	25
6.	Takanori NAKASHIMA	GMP/Validation-2	0	38
6-1.	Takanori NAKASHIMA	Final Production	0	31
7.	Hidoe OKUMA	Organization Management	10	10
8	Shinji NAKAJIMA	Bulk Production-2	30	34
9	Kazunori MIYAGAWA	D. Product Manager/ Final Productio-1	128	122
10	Shuichi BABA	Final Productio-2	105	0
11	Nobuyuki IHARA	Final Productio-3	15	15
12	Kenichi BABA	QC-1	60	70
13	Fumio YOSHIDA	QC-2	90	115
14	Rikio OIKAWA	QC-4	36	26
15	Mitsuo NAOI	Medium Preparation	71	71
16	Tetsuo NAKAYAMA	QA-2	7	7
17	Shuzo ISHIKAWA	Facilities Validation	0	39
18	Hirohisa KAJIOKA	Process Water Validation	15	15
19	Haruo HIROSE	Vial Washing and Sterilization Validation	15	11
20	Keisuke SUZUKI	Filling Machine Validation	15	15
21	Toshiki YAMANOUCHI	Freeze Drying Machine Validation	15	15
22	Kaoru TOMIYAMA	Steam Sterilization Machine Validation	7	7
23	Mr. Song	Freeze Drying Machine Engineer		
Daily Total		Plan	869	879
		Actual		
Total Days		Plan	869	(1486)
		Actual	879	(1486)

No.	Name of Expert	Responsibility	Total days Plan	Total days Actual
1	Mr. Ishikawa		30	60
2	Dr. Lee		30	30
3	Mr. Hirayama		45	41
4	Mr. Nakashima		0	86
5	Mr. Miyagawa		82	90
6	Mr. Shuichi BABA		45	0
15	Mr. Ihara		60	41
7	Mr. Baba K		30	42
8	Mr. Yoshida		60	84
9	Mr. Naoi		34	34
10	Mr. Ishikawa		60	21
	Mr. Hirohisa KAJIOKA		15	0
	Haruo HIROSE		15	0
	Keisuke SUZUKI		15	0
	Toshiki YAMANOUCHI		15	0
	Yukihiro MOTOKI		30	0
	Kaoru TOMIYAMA		21	0
11	Mr. Kaname HIROSE		0	21
12	Mr. Takaya BAN		0	21
13	Mr. Sato F		15	26
14	Mr. Shinji Nakajima		15	0
16	Mr. Oikawa		0	10
Daily Total		Plan	617	607
		Actual		
Total Days		Plan	617	(1486)
		Actual	607	(1486)

Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production

Yearly Schedule in FY2007 (2nd Year)

Date; 10-Mar-2008

Rev- 24

Legend; ; Confirmed Schedule ; Plan ; This application

No.	Description	PIC	Grade	Apr 2007				May 2007				Jun 2007				Jul 2007				Aug 2007				Sep 2007				Oct 2007				Nov 2007				Dec 2007				Jan 2008				Feb 2008				Mar 2008				Total days				Total Trips				Remarks
				1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	1W	2W	3W	4W	Plan	Actual		Total △	Plan	Actual		Total △	
Work Schedule	General	JCC																						9/20																				TET															
		Intermediate Evaluation (JICA)				★19 Apr. Contract to Begin the Project																																																				
		Clinical Trial																																						Clinical Trial →																		Up to May?
	Final Production	+Calibration				Protocol			Execution																																																
		+HVAC Validation					Protocol			Execution																																															
		+Formalin Fumigation										☆	☆	☆				☆		☆		☆			☆				☆				☆				☆				☆				☆				☆									
		+ PQ									Protocol				PQ, Execution																																										
												◎Non St. PQ						◎St. PQ																																										
		+ MFT																		MFT ①		MFT ②③																																						
		+ PV																										① Stability test Data collect/arrange				② Stability test Data collect/arrange				③ Stability test Data collect/arrange																								
		+Lyophilizer Test	+Optimization					Preparation				Optimization																																													
			+ Scale UP																																							Scale up 10,000⇒30,000Vial/Batch																	
	Bulk Production	+ PQ																																																						
		+ MFT (For Bulk Production Only)																																																						
		Project Manager	Arai	2																				9/18 6 9/23														12/11 10 12/20																16	16		0	2	2		0	
		Deputy PJ Mger /Engineering	Ishikawa	3						5/27 0 12 6/07				6/25 34				7/28				9/03		34			10/06							11/26				27		12/22		1/7 27			2/2			2/27 24 12		3/9						146	146		0	5	5		0	
		Deputy PJ Mger /Production Manager (1)	Lee	3			4/23	13	5/5							7/18 13 14		7/31						9/13	13	9/25		10/08	13	10/20						12/08	13	12/20			1/13	13	22	2/3											78	88		10	6	6		0	
		Production Mger (2)	Sasaki K	4																				9/18	10	9/27																														10	10		0	1	1		0	
		GMP/Validation (1)	Hirayama	3			4/22	15	5/6																	9/25	20	11	18	10/12	10/21	18	20	25	11/14																						53	58		5	3	3		0	Kansai AP
		Administration Mger (1)	Okuma	5																				9/18	6	9/23																														6	6		0	1	1		0	
		Administration Mger (2)	Tamura	5							6/4 9 6/12													9/18	6	9/23												12/11 7 12		12/22																22	27		5	3	3		0	
		Bulk Production (1)	Sato	5					5/14				62			7/14				8/13			27		9/08								11/26				27	5	48		1/17						27	0							143	137		-6	4	3		-1	
		Bulk Production (2)	Nakajima	5																												27	0											48	0												75	0		-75	2	0		-2	
		Bulk Production (3)	Katsuda	6					5/14	41	34	6/16																													12/26			48	35	40	2/3		2/18	0	20	3/8					89	94		5	2	3		1	
		Final Production (1)	Miyagawa	5			4/23		48		6/9					7/09				34	48	8/25								10/15				34	48	12/01					1/7	27	5	27	2/7											143	171		28	4	4		0	
		Final Production (2)	Baba S	5					5/14	20	6/02					0 7 7/08	7/14					9/03	0 13	9/15						10/23		13	20	11/11																							33	60		27	2	4		2	
		Final Production (3)	Ihara	5				4/30	20	5/19						7/16	11	7/26																								1/7	0	21	1/26												31	52		21	2	3		1	
		Quality Control (1)	Baba K	5			4/23		34	5/26						7/16	20	8/04											20 0																											74	54		-20	3	2		-1	
		Quality Control (2)	Yoshida	5					5/14		48		6/30				7/30	62	27	17	8/25								10/22		20	34	39	11/29	12/10	0	34	1/12																	130	138		8	3	4		1	
		Quality Control (4)	Yoshino	5						5/28	19	18	6/14																	10/22		12	27	32	11/22																						31	50		19	2	2		0	
		Quality Control (5)	Hisashima	5						6/04	13	6/16																																														13	13		0	1	1		0	
		Quality Control (6)	Urayama	5						5/28	19	18	6/14																																													19	18		-1	1	1		0	
		Medium Preparation	Naoi	5							6/11			34	41		7/21										10/01	20	13	10/13																			1/21 0 13		2/2						54	67		13	2	3		1	
		Quality Assurance (1) /GMP/Validation (2)	Nakashima	3			4/22		27	5/18	6/03	27	34	41		7/13	8/05		27		8/31			9/25		27	32	10/25				11/18		27		12/14			1/13	20	15	1/27			2/24	27	13	3/7					182	182		0	7	7		0	Kansai AP
		Quality Assurance (2)	Nakayama	3																								10/10 10 7 10/16						10 0					1/27	10	8	2/3												30	15		-15	3	2		-1	
		Facilities Validation (1)	Ishikawa	4			4/23		34	5/26																																														34	34		0	1	1		0	
HVAC		Facilities Validation (2)	Matsumoto	5					5/13	21	22	6/03																																													21	22		1	1	1		0	Kansai AP
HVAC		Facilities Validation (3)	Shibata	5					5/13	21	22	6/03																																													21	22		1	1	1		0	Kansai AP
P Water		Equip Validation (1)	Kajioka	5																11 0																																					11	0		-11	1	0		-1	
Vial Washing		Equip Validation (2)	Takamori	5							5/28	13	6/09																																													13	13		0	1	1		0	
Filling		Equip Validation (3)	Suzuki	6																11 0																																						11	0		-11	1	0		-1	
Freeze Drying		Equip Validation (4)	Yamanouchi	5																	11 0																																					11	0		-11	1	0		-1	
Freeze Drying		Equip Validation (4)	Iwami	5																		9/04 11 9/14																																						0	11		11	0	1		1	Kansai AP
Freeze Drying		Equip Validation (4)	Kasuya	5																		9/05 0 11 9/15																																						0	11		11	0	1		1	
Laminar		Equip Validation (5)	Motoki	5							5/21	20	6/9																																													20	20		0	1	1		0	
Autoclave		Equip Validation (6)	Tomiyama	5																			11 0																																		11	0		-11	1	0		-1	
Calibration (1)		Equip Calibration (1)	Hirose	5							5/17 21 9 5/25																																															21	9		-12	1	1		0	Kansai AP
Calibration (2)		Equip Calibration (2)	Ban	6						5/06	21	20	5/25																																												21	20		-1	1	1		0	Kansai AP
Calibration (3)		Equip Calibration (3)	Tada	5						5/12	0	9	5/20																																												0	9		9	0	1		1	Kansai AP
																																																							1573	1573		0	70	70		0	
																																																						Plan	Actual		Total △	Plan	Actual		Total △	
																																																						100.0%				100.0%			

Dispatch Schedule of Expert

Project for Strengthening Capacity for Measles Vaccine Production (3rd Year)

Dispatch Plan of Experts

Rev-15
10 February 2009

Legend; ; Confirmed Schedule ; Plan ; This application

No.	Category		Description	PIC	Class	Schedule (Apr 2008 – Mar 2009)	Total days Plan	Total days Actual	Total days △ Present	Total days △ Total	Total Trips Plan	Total Trips Actual	Total Trips △ Present	Total Trips △ Total	Remarks
1	General / Event	General	JCC			9/26; TET									
			WHO HQ/WPRO												
			Clinical Trial			Clinical Trial Process									
		All Dept.	+Calibration			Preparation & Protocol; Execution (Bulk⇒Medium⇒QC⇒Final)									
			+HVAC Periodical Validation			Preparation & Protocol; Execution (Bulk⇒Medium⇒QC⇒Final)									
		Medium &QC	Retrospective Validation	Water (WFI, PS, UFW)		Execution									
				Environmental Monitoring		Execution									
		Final Production	+ Re-PQ Validation (Including QC and Medium)			Preparation & Protocol; Execution									
			+ MFT (Lot Size 5,000Vials)			Preparation & Protocol; MFT Pre.; MFT ①; MFT ①									
			+ PV (Lot Size 30,000Vials)			Preparation & Protocol; PV① PV② PV③									
			+Lyophilization Test	+ Scale UP		Preparation & Protocol; 10,000⇒30,000Vial/Batc; ①Placebo; ②Active; Scale up No.3; Scale up No.4; Scale up No.5 and No.6									
		Bulk Production	+ Re -PQ Validation			Preparation & Protocol; Execution									
			+ PV			Preparation & Protocol; PV ①; PV②; PV③									
2	Management		Project Manager	Arai	2	9/23 6 9/28	6	6	0	0	1	1	0	0	
			Deputy PJ Mger /Engineering	Ishikawa	3	6/2 20 6/21; 6/30 20 7/19; 9/8 27 34 10/11; 11/10 20 11/29; 1/29 20 11 2/8; 2/22 13 15 3/08	120	120	0	0	6	6	0	0	
			Deputy PJ Mger /Production Manager (1)	Lee	3	5/26 13 6/7; 8/17 13 7 8/23; 9/14 13 15 9/28; 12/24 21 25 1/17	60	60	0	0	4	4	0	0	
			Production Mger (2)	Sasaki K	4	9/23 10 10/2	10	10	0	0	1	1	0	0	
			Administration Mger (1)	Okuma	5	9/23 6 9/28	6	6	0	0	1	1	0	0	
			Administration Mger (2)	Tamura	5	4/23 11 5/3; 9/23 11 10 10/2; 2/25 11 11 3/07	33	32	-1	-1	3	3	0	0	
			GMP/Validation (1)	Hirayama	3	6/22 13 7/4; 8/12 13 8/24; 10/21 13 18 11/07	39	44	5	5	3	3	0	0	
3	QA/GMP		Quality Assurance (1) /GMP/Validation (2)	Nakashima	3	5/4 34 6/6; 7/20 27 8/15; 9/28 27 10/24; 11/23 27 13 12/5; 1/4 13 20 1/23; 2/8 13 20 2/27	141	141	0	0	6	6	0		
			Quality Assurance (2)	Nakayama	3	6/3 7 6 6/8; 9/22 7 6 9/27; 1/14 7 9 1/22	21	21	0	0	3	3	0	0	
4	BP		Bulk Production (1)	Sato	5	7/13 41 28 8/9; 10/5 41 21 10/25; 20 0	102	49	-53	-53	3	2	-1	-1	
			Bulk Production (2)	Katsuta	6	8/25 34 27 9/20; 10/22 34 25 11/15	68	52	-16	-16	2	2	0	0	
5	FP		Final Production (1)	Miyagawa	5	9/1 27 9/27; 12/24 20 25 1/17	47	52	5	5	2	2	0	0	
			Final Production (2)	Baba S	5	5/12 13 14 5/25; 6/30 0 27 7/26; 13 0; 10/6 0 13 18 10/23	26	59	33	33	2	3	1	1	
			Final Production (3)	Ihara	5	5/5 13 5/17; 12/08 13 12/20	26	26	0	0	2	2	0	0	
6	QC		Quality Control (1)	Baba K	5	12/15 13 12/27	13	13	0	0	1	1	0	0	
			Quality Control (2)	Saijo	5	6/30 27 7/26; 10/27 20 11/15	47	47	0	0	2	2	0	0	
			Quality Control (6)	Urayama	5	8/14 11 15 8/28	11	15	4	4	1	1	0	0	
7	MP		Medium Preparation	Naoi	5	11/17 13 11/29	13	13	0	0	1	1	0	0	
8	Validation / Engineering	Facilities General	Facilities Validation (1)	Ishikawa	4	4/15 34 5/18	34	34	0	0	1	1	0	0	
		HVAC(1)	Facilities Validation (2)	Matsumoto	5	5/4 13 6 5/9	13	6	-7	-7	1	1	0	0	
		HVAC(2)	Facilities Validation (3)	Shibata	5	5/4 13 20 5/23	13	20	7	7	1	1	0	0	
		Freeze Dryer(1)	Equip Validation (1)	Iwami	5	13 0; 10/6 0 13 18 10/23	13	18	5	5	1	1	0	0	
		Freeze Dryer(2)	Equip Validation (2)	Kasuya	5	10/6 0 13 18 10/23	0	18	18	18	0	1	1	1	Additional
9	Summary						862	862	0	0	48	49	1	1	
							Plan	Actual	△ Present	△ Total	Plan	Actual	△ Present	△ Total	
								100.0%				102.1%			

Project for Strengthening Capacity for Measles Vaccine Production (4th Year)

Dispatch Plan of Experts in FY2009

Rev-16
25 Feb. 2010

Legend; Confirmed Schedule (red line); Plan (dotted line); This application (magenta line)

No.	Category		Description	PIC	Class	Schedule (Mar 2009 – Mar 2010, 1W–4W)	Total days Plan	Total days Actual	Total days △ Present	Total days △ Total	Total Trips Plan	Total Trips Actual	Total Trips △ Present	Total Trips △ Total	Remarks
1	General / Event	General	+ Final Evaluation / JCC No.5			Final Evaluation/JCC No.5 (Nov 2009); TET (Feb 2010)									
			+ 2nd Clinical Trial(CT-2)			Approval by NICVB; Approval by EC; 2nd Clinical Trial (Bridging Study); Report; Approval by EC									
			+ Marketing License(ML-1 and 2)			1st Marketing License; Expected 2nd Marketing License									
			+ WHO HQ/WPRO			Final Assessment									
			+ Application for WHO Pre Qualification (POLYVAC)			Application									
		All Dept.	+Calibration												
			+HVAC Periodical Validation												
		Common	+ Periodical Validation	Water (WFI, PS, UFW)											
				Environmental Monitoring											
		Final Production	+ PV (Lot Size 30,000 vials)			PV②; PV③; PV④; PV (WFI); QC Results									
			+ Actual Production (Lot Size 30,000 vials from Imported bulk)			300									
			+ Packaging and Shipping (Doses)			300; 300; 900									
			+ MFT (Lot Size 5,000 vials) Change control			Preparation & Protocol; MFT									
			+ Actual Production (Lot Size 30,000 vials)			Production ①; ②; ③; ④; ⑤									
		Bulk Production	+ MFT (PST)												
			+ Re -PQ Validation/Calibration, etc.												
			+ Actual Production (For 30,000 vials)			16/3 to 8/4 ①; 29/4 to 26/5 ③; 8/7 to 4/8 ⑥; 9/9 to 6/10 ⑨; 06/11 to 03/12 ⑫; 1/4 to 28/4 ②; 13/5 to 9/6 ④; 29/7 to 25/8 ⑦; 23/9 to 20/10 ⑩; 20/11 to 17/12 ⑬; 27/5 to 23/6 ⑤; 26/8 to 22/9 ⑧; 21/10 to 17/11 ⑩									
2	Management		Project Manager	Arai	2	11/8 8 11/15	8	8		0	1	1		0	
			Deputy PJ Mger /Engineering	Ishikawa	3	4/15 20 5/4; 5/20 5 5/24; 9/7 13 9/19; 10/27 20 11/15; 1/25 20 16 2/9; 2/22 13 12 3/5	86	86		0	5	5		0	
			Deputy PJ Mger /Production Manager (1)	Lee	3	8/17 13 8/29; 11/2 20 18 11/19; 1/4 13 17 1/20	46	48		2	3	3		0	
			Production Mger (2)	Sasaki K	4	1/31 7 2/6	7	7		0	1	1		0	
			Administration Mger (1)	Okuma	5	11/8 8 11/15	8	8		0	1	1		0	
			Administration Mger (2)	Tamura	5	11/8 11 11/18	11	11		0	1	1		0	
			GMP/Validation (1)	Hirayama	3	6/22 13 7/4; 8/24 20 13 9/5; 11/16 13 11/28	20	39		19	1	3		2	
3	QA/GMP		Quality Assurance (1) /GMP/Validation (2)	Nakashima	3	5/17 20 13 5/29; 7/20 13 8/1; 13; 9/21 13 20 10/10; 13; 12/7 13 20 12/26	85	66		-19	6	4		-2	
			Quality Assurance (2)	Nakayama	3	9/17 11 9 9/25	11	9		-2	1	1		0	
4	BP		Bulk Production (1)	Sato	5	5/11 20 5/30	20	20		0	1	1		0	
			Bulk Production (2)	Katsuda	6	5/23 20 6/11	20	20		0	1	1		0	
5	FP		Final Production (1)	Miyagawa	5	5/10 7 5/16; 10/12 20 10/31; 3/3 11 3/13	27	38		11	2	3		1	
			Final Production (3)	Ihara	5	6/29 20 7/18	20	20		0	1	1		0	
6	QC		Quality Control (1)	Baba K	5	5/3 7 5/9	7	7		0	1	1		0	
			Quality Control (2)	Saijo	5	7/20 27 8/15	27	27		0	1	1		0	
7	MP														
8	Validation / Engineering	Facilities General	Facilities Validation (1)	Ishikawa(NS)	4	5/25 34 6/27	34	34		0	1	1		0	
		Process Water	Equip Validation (1)	Kajioka (Organo)	5	6/21 7 6/27	7	7		0	1	1		0	
		Freeze Dryer	Equip Validation (2)	Iwami (IMA Edwards)	5	5/25 20 6/13	20	20		0	1	1		0	
9	Summary						464	475		11	30	31		1	
							Plan	Actual	△ Present	△ Total	Plan	Actual	△ Present	△ Total	
								102.4%				103.3%			

(2) Counterpart Training
(F2006 – F2009)

LIST OF COUNTERPART TRAINING IN JAPAN

Updated on 10/3/2010

No.	Full name	Position	Purpose of Training	Period	Expense source	Name and address of overseas partner
1	Ms. Tran Thi Bich Hanh	Staff of QC	Antibody serum	18/1-17/3/2007	JICA	Kitasato University, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
2	Ms. Pham Anh Thu	Staff of QC	Antibody serum	18/1-17/3/2007	JICA	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
3	Ms. Nguyen Thuy Huong	Vice Manager of QA Dept.	Training about quality assurance and verification of Vaccine quality	2/4-3/5/2008	JICA	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
4	Ms. Nguyen Nu Anh Thu	Vice Manager of QC Dept.	Training about quality control and verification of Vaccine quality	4/2-5/3/2008	JICA	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
5	Mr. Nguyen Dang Anh	Manager of Engineering Dept.	Training about maintenance, operation of equipment and trouble shooting	18/7-2/8/2008	Vietnamse side	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
6	Mr. Nguyen Manh Dung	Staff of Engineering Dept.	§ Training about maintenance, operation of equipment and trouble shooting	18/7-2/8/2008	Vietnamse side	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
7	Mr. Cao Minh Duc	Staff of Engineering Dept.	§ Training about maintenance, operation of equipment and trouble shooting	18/7-2/8/2008	Vietnamse side	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan

8	Ms. Dang Bich Lien	Staff of Accounting Department	Confirm copyright system and supervise accounting system	18/7-2/8/2008	Vietnamse side	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
9	Ms. Nguyen Thi Thanh Mai	Vice Manager of Accounting Department	Confirm copyright system and supervise accounting system	18/7-2/8/2008	Vietnamse side	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
10	Mr. Tran Trong Hai	Staff of Material and Planning Department	Training about system of controlling inventory and buying material	18/7-2/8/2008	Vietnamse side	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
11	Mr. Ta Kim Quoc	Vice Manager of Final Production Department	Reconfirm technique transferred by experts. Learn the way of management and working in KI	13/9-10/10/2009	JICA	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan
12	Mr. Ha Hoang Phuong	Vice Manager of Bulk Dept.	Reconfirm technique transferred by experts. Learn the way of management and working in KI	13/9-10/10/2009	JICA	Kitasato Institute, 6-111 Arai, Kitamoto shi, Saitama 364 -0026, Japan

(3) List of Provided Equipment
(F2006)

List of Provided Equipment in Vietnam by JICA in F2006

Date : 14 Sept 2009

Prepare by : Hai (procurment) ; Thu (QA)

No.	Date	Code No.	Name of Equipment	Brand Name	Model No.	Q'ty	POLYVAC dept.
1	**F2006**	A-1	Vibration Meter	Rion - JP	VM-63A	1	Engineering
2		A-2	Sound Level Meter	Rion - JP	NL-20	1	Engineering
3		A-3	Stopwatch	Seiko - JP	SVAE-997	1	Engineering
4		A-4	Thermo-Hygro Recorder	T&D - JP	TR-72U	30	Engineering
5		A-5	Aerosol Generator	TSI - USA	3079	1	Engineering
6		A-6	Mist Generator	Shiro - JP	SCM-2000	1	Engineering
7		A-7	Particle Counter	Rion - JP	KC-01E	1	Engineering
8		A-8	Gas Detector Set	Gastec - JP	GV-100S	2	Engineering
9		A-9	Gas Mask	Shigematsu - JP	GM-165	2	Engineering
10		A-10	Gap Torque Meter	Imada - JP	DTX-2	1	Engineering
11		A-11	Spectrophotometer	Themo Electron - EN	Helios Gamma	1	Engineering
12		A-12	Measuring Tape	KDS - JP	GL-12-30	1	Engineering
13		A-13	Digital Strobosope	A&D - JP	DT-2239A	1	Engineering
14		A-14	Electric Balance	A&D - JP	GX-200	1	Engineering
15		A-15	Digital Surface Themometer	TES - Taiwan	TES-1304	1	Engineering
16		A-16	Low Temperature Water	Eyela - JP	PSL-1800	1	Engineering
17		A-17	Standard Thermometer	Sato - JP			Engineering
		A-17-1	Standard Thermometer (-50 ÷ 0 degC)	Sato - JP	No-0022	1	
		A-17-2	Standard Thermometer (0 ÷ 50 degC)	Sato - JP	No-0022	1	
		A-17-3	Standard Thermometer (50 ÷ 100 degC)	Sato - JP	No-0022	1	
		A-17-4	Standard Thermometer (100 ÷150 degC)	Sato - JP	No-0022	1	
18		A-18	Hygrometer	Sato - JP	7450-60	1	Engineering
19		A-19	Multifunction Calibration	Yokogawa - JP	CA-71	1	Engineering
20		A-20	Weight Calibration				Engineering
		A-20-1	Weight Calibration (20kg)	Troemner LLC - USA	7508-F2PW	1	
		A-20-2	Weight Calibration (10kg)	Troemner LLC - USA	7509-F2PW	2	
		A-20-3	Weight Calibration (1kg)	Troemner LLC - USA	7513-F2PW	1	
		A-20-4	Weight Calibration (500g)	Troemner LLC - USA	7514-F2PW	1	
		A-20-5	Weight Calibration (100g)	Sansho - JP	61-1173	1	
		A-20-6	Weight Calibration (20g)	Sansho - JP	61-1171	2	
		A-20-7	Weight Calibration (10g)	Sansho - JP	61-1170	2	
		A-20-8	Weight Calibration (5g)	Sansho - JP	61-1169	2	
		A-20-9	Weight Calibration (2g)	Sansho - JP	61-1168	2	
		A-20-10	Weight Calibration (1g)	Sansho - JP	61-1167	2	
		A-20-11	Weight Calibration (100mg)	Sansho - JP	61-1164	2	
21		B-1	Intergrity Tester	PALL		1	Medium
22		C-1	Spare Parts				Engineering
		C-1-1	Thermocouple for Sakura Atuclave (Type T)	Okazaki - JP		80	Engineering
		C-1-2	Thermocouple for Sakura Atuclave (Type K)	Okazaki - JP		15	Engineering
		C-1-3	Thermocouple for Airtech Japan (Type K)	Okazaki - JP		16	Engineering
		C-1-4	Thermocouple for BOG Edward (Type T)	Okazaki - JP		60	Engineering
23		C-2	Hybrid Recorder	Yokogawa - JP	DR232-12-00	2	Engineering
24		D-1	Sensor Fitting	Sakura SI - JP		3	QC,Bulk,Final
25		E-1	Temperature Calibrator	JOFRA/ AMETEK - DENMARK/EU	ITC-320A	1	Engineering
26		E-2	Pressure Calibrator	JOFRA/ AMETEK - DENMARK/EU	CPC-200CBXXG	1	Engineering

No.	Date	Code No.	Name of Equipment	Brand Name	Model No.	Q'ty	POLYVAC dept.
27		F-1	Accessories for Freeze Dryer				Final
		F-1-1	Tray	Suzuki - JP		2	Final
		F-1-2	Frame (Size(mm): W391 x D565.5 x H28.5)	Suzuki - JP		1	Final
		F-1-3	Frame (Size(mm): W391 x D557 x H30)	Suzuki - JP		79	Final
		F-1-4	Loading Bar	Suzuki - JP		2	Final
28		G-1	Tank Tansporter	Ikemoto - JP	ESB - 5	1	Final

(4) List of Equipment for Experts
(F2006 – F2008)

List of Equipment for Experts (FY 2006-FY 2008)

Date : 14 Sept 2009

Prepare by : Hai (procurment) ; Thu (QA)

No.	Date	Code No.	Name of Equipment	Brand Name	Model No.	Q'ty	POLYVAC dept.
1	**F2006**	CE-0601	Tank Transporter	Ikemoto - JP	ESB-5	2	Final
2		CE-0602	Package Leak Tester	Takachino Seiki - JP	PLT-3021FX	1	Final
3		CE-0603	CO2 gas Analyzer	Bacharach - US	11-9026	1	Final
4		CE-0604	Flange for Tank for Bulk	Shirai	Special	3	Final
5	**F2007**	CE-0701	Digital temperature indicator	Ametek	DTI-1000	1	Engineering
6		CE-0702	Pipe Heater	As-one	Type B	3	Bulk
7		CE-0703	Pressure resistance and ezplosion-proof type electric power pumps	SHOEI	HC-100	1	Bulk
8		CE-0704	Electric handy pump-1	KYORITUKIKO	HP-601	1	Medium
9		CE-0705	Electric handy pump-2	KYORITUKIKO	HP-701	1	Medium
10		CE-0706	Electronic balance for guinea pig	METTLER TOLEDO	XS-400S	1	QC
11		CE-0707	Electronic balance for mouse	METTLER TOLEDO	XS-802S	1	QC
12		CE-0708	Printer	METTLER TOLEDO	RS-P42	2	QC
13		CE-0709	Dry block temperature calibrator	AMETEK	ITC-155A	1	Engineering
14		CE-0710	Anemometer	KANOMAX	6541/6543	1	Engineering
15		CE-0711	Micro manometer	HALSTRUP KRONE COMPANY	KAL 84	1	Engineering
16		CE-0712	Particle counter	HACH ULTRA ANALYTICS	237B	1	Medium
17		CE-0713	Aerosol generator	KANOMAX	TDA-4B	1	Engineering
18	**F2008**	CE-0801	Portable Generator	KAME	KDE25T3D	1	Engineering
19		CE-0802	Oil Bath	EYELA	OHB-2000S	1	Engineering
20		CE-0803	Heater controller	Hakko	DGC2150	3	Bulk
21		CE-0804	Weight for Calibration	Sartorius	YCW553-00, YCW613-00,	1	Bulk
22		CE-0805	Industrial Scales w/Weight	Sartorius	FBG64EDE-S	1	Medium
23		CE-0806	Automatic Homogenizer	Nihomseiki Kaisha, Ltd	ED-3	1	QC

(5) List of Operational Cost in Vietnam (F2006 – F2009)

List of Operation Cost in Vietnam

1. FY2006(First Year)

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)−(B)
Personnel Cost	3,415,494	3,163,511	251,983
Maintenance/Management for Equipment Cost	62,808	67,939	▲ 5,131
Consumables Cost	496,500	480,083	16,417
Communication/Transportation Cost	124,960	128,483	▲ 3,523
Rental Fee	1,055,336	1,152,377	▲ 97,041
Miscellaneous Cost	163,396	188,159	▲ 24,763
Sub Total	5,318,494	5,180,552	137,942
Adjustment	▲494	▲494	
Total	5,318,000	5,180,000	138,000
Final Adjustment	**5,318,000**	**5,171,000**	**147,000**

2. FY2007(Second Year)

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)−(B)
Personnel Cost	5,420,542	4,804,437	616,105
Maintenance/Management for Equipment Cost	89,540	56,304	33,236
Consumables Cost	528,000	510,255	17,745
Communication/Transportation Cost	227,920	169,517	58,403
Rental Fee	1,579,160	1,468,139	111,021
Miscellaneous Cost	44,400	23,100	21,300
Sub Total	7,889,562	7,031,752	857,810
Adjustment	▲562	▲562	
Total	7,889,000	7,031,190	857,810
Final Adjustment	**7,889,000**	**7,031,000**	**858,000**

3. FY2008(Third Year)

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)−(B)
Personnel Cost	4,230,672	4,370,287	-139,615
Maintenance/Management for Equipment Cost	70,070	14,760	55,310
Consumables Cost	460,625	415,042	45,583
Communication/Transportation Cost	440,860	314,018	126,842
Rental Fee	1,466,630	1,333,338	133,292
Miscellaneous Cost	0	0	0
Sub Total	6,668,857	6,447,445	221,412
Adjustment	▲857	▲857	
Total	6,668,000	6,446,000	222,000
Final Adjustment	**6,668,000**	**6,446,000**	**222,000**

4. FY2009(Fourth Year)

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)−(B)
Personnel Cost	5,717,503	4,604,437	1,113,066
Maintenance/Management for Equipment Cost	24,485	7,840	16,645
Consumables Cost	391,875	432,017	-40,142
Communication/Transportation Cost	300,960	210,129	90,831
Rental Fee	1,247,730	1,114,707	133,023
Miscellaneous Cost	0	0	0
Sub Total	7,682,553	6,369,130	1,313,423
Adjustment	▲553	▲553	
Total	7,682,000	6,368,000	1,314,000
Final Adjustment	**7,682,000**	**6,367,000**	**1,315,000**

However, the balance after the appropriation to the fee of dispatch of expert was 348,000 yen.

(6) PDM Revised Edition
(2nd Edition)

Appendix 2 Project Design Matrix (PDM) (Version 2) **Date: December 19, 2007**

Project title: Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production **Project Duration: 4 years, from March 24, 2006**

Target Area: The Socialist Republic of Vietnam **Target group: Children in the Socialist Republic of Vietnam (focus on those under 5 years old)**

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumptions
Super Goal **The health status of the children in the Socialist Republic of Vietnam is improved.**	・ Infant mortality rate in the Socialist Republic of Vietnam	Ministry of Health	
Overall Goal **Measles Infection Rate in the Socialist Republic of Vietnam will be decreased from the current level.**	・ Rate of children infected with measles in the Socialist Republic of Vietnam. ・ Number of children immunized with measles vaccine in the Socialist Republic of Vietnam.	Ministry of Health	・Public Health activities in the Socialist Republic of Vietnam is strengthened. ・The vaccine is licensed by NRA.
Project Purpose **POLYVAC will be capable to produce necessary amount of measles vaccine for use of measles control activities in the Socialist Republic of Vietnam complying with Vietnam-GMP which has met WHO-GMP standard.**	1.Measles vaccines are produced in POLYVAC at a rate of 300,000 doses x 25 batch (i.e. 7,500,000 doses)/year. 2.Clearance on the Production and quality management by NRA which has met WHO-GMP	Ministry of Health, NRA(NICVB) POLYVAC WHO	・ EPI activities will be sustained and enhanced.
Outputs			
1 Staff of POLYVAC acquires appropriate technical skill to produce quality measles vaccine.	1-1 Number of Staff in POLYVAC who get technical training to reach a sufficient technical level (i.e. level 4 * for staff categorized as A)for measles vaccine production. *level 4 : be able to work by themselves and could train others 1-2 Standard Operating Procedure (SOP), equipment maintenance list, equipment inventory and other necessary documents for operation and maintenance of the facilities and production equipment by POLYVAC shall be prepared. 1-3 Details on equipment, apparatus, raw materials, spare parts and consumables are properly administrated and inventory is properly managed.	Ministry of Health POLYVAC	・ GMP inspection will be done by NRA.
2 Production and quality management meet Vietnam-GMP which has met WHO-GMP standard.	2-1 Performance Qualification (PQ) and Process Validation (PV) are executed as scheduled. 2-2 Validation complying with VN-GMP is conducted periodically by POLYVAC. 2-3 GMP documentation complying with VN-GMP is prepared. 2-4 SOPs complying with VN-GMP are prepared and production process is done according to the SOPs.	WHO Ministry of Health, NRA(NICVB) Records of production, quality control, validation, maintenance of equipments and facilities, and quality assurance of POLYVAC	

Activities	Inputs		
1 Staff of POLYVAC acquires appropriate technical skill to produce quality measles vaccine.	**Japan**	**Vietnam**	・Trained Staff will not leave POLYVAC.
1-1 Conduct technical transfer on bulk, filling, freeze-dry through the process of producing vaccine from the imported bulk. 1-2 Conduct technical transfer on production of bulk vaccine through the processing of producing bulk vaccine from the seed virus. 1-3 Conduct technical transfer on proper operation of mass production (7.5 million doses/year) of the measles vaccine. 1-4 Conduct technical transfer on quality control of the products. **2 Production and quality management meet Vietnam-GMP which has met WHO-GMP standard.** 2-1 Conduct PQ/PV for vaccine production from bulk vaccine. 2-2 Conduct PQ/PV for vaccine production from seed virus. 2-3 Establish validation system for the production and strengthen the validation skill of the staff. 2-4 Establish and implement quality assurance functions complying with Vietnam-GMP which has met WHO-GMP standard. 2-5 Prepare and implement necessary SOP for the process of production, storage, carrying in/out of the products, etc. 2-6 Conduct technical transfer on preparation of documents that need to meet Vietnam-GMP which has met WHO-GMP standard and to be approved by NRA in the Socialist Republic of Vietnam.	***Experts*** (1) Chief Advisor / Vaccine Production (2) Bulk Production (3) Medium Preparation (4) Final Production (5) Quality Control (6) Management of Experimental Animals (7) Quality Assurance (8) GMP (9) Validation (10) Facility Management ***Other necessary fields.*** ***Full-time project staff*** (1)Secretary (2)Interpreter ***Training in Japan*** (1)Production management (2)Quality management ***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. ** The equipment to be provided will be subjected to change due to the budgetary conditions of the Japanese side.* ***Local cost*** (1)Training textbooks, and materials (2)General expenses of the project office	***Counterpart officers*** (1) Director (2) Vice Director (Production Management) (3) Vice Director (Quality Management) (4) Chief of WHO-GMP license ***Full-time project staff*** (1)Production Unit Staff (2)Quality Management Unit staff (3)Engineering Staff ***Equipment and materials*** (1)Project Office facilities (2)Stationary (3)Cosumables for Vaccine Production ***Local cost*** (1) Vaccine Bulk (2) Maintenance for equipment	**Pre-conditions** NRA of Vietnam including NICVB will be functioning according to WHO recommendation. The policy of promotion on measles elimination programme will be sustained.

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

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

Rev.-0

(Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production)

Minutes of Joint Coordinating Committee (JCC)

No.1 (First) Conference

-Date & Time : 28 September 2006, 09h30-12h10

-Place : Conference Room on 3rd Floor, Polyvac

-Attendance : See the attached list

Minutes

1. **Dr. Hien,** Director of Polyvac, opened the meeting and introduced participants and presented the content of meeting.

2. **Dr. S. Arai,** Project Director of Kitasato Institute, explained the Inception Report prepared by Japanese side in brief, especially the background to set up the project, objectives and outcomes. The indicators for the outcomes shall be discussed and confirmed in the next JCC meeting.

3. **Dr. Lee,** Deputy Project Director of Kitasato Institute, introduced measles vaccine production process, the contents of technology transfer in brief and its implementation schedule. And the latest update on project progress was presented as follows;
   (1) Coordinating meeting:
   - In Japan: Already organized the first and second meeting
   - In Hanoi: Already organized 11 weekly meetings

   (2) Dispatch of Experts: The actual days are 520/572 expected days (achieve 91% of monthly plan at the end of Sept., 2006)
   (3) Studied freeze drying process: Already carried out 4 tests and test number 4 already passed the requirement of WHO.
   (4) Set up documents system: Is being implemented.
   (5) Set up material order system: Is being implemented

   Dr. Hien: Dr. Lee already made the report in detail about the general plan of the project including 2 programs, 1st program is the process for final production from imported bulk and 2nd program is all of the process from imported SPF egg to the final production using measles seed virus of Kitasato

Institute. Polyvac would ask the authorities concerned for the licensing of above 2 kinds of products.

4. The opinions from participants and comments on discussion

(1) **MA. Giang Huong,** Deputy Director of International Relationship Dept., Ministry of Health (MOH), expressed her happiness participating in the first JCC meeting of technical cooperation project for strengthening capacity for measles vaccine production (the project) in Vietnam. On behalf of MOH and Polyvac, she would like to show deep gratitude to Japanese government and Kitasato Institute for helping Vietnam to build the latest measles vaccine production building in South East Asia. For Vietnam, there are also a lot of works to do, especially in the coming time, would cooperate with Japan and Polyvac for assistance and provide the solution to the arising problems. MOH would try the best to create good condition for the articles in the project to be implemented in time. One more time, thanks for the help of government and people of Japan for Vietnam in general and for MOH in particular. Thanks JICA and WHO. At the same time, kindly requested all the institutions to try more to help Vietnam self produce measles vaccine satisfying the requirements of WHO. Wished all the participants to have good health and wish the project to be successful.

(2) **Mr. Yasuhiro TOJO,** Senior Deputy Resident Representative of JICA Vietnam office, expressed the gratitude about the start of this project and the arrival of the Japanese experts to Vietnam on behalf of JICA Vietnam office. JICA is expecting that this project will be implemented according to the schedule. In that sense, the project management in the next few months will be important, and above all, procurement of validation equipments will be crucial for the technical transfer and the entire project management accordingly. He said it would be appreciated that Vietnamese Government could reconsider the situation and give the project approval at their soonest, which is followed by submitting A4 form. JICA will make necessary follow-up on this if it is necessary.

(3) **Mr. Nguyen Van Quang,** Financial & Planning Dept., MOH, informed that during this year, already submitted 4 projects with capital 1 million USD/ one project including this project. This project is submitted to government with urgency On 25 Sept. Ministry of Plan and Investment (MPI) already sent the official document to Office of Prime Minister and hope that the Prime Minister would approve officially in the short coming time. By the way, he also promised to speech up the project to get Approval soon. Mr. Quang mentioned item 5 in the section 3 of

draft to the meeting. The item carried out by Vietnamese government. MOH would cooperate with Polyvac for reasonable adjustment and supply 5.4 billions VND of corresponding capital for buying consumable materials. MOH also submitted A4 form to MPI relating to A4 form also, Mr. Quang kindly requested JICA to consider the form whether there is any change prior to the submission by MPI to Government for approval.

Dr. Hien: Kindly requested Mr. Quang to show the procedures to receive material and equipment?

Mr. Quang: Both lists of equipment and A4 form were already submitted for approval. When goods comes to Vietnam, Polyvac would write the aid confirmation for duty free, in order to avoid being kept in store for too long time, kindly requested Japanese side to inform Vietnamese side for procedures to confirm the aided goods to MOH for duty free.

Dr. Hien: Aid capital, 5.4 billion VND shall be used to buy some chemicals, consumable materials and some equipment of Animal lab. However, in order to operate, it is necessary to have budget to pay for consumption of electricity, water and maintenance and kindly requested all sides to consider for help, relating to this matter.

(4) **Mr. Son,** Equipment Department, MOH, presented that I was very happy to listen to the speech about the project. We also took part in writing the draft and setting up this project, for the progress of project approval, Mr. Quang already gave information that the documents were already submitted to Prime Minister for approval. Focusing on the corresponding project of Vietnam: He promised to strengthen cooperation in all aspects as well as about the way to use corresponding capital of MOH. He said that previously, he also was an advisor for Polyvac to submit the list of equipment which needs being bought to MOH and he knew about this project very clearly. He said that he would cooperate with each side to implement the project in time.

Dr. Hien: Thanks Mr. Son for his enthusiastic help to Polyvac in approval of estimated expenses in past and hoped that in the coming time, Mr. Son would help Polyvac more.

(5) **Professor, Dr. Do Si Hien,** Head of National EPI, On behalf of National EPI of Vietnam, thanked Japanese government and JICA for help of National EPI of Vietnam during the past time to implement the immunization for Vietnamese children. With the great help of Japanese government, Vietnam already eliminated poliomyelitis. Vietnam is trying the best to control measles in 2010 with valuable help of Japan. For using measles vaccine and measles control in the year of 2010 means that only less than one child among 1 million Vietnamese people gets measles and only less than 83 measles case among 83 million people. In Vietnam, after control

of measles, it is necessary to have some more years to eliminate this disease, which means it is very necessary to produce measles vaccine and it is important to know the way to use vaccine.

Dr. S. D. Hien also expressed that du to the difficulties in measles vaccine availability for past 4 months, Vietnamese children have not been immunized with measles vaccine and in the afternoon of 29 Sept., 2.3 million doses of measles vaccine were imported into Vietnam. If measles vaccine were produced in Vietnam, National EPI would not have had the difficulties like this. He also showed his worry on the schedule of project, which sets that in 2010 Vietnam to be capable of integrated producing 7.5 million doses of measles vaccine, would mean that National EPI suffers from the similar difficulties in measles vaccine import in next 4 years. He suggested that it is necessary to consider speeding up measles vaccine production progress so that Vietnam could self control vaccine supply to help measles immunization program for Vietnamese children.

Dr. Arai presented that in Japan, at this moment there were many cases of measles infection not due to the poor quality of measles vaccine because these children just get only one dose of measles immunization. For this reason, Japanese government already decided that in the coming time, Japanese children would be provided for 2 dose measles immunization. He believed that if Vietnamese children were provided for 2 measles vaccine immunization, Vietnam would soon control measles epidemics.

Dr. Lee, for KI, we would try our best to speed up the measles vaccine production in Vietnam. In order to achieve the purpose, PQ and PV must be implemented in time.

Dr. Hien, from the time of the project implementation, weekly, monthly and annual working schedule of all the Depts. are always cooperated well with Kitasato Institute for implementation. Every Monday, Polyvac has a meeting for unification and problem solution. Every Thursday, Polyvac has meeting with Kitasato Institute to share the problem and cooperate to solve the schedule and find the solution for remaining problems. Dr. Hien also pointed out one very important thing relating to the issue of Approval of product. In order to have Approval of product, it is necessary to do clinical test. According to schedule, Polyvac must have 2 clinical tests and apply for Approval for products twice.

(6) **MA. Le Hieu,** Training and Science Dept., MOH, presented that at this time, MOH already issued one direction for Vaccine clinical test and biological product according to direction of ICH and WHO. Measles vaccine clinical test must be followed to that direction. Procedure and clinical test consideration would be done by Science Council of MOH and based on this result,

MOH would approve the test. Kindly requested Polyvac to follow the procedures for clinical test application promptly.

Dr. Hien replied that Polyvac would have a meeting for detailed discussion of this problem. Relating to a draft of the protocols of clinical test that was already prepared, Polyvac was asking opinions from KI experts and after that would submit these documents to MOH.

Relating to the issue of approval, kindly request MA Hang to give ideas

(7) **MA. Hang,** Preventive Medical Dept., MOH, presented that Approval issue must follow the regulation adhered to the decision of the year 2003. There would be an assessment committee to check the quality in the laboratory in the approval application process. The professional experts would consider the documents relating to vaccine and then submitted to advisory council for consideration and approval issue. In the approval issue process, we would cooperate with Function Dept. as well as submitted the necessary documents to help Polyvac to have approval soon.

Dr. Hien showed great gratitude to the help of MA. Hang to Polyvac in the approval application of capacity and hoped that Polyvac would receive help in the first and second approval of applications.

(8) **Dr. Hong,** Cencobi, presented that Cencobi already validated capacity of Polyvac in IQ and OQ period, in April 2006 as in time of commitment with manufacturer and already have procedures to be submitted to MOH, kindly requested manufacturer to complete the documents (the documents need being translated into Vietnamese), and kindly requested Polyvac to complete the documents in time of PQ and PV. In the report of Dr. Lee, Polyvac already did 4 freeze drying tests and the forth result already passed the requirement of WHO. In order to do PQ, Polyvac must write protocols. Representative of Cencobi already promised to accept PQ documents for consideration and validation soonest and after that would issue the approval for quality, which is one important step of approval issue of MOH.

Dr. Hong informed that at this moment Cencobi already sent two staff to Japan to study measles vaccine validation. Regarding to functions of Cencobi, Cencobi already applied for official submission including the clinical test for Vaccines, which were imported the first time to Vietnam. The clinical test of new imported vaccine would be done by MOH. Normally after consideration of clinical test, there would be a Science Validation Council of documents and submitted to Science Council of MOH for consideration.

Dr. Hong also expressed her wish that Polyvac would cooperate closely with Cencobi so that upon having result of clinical test, Polyvac can receive Approval.

(9) **Dr. K. Tsukamoto,** Medical Officer of WHO Vietnam Office, presented that WHO would directly assist Cencobi because Cencobi would validate Vaccine quality for Polyvac. WHO would try their best to help Cencobi so that Polyvac would receive the approval. He promised to try his best to help Polyvac to produce Measles Vaccine the soonest, for this reason, Vietnam can eliminate Measles.

(10) **Mr. T. Okada,** the first Secretary of Japanese Embassy, presented that Japanese government always used a lot of aid in the health sector of Vietnam, he is very optimistic of this project. He also expressed the effect of this project and clear purpose of this project is one of the important points to persuade Japanese government to aid this project.

5. Conclusion of Meeting

Dr. Hien summarized the contents given in the meeting.

Representative of Polyvac committed that they would focus all their effort for the success of the project, and at the same time, Polyvac also requested for continued help from relating parties.

The first JCC meeting has been closed successfully. Dr. Hien thanked for the attention of participants and declared that the meeting finished.

Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production

Minutes of Joint Coordinating Committee (JCC)

No.2 (Second) Conference

-Time : 9h30-12h30 Date : 20/Septmeber/2007

- Location : Conference Room, Measles vaccine production facilities – Center for Research and Production of Vaccines and Biologicals – No. 418 Vinh Hung, Thanh Tri, Ha Noi

- Attendant: (Name list attached)

Agenda & Discussions

1. Dr. Nguyen Dang Hien opened the meeting and introduced the guests and agenda of the meeting.
2. Mr. Nakagawa, Resident Representative of JICA Vietnam office congratulated all concerned on the achievements of the project. He also assured that JICA will continue to extend enthusiastic support to make the project successful.
3. Dr. Cao Minh Quang, Vice Minister of MOH made a speech. The Vice Minister thanked the Japanese Government for assistance in public health in general and for Measles Vaccine production project in particular. This project was implemented according to the strategy of public health of Vietnam. On behalf of MOH management board, the Vice Minister congratulated the achievements of the project and expressed his belief that the project was on schedule. Furthermore, the Vice Minister stressed some points which he believed that Polyvac had to do to make the project successful. The Vice Minister clarified that he had already reminded relevant Departments and offices to be committed as Japanese Side to make the project successful.
4. Dr. S. Arai, Project Director, Kitasato Institute reported on overall summary of project.
5. Dr. T. Lee, Deputy Project Director, Kitasato Institute reported on validation result: performance validation stage (PQ) and Medium filling test (MFT).
6. Mr. S. Ishikawa, Deputy Project Director, Kitasato Institute assessed the progress of the project very roughly from PDM point of view.
7. Opinion of attendants of JCC meeting:

(1) Dr. Nguyen Dang Hien- Director of Center for Research and Production of Vaccines and Biologicals, discussed some upcoming works of the project and about difficulties in project implementation process and some issues which need to be discussed:

- Proposed to add some more criteria (Indicator) to evaluate project of PDM, to further enhance evaluation and project implementation.
- Japan International Coordinated Agency (JICA) and Vietnamese government will carry out a mid-term evaluation of the project.
- Asked permission to produce 3 lots of Measles Vaccines from Imported Bulk supplied by Kitasato Institute to carry out clinical trial, the first lot was planned to commence production in Oct. 2007 and to complete production in Nov. 2007. Kindly requested relevant partners to organize clinical trial and carry out it as soon as possible.

- According to plan, the centre would receive clean SPF eggs from China in 2006, bird flu epidemic broke out in many countries including China, and therefore, the centre had already engaged to receive eggs from one company in Germany. Due to extreme distance in transportation, quality of egg was not reliable. Rate of decayed eggs during transportation was up to 30%, affecting the production process and final Measles vaccine price. The centre already had a reporting session with Dr. Truong Quoc Cuong – Director General of Pharmaceutical administration department of Ministry of Health (MOH) about this problem and proposed MOH to find a solution, so that the centre could take effective action to secure SPF egg source for production.
- Expense for operating Measles Vaccine production facilities is the biggest difficulty during project implementation. Up to now, MOH had already helped and supported a lot to make project to be implemented according to proposed process. Expected in August 2008 permit for release of Measles vaccine would be issued which would put the vaccine into circulation in the market and create a source of income for the centre. From now till the time the vaccine is permitted to be put into circulation, the centre needs to receive more assistance from MOH for operation expenses of Measles production facilities.

(2) Mr. Rinya Yutani- Embassy of Japan in Vietnam: Japanese side highly appreciates the efforts of the concerned parties in implementing the project. Project was implemented in the right process. In the near future, there would be need to twice ask for permission concerning the product, Therefore, experts of Kitasato Institute and the centre need to have close co-operation and MOH would assist expense to enable the project to proceed properly. This project is a project with clear purpose and Japanese government was committed to support to build Measles Vaccine facilities and the following technical assistance project to transfer vaccine production technology to Vietnamese side. It is hoped that the facilities would soon come into production and supply stable Measles vaccine to protect and take care of health for Vietnamese children.

(3) Pro. Le Van Phuong- Director of National Institute for Control of Vaccines and Biologicals (NICVB) highly evaluated implementation of project. Nearly all objectives stated for this project have already been attained. There are 3 problems, that we have to solve in the future:
- Firstly, Get GMP/VN certificate issued by MOH. NICVB was a consultancy office about profession for MOH. The centre would prepare documents to ask GMP certificate issued by MOH according to resolution No 5405/Q§-BYT dated 31/12/2002.
- Secondly, carry out Measles vaccine clinical trial. Clinical trial documents are drafted according to decision No. 01/Q§-BYT dated11/1/2007.
- Thirdly, asked for permit according to decision No. 4012/Q§-BYT dated 30/7/2003 and circular 08 dated 13/6/2006. The centre needs to be proactive in document preparation and submission to MOH for approval.

(4) Dr. Truong Quoc Cuong , Director General of Pharmaceutical administration department of MOH highly evaluated co-operation of the parties in implementing project and kindly requested the centre to:
- Contact Training and Science Department and prepare documents for permission to carry out clinical trial.

- Contact Pharmaceutical Administration Department of MOH about registration for product release.
- Be proactive in reporting to MOH about experience in clinical trial and expenses for operating Measles Vaccine facilities.

Pharmaceutical Administration Department would direct functional Departments to consider documents and inspect the facilities and then issue the permit. Pharmaceutical Administration Department would have documents to submit to leaders of MOH, so that leader of MOH could direct Training and Science Department to receive clinical trial documents. Pharmaceutical Administration Department already had document to confirm GMP accreditation of the Measles Vaccine Production facilities on 10th Sept. 2007 and official document to Ministry of Agriculture and Rural Development about import of SPF eggs of China, kindly requested the centre to contact Veterinary Department, Ministry of Agriculture and Rural Development about this problem.

On this occasion, he also expressed gratitude to experts of Kitasato Institute for help in technical transfer to enable the project to proceed properly. He kindly requested that Japanese side consider support for realizing domestic production of SPF eggs.

(5) MA Tran Thi Giang Huong – Deputy director of International Co-operation Dept. –MOH expressed pleasure in participating in the Second JCC meeting of Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production. On behalf of MOH and POLYVAC, MA Tran Thi Giang Huong highly evaluated effort of experts in Kitasato Institute in helping and directing Measles production technology for Vietnamese side, so that the project could proceed properly. She confirmed that MOH of Vietnam would expend best efforts to assist completion of the project. One more time, thanked Japanese Government and the Japanese for helping Vietnam in general and MOH in particular, thanked Japan International Cooperation Agency (JICA) and at the same time kindly requested the parties to extend further assistance to the project and help Vietnam self-produce Measles vaccine conforming with WHO criteria and further wished the participants to have good health and wished the project to be successful.

(6) Ms. Junko Sato, Senior Project Formulation Advisor, Japan International Cooperation Agency (JICA) Vietnam office reported on some issues relating to the project:

- JICA delegation will be dispatched to conduct a mid-term evaluation of the project to review its progress, mostly likely in Dec. 2007. JICA will inform the Vietnamese side about the subsequent plans.
- JICA will comment on the proposed indicators after discussing with JICA headquarters in Japan.

(7) Dr. Nguyen Dang Hien, Director of Centre for Research and Production of Vaccines and Biologicals would like to thank direction of Director and in the future the centre would submit official documents to Pharmaceutical Administration Department for assistance in PV inspection, expected in

Nov. 2007 and official document to National Institute for Control of Vaccines and Biologicals in allocating verification of the 3 vaccine lots.

Thanked the personal contribution of Ms. Sato for project and wished her good health and success in life.

8. Conclusion:

Dr. Nguyen Dang Hien summarized discussions of the meeting. Representative of POLYVAC expressed renewed commitment to complete the project and he also requested relevant offices for their assistance. He declared the meeting successful. And he finally thanked the participants and declared the meeting closed.

Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production

Minutes of Joint Coordinating Committee (JCC)

No.3 (Third) Conference

MINUTES OF THE SIGNATURE CEREMONY OF MINUTES OF MEETING OF MID-TERM EVALUATION ON THE TECHNICAL COOPERATION PROJECT FOR STRENGTHENING CAPACITY OF MEASLES VACCINES PRODUCTION IN THE SOCIALIST REPUBLIC OF VIETNAM

- Time : 14h30-16h00 Date : 19th December 2007
- Location : Conference Room, Third Floor, Administration Building, Measles vaccine production facilities – Center for Research and Production of Vaccines and Biologicals – No. 418 Vinh Hung, Thanh Tri, Ha Noi
- Attendant: (Name list attached)

Agenda & Discussions

Content:

1. Dr. Nguyen Dang Hien opened the meeting and introduced the guests and agenda of the meeting.
2. Speech by Representative of Ministry of Health (Mrs. Tran Thi Giang Huong, Deputy Director of International Cooperation Dept.)
3. Speech by Mr. Hiroaki NAKAGAWA – Resident Representative of JICA in Vietnam/ Leader of JICA Mid-Term Evaluation Team.
4. Presentation by Ms. Tomomi IBI – Member of JICA Mid-Term Evaluation Team on Summary Report of Mid-Term Evaluation included contents as: Project Framework, Revision of PDM, Outputs of project and Recommendations included eight items (Refer to the attached files).
5. Attendants discuss on Recommendation items:

(1). Dr. Hien: The first 4 recommendations related to POLYVAC. POLYVAC would implement those items in the remained duration of the project with directions of the Kitasato experts.

(2). Mr. Nguyen Quang An – Deputy Director of Planning and Financial Dept, MOH. stated on the 5th items of Evaluation Report that his Dept. would coordinate with others related Dept. of MOH to grant budget for procurement of raw materials and maintenance of the Measles Vaccine Production Facility.

(3). MA Tran Thi Giang Huong – Deputy Director of International Co-operation Dept. –MOH: MOH had met WHO Vietnam Country office and other Authorities concerned of the Government of Vietnam on round-table conference to bring forward resolution supporting this project. MOH also had sent official document to the Ministry of Agriculture and Rural Development to approve

importing the SPF egg from China but MOH have not received the answer. In coming days, Depts. of MOH would try their best to support the project going in time.

(4). Ms. Nguyen Minh Hang – Vietnam Administration of Preventive Medicine, MOH: The Dept. will issue GMP license, issue the approval for putting Measles Vaccine produced at POLYVAC into circulation according to regulation.

(5). Dr. Hoang Thi Hong – Deputy Director of NICVB: NICVB would conduct a GMP inspection with Measles Vaccine Production Facility – POLYVAC on 24-27th of Dec., 2007. That inspection would follow Vietnam GMP Doc., WHO GMP Doc. (WHO TRS No. 822, 823 and Guide for GMP Inspection). NICVB is also responsible for issuing Quality Certificate for vaccines produced in Polyvac to complete documents for license for product circulation according to regulations of MOH. Mrs. Hong also added that 2 main functions of NICVB are to release and inspect GMP evaluated to be well done by WHO, other functions of NRA relating to clinical trial and license for Vaccine circulation issued by another Dept.s of MOH.

(6). Dr. Sukamoto – Representative of WHO office in Vietnam: WHO would assist NICVB more in implementation of NRA function.

(7). Prof. Dr. Do Si Hien – Director of EPI: The project has been done on progress and achieved proposed target. In order to produce Measles Vaccines in POLYVAC, which are satisfied GMP standard according to target of project, it is time for Vietnam to have NRA to implement all of 6 functions according to regulation of WHO, kindly requested leader of MOH to consider this matter. Vietnam EPI also wishes to receive Measles Vaccine produced by Polyvac satisfying GMP standard with reasonable price.

(8). Dr. Nguyen Dang Hien, Director of POLYVAC: Measles vaccine of POLYVAC is a vaccine produced in the new facility abiding with the GMP standard (both domestic and WHO) may have high cost than other measles vaccines produced in the old facilities even foreign manufactures. There fore, he kindly requested authorities concerned of Vietnamese Gov. consider measles vaccine cost with highly assistance.

(9). Mr. Rinya Yutani – Representative of Embassy of Japan in Vietnam: Thanked Appropriate Authorities of Vietnamese Government for assistance to complete project on progress. To complete the following stage of project, there would be a lot of works relating to MOH, kindly requested MOH to help more.

6. Complete the discussion of attendants

The Minutes of Meetings was signed by Mr. Hiroaki NAKAGAWA – Resident Representative Vietnam Office - JICA, MA. Tran Thi Giang Huong, Deputy Director of International Cooperation Dept.- MOH and Dr. Nguyen Dang Hien Director of POLYVAC with witness of all attendants in the meeting.

Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production

Minutes of Joint Coordinating Committee (JCC)

No.4 (Fourth) Conference

- Time : 10h30-12h45 Date : 26th Sept. 2008
- Location : Conference Room, Third Floor, Administration Building, Measles vaccine production facilities – Center for Research and Production of Vaccines and Biologicals – No. 418 Vinh Hung, Thanh Tri, Ha Noi
- Attendant : (Name list attached)

Agenda & Discussions

1. **Dr. Nguyen Dang Hien** opened the meeting and introduced the guests and agenda of the meeting.
2. **Speech by Mr. YASUHIRO TOJO (Senior Deputy Resident Representative of Jica in Vietnam)**: Congratulates for achievements of the project especially in term of clinical trial of Measles vaccine. At the same time, he also expressed his wish that Vietnamese children will be inoculated in EPI with Measles vaccine produced by Polyvac soonest. By the way, Mr. Yasuhiro TOJO also promised that JICA would try the best to make project successful. However, he also states the following shortcomings of the project:
    i. **About (National Regulation Agency) NRA in Vietnam:** Jica kindly requests Ministry of Health of Vietnam and WHO to co-operate to settle the benefit contradiction of Morals Committee in approving clinical trial and hopes that this problem would be solved before issuing license for Measles Vaccine circulation.
    ii. **About clinical trial of Measles vaccine produced by virus seed:** Kindly request MOH to consider and apply bridging study method in clinical trial for Measles vaccine produced by virus seed.
    iii. **About finance of project:** Kindly request MOH to assist more budgets during the time that Polyvac has not had product for circulation yet.
    iv. Power cut continuously happens, which leads to bad effect to machines, equipment as well as validation result ...ect, kindly request POLYVAC to

find the way to overcome this problem such as buy one more generator for MVPF.

3. **Speech by Dr. Cao Minh Quang (Vice Minister of MOH)**: I would like to thank Japanese Government for assistance in medicine in general and Measles Vaccine production in particular. Strategy of Health Sector of Vietnam is to have Measles Vaccine to control Measles in 2010 and the project has already met our target. On behalf of Management board of MOH, the vice Minister congratulates for achievements of project and is very happy to know that project has gone to right process. Besides, the Vice Minister also gives 4 problems that need discussing by the parties:

   i. Total investment of the project is USD30 million with target to manage to produce Measles vaccine meeting GMP standard of Vietnam and GMP standard of WHO. By the way, we should have strategy to export Measles vaccine. To achieve this target, MOH already registered with government the route to complete 6 functions of NRA in June 2009.

   ii. Speed up training program for POLYVAC staffs to keep Measles vaccine facility on from production to product circulation according to 10 current GMP regulations.

   iii. Arrange budget of MOH for project and have financial mechanism for facility's effective operation after Measles Vaccine Production Facilities goes into official operation.

   iv. Use Measles vaccine in EPI: We are considering whether Measles vaccine is used in EPI or not because it relates to quality and price. This is difficulties and challenge of POLYVAC because we had to compete with many kinds of foreign vaccine. MOH requests POLYVAC to make the report of price calculation, loss compensation rate in price, time for lost compensation as well as quality assurance of vaccine.

4. **Speech by Dr. Arai (Project Director – KI):** Reports overall project briefly, in which he highlights implementation mode of project this year based on result of mid-term evaluation of JICA with purpose that POLYVAC could produce Measles vaccine with GMP/WHO satisfaction and 7.5 million doses of capacity per year for EPI in 2009,

POLYVAC self-runs and manages Measles vaccine according to GMP/WHO. Due to some troubles during implementation of the project, therefore, rate of the progress is two months late than schedule. However, the plan of the whole project will not change.

5. **Speech by Dr. Lee (Project Deputy director - KI):** Makes a speech of detailed plan for project implementation relating to validation of bulk and final production, clinical trial…ect and increasing up to 30,000 vials in Nov. and Dec. 2008. He also explains detail of some troubles slowing down rate of progress of project such as sensor of dry oven is out of order, therefore, must buy the new one; centrifugal gets trouble, therefore, PV1 result does not pass.

6. **Speed by Dr. Dinh Hong Duong (MAM):** Reports result of the first and second phase of Measles vaccine clinical trial briefly. As a result, the trial has been done according to instruction of MOH and initial result of clinical trial and pre-clinical trial is good.

7. **Speed by Dr.Tetsu Nakayama (KI)**: The bridging study is being applied in all over the world to shorten time for clinical trial, however, it still guarantees to meet GMP/WHO standard for Measles vaccine.

8. **Speed by MA Tran Thi Giang Huong (Director of International Cooperation Department of MOH):** Makes a speed of summary of schedule to complete 6 functions of NRA of Vietnam, at the same time, MA Tran Thi Giang Huong also on behalf of MOH commits to assist the project:

i. Drug Administration of Vietnam of MOH is completing document system including instruction of procedure to complete registration documents for vaccine circulation; Standard operation procedure (SOP) about registration for vaccine circulation; manual of quality assurance for registration of vaccine circulation; complete forms and validation reports.

ii. General Department of Preventive Medicine and Environmental Health of MOH will be responsible for supervision after inoculation. The Dept. will co-operate with Drug Administration of Vietnam to direct Inoculation bases to have schedule to intensify supervision of storage and transportation of Vaccine and its quality (on the base to supervise reaction after inoculation and co-operate with quality control).

iii. Science and Training Dept. is responsible for clinical trial. At present, the Dept. is proposing the regulation of medical test by clinical trial and contacts with FDA, United State and International organizations to set up SOP procedure for Morals committee to complete and follow the international instruction about this content.

iv. National Institute for control of Vaccines and Biologicals (NICVB) is responsible for controlling and finishing vaccine. The Dept. has already set up training plan for staffs in term of control technique, vaccine quality check, Labo quality system (LQS), GMP inspectors of Vaccine and Biologicals ect….

9. Opinion of JCC attendants:

a. **Dr. Nguyen Dang Hien- Director of POLYVAC:** Makes a speech of recommendations relating to project implementation:

i. Use vaccine produced by the project: Nov. 2007 POLYVAC already produced 300,000 doses of Measles vaccine from bulk imported from Kitasato Institute in Japan. After clinical trial as well as completing administrative procedure for one new vaccine to request the license for circulation, the expiry period is only 1/3 left (will expire in Nov. 2009), kindly requested MOH and EPI to have schedule in using this vaccine and The Drug Management of Vietnam quickly licenses after POLYVAC applies for license.

ii. Vaccine price: This is the first lots produced by a completely new conveyor, quantity of vaccine is not much, and therefore, price is rather high. Kindly request MOH to assess and approve price to be evidence to supply vaccine for EPI.

iii. This is the third year since the factory started operation, expenses for operation, maintenance, repair, calibration and validation are a lot, hope to have assistance of MOH. In 2008, project is approved to add VND19.5 billion, however, until now POLYVAC has not received yet.

iv. According to plan until end of 2009, vaccine produced from virus seed is just licensed (self production). Until 2010, the factory will just supply vaccine and have source of income and be able to cover all expenses. Kindly requested MOH to assist operation expenses in 2009.

v. During this time due to continuous power-cut, therefore, operation of Measles Vaccine production facilities will be much affected, kindly request POLYVAC to buy one more generator.

b. **MA Nguyen Viet Hung (Deputy Director of Drug administration of Vietnam)** highly appreciates co-operation of the parties in implementing project and answers the problems relating to the Dept. as followed:

i. The Dept. already set up detailed schedule to complete 02 functions including GMP license and inspection of vaccine production facilities.

ii. About proposal relating to production of other vaccines in the production line of Measles vaccine such as mump and rubella, the Drug Administration agrees basically. However, kindly request POLYVAC to set up detailed project to guarantee that there is no contamination.

iii. Kindly request POLYVAC to continue implementing works relating to validation of equipment, sanitation and sterilization...ect.

iv. Usage of 300,000 doses of Measles vaccine for will be reported to Management Board of MOH, however, POLYVAC should quickly complete according to regulation, drug administration Dept. would assist license and registration No. of Measles vaccine.

c. **Mr. Nguyen Van Quang (Financial planning Dept.):** Financial problem including problems of investment and technical assistance projects. Investment project will be completed on 31/12/2008. POLYVAC will work with authorities to settle problems relating to administrative formalities in withdrawing budget for project. About expenses for operation of MVPF in 2009, POLYVAC should have official documents to MOH for detailed statement. Budget for technical assistance project is provided almost sufficiently comparing with requirement budget.

d. **Mr. Rinya Yutani** (Japanese Embassy in Vietnam): Expresses his satisfaction after listening to the report of the parties relating to project implementation as well as speech of Mr. Nguyen Van Quang – Financial Planning Dept. - MOH of budget for project and highly appreciates this effort of MOH. The project is being done according to schedule. He also expresses that he wishes MOH to assist more for project in the coming time.

e. **Dr. Keiko Sasaki (Production manager of project –KI):** Informs the lecture of Measles vaccine on Tuesday, 30/9/2008.

10. **Conclusion:**

Dr. Nguyen Dang Hien summarized discussions of the meeting. Representative of POLYVAC expressed renewed commitment to complete the project and he also requested relevant offices for their assistance. He declared the meeting successful. And he finally thanked the participants and declared the meeting closed.

Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production

Minutes of Joint Coordinating Committee (JCC)

No.5 (Fifth) Conference

- Time : 9h30-12h00 Date : 13th Nov. 2009
- Location : Conference Room, Third Floor, Administration Building, Measles vaccine production facilities – Center for Research and Production of Vaccines and Biologicals – No. 418 Vinh Hung, Thanh Tri, Ha Noi
- Attendant : (Name list attached)

Agenda & Discussions

1. **Dr. Nguyen Dang Hien** opened the meeting and introduced the guests and agenda of the meeting.
2. **Dr. Tran Thi Giang Huong** read the speech of Dr. Cao Minh Quang - Vice Minister of MOH in which the Vice Minister would like to warmly congratulate the success of the project and commend the encouragable achievement of the project. MOH acknowledged and highly appreciated the effort of the two parties taking part in the project, Vietnamese Government, Japanese people and Government in supporting Vietnam to build the Measles Vaccine Production Facilities meeting GMP criteria, coordination of JICA and effective execution of aid of the Japanese in Vietnam. Kitasato Institute already transferred technology in Measles vaccine production for staffs of POLYVAC and especially The Vice Minister already commended all leaders and all staffs of POLYVAC for their effort in overcoming difficulties of the project. On this occasion, the Vice Minister would like to thank for the support of Governmental Office, Ministry of Planning and Investment, relevant Departments and bureaus, EPI to make the project successful. The Vice Minister would like to propose the followings:
   - **For POLYVAC**: To continue maintaining and completing the technology and quality control system to get Pre-qualification of WHO; to research to reasonalize the technology to lower the price of the product. To use modern Production Facilities by researching to produce combined Vaccine including Rubella, Measles and Mum and Flu Vaccine. To set up the plan to evaluate post marketing license. To propose with

MOH and relevant Departments to have mechanism and policies to increase the effect in exploitation of management human resources and technicians for the project.

- **For Drug Administration Department of MOH:** To speed up validation of Measles Vaccine registration (completed in Quarter IV, 2009); Have periodical and sudden plan to check activities of POLYVAC to meet GMP/WHO criteria. To hold and co-operate with relevant Departments, bureaus and Institutes to complete the system and 6 functions of NRA in accordance with internal evaluation plan to invite experts of WHO for evaluation and acknowledgement in quarter I of 2010.
- **For Training and Science Department – MOH**: To instruct POLYVAC to assess the effect of Measles Vaccine after licensing, to be responsible for instructing and supervising this duty of POLYVAC. To propose ministerially technological and scientific duties of 2010 so that POLYVAC could research application of technology in combined vaccine production (Measles and Rubella), MMR (Measles, MUM and Rubella) and flu Vaccine.
- **For Preventative Medicine and Environmental Department and EPI**: To propose with Ministerial leaders about the mechanism so that POLYVAC could provide Measles vaccine for EPI including expense from State beget and foreign aid.
- **For Financial Planning Department – MOH**: Propose the mechanism and prepare the content, so that MOH could discuss with Ministry of Finance about budget and price of Measles Vaccine produced by POLYVAC severed for EPI in 2010 and the following years.
- **For WHO and JICA**: MOH would like to kindly request Japanese Government to continue supporting in technical transfer to implement the second stage of the Project: To set up the plan to assign experts to help POLYVAC to meet the demand in accordance with Pre-qualification procedure of WHO. WHO should have detailed plans to support Bureaus, Department and Institutes of MOH to execute the plan "Pre-qualification" in implementation of 6 NRA functions.

3. Sir Motonori TSUBI, Chief of Representatives of JICA in Hanoi made the speech to congratulate the achievement of the project reported by Final Evaluation Team of JICA, especially congratulated POLYVAC to produce 600,000 doses of Measles Vaccine to provide for EPI and result of phase 3 of clinical trial shows that

immunogeinity of all children immuned by Measles Vaccine produced by POLYVAC is high.

4. **Dr. Arai, Director of the Project**, **Kitasato Institute** would like to make the speech to thank for support of WHO, MOH of Vietnam, relevant authorities of Vietnam, Japanese Embassy and JICA since the project started. Dr. Arai also deeply express admire to Associate Professor and Dr. Nguyen Dang Hien, Director of POLYVAC already faced with a lot of difficulties, deeply understood and upheld the leadership to make the project successful as today.
5. **MA Tran Thi Hong Thuy – Production Manager and Dr. Nguyen Thuy Huong- Manager of Quality Assurance** Dept. made the report of project implementation with two following contents: Production Management and GMP system. In accordance with their report, all proposed targets of project have been done in accordance with the schedule.
6. **Dr. Mitsuhiro Ushio – Leader of Evaluation team of JICA and members in the team** made the report of project implementation during working time in POLYVAC from 2nd to 13th Nov. 2009. The Evaluation Team already expressed the success of the project in accordance with PDM and 05 criteria given by JICA. The team also stated 8 proposals for Vietnamese side relating to POLYVAC, MOH and relevant authorities.
7. **Dr. Marc Olive', Representative chief of WHO in Vietnam** already made the speech and highly appreciated the success of POLYVAC in Measles Vaccine production, which would be very good for elimination of Measles in Vietnam. Dr. Marc Olive' also undertook that WHO would try the best to support for NRA of Vietnam to complete 6 functions and POLYVAC in getting Pre-qualification of WHO.
8. **Dr. Mitsuhiro Ushio- leader of Final Evaluation Team of JICA**: Dr**. Nguyen Dang Hien – Director of POLYVAC, Dr. Tran Thi Giang Huong, Director of International Co-operation Department of MOH and Dr. Marc Olive' – Representative chief of WHO** in Vietnam already signed the minutes of Meetings and Final Evaluation documents of the Project.
9. **Conclusion:**

Associate Professor, Dr. Nguyen Dang Hien concluded the content of the meeting. The fifth JCC meeting ended successfully. Associate Professor, Dr. Nguyen Dang Hien thanked participants and declared that the meeting finished.

(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 (formulation, culture media, bulk and quality control departments), validation work plan, technology transfer plan for the following year, scale-up work plan, mass production technology transfer plan and minutes of meetings held in Japan.

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 validation work schedule 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 2006 (First Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Various training materials for technology transfer in building the GMP implementation system	Japan	
2.	Training materials for technical guidance in final production process	Japan and Vietnam	Mainly in Japan
3.	Technology Transfer Plan (draft) for technology transfer of bulk production process to be implemented in the second year	Japan	
4.	Various training materials relating to quality control	Japan	
5.	Final production process PQ Implementation Plan (draft) for guidance in final production process	Japan and Vietnam	
6.	PQ Report Preparation Manual	Vietnam	
7.	Various training materials for culture media and formulation	Japan and Vietnam	Mainly in Japan
8.	List of training materials	Japan	
9.	GMP-related standards and other standards	Japan	
10.	QC Validation Master Plan	Japan	
11.	Minutes of Meetings in Japan No.1 - No.7	Japan	English
12.	Technical Cooperation Plan, Operation/Inception Plan Report (draft)	Japan and Vietnam	Japanese and English
13.	Technical Cooperation Plan, Operation/Inception Plan Report	Japan and Vietnam	Japanese and English
14.	Minutes of Meeting of Joint Coordination Committee (JCC)	Vietnam	English
15.	Minutes of Weekly Meetings with POLYVAC No.1 - No.33	Vietnam	English
16.	Project Progress Report (No. 1)	Japan and Vietnam	Japanese and English
17.	Project Progress Report (No. 2)	Japan and Vietnam	Japanese and English

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
23.	Work Completion Report (1st Year)	Japan and Vietnam	Japanese

Fiscal 2007 (Second Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Various training materials for technology transfer in building the GMP implementation system	Japan	
2.	Training materials for technical guidance in final production process	Japan and Vietnam	Mainly in Japan
3.	Training materials for technical guidance in bulk production process	Japan	
4.	Various training materials relating to quality control	Japan	
5.	PQ, MFT and PV work plans for technical guidance in final production process	Japan and Vietnam	Mainly in Japan
6.	PQ and MFT work plans for technical guidance in bulk production process	Japan and Vietnam	Mainly in Japan
7.	Manuals for preparation of various reports	Vietnam	
8.	Training materials for guidance in culture media and formulation	Japan and Vietnam	Mainly in Japan
9.	List of training materials for production processes	Japan	
10.	GMP-related standards and other standards	Japan	
11.	Table of Educational Guidance Achievements	Vietnam	Japanese/Vietnamese
12.	Education/Training Completion Report (Certificate)	Vietnam	Japanese/Vietnamese
13.	Sample of calibration work plan for guidance	Japan and Vietnam	Mainly in Japan
14.	Project management materials (Schedule management, problem solution scheme, documentation rules, etc.)	Vietnam	English
15.	Materials for management of facilities and equipment	Vietnam	English
16.	Materials for procurement management, materials for risk management	Vietnam	Japanese/Vietnamese
17.	Minutes of 2nd and 3rd Meetings of Joint Coordination Committee (JCC)	Vietnam	English
18.	Minutes of Weekly Meetings with POLYVAC No.39 - No.82	Vietnam	English
19.	Minutes of Meetings in Japan No.8 - No.15	Japan	Japanese
20.	Work Schedule	Japan and Vietnam	Japanese
21.	Project Progress Report (No. 3)	Japan and Vietnam	Japanese and English
22.	Final Production Technology Transfer Report	Japan and Vietnam	Japanese and English
23.	Report on Preparatory Survey for Project Mid-term Evaluation	Japan and Vietnam	Japanese and English
24.	Quality Control Technology Transfer Report	Japan and Vietnam	Japanese and English
25.	Project Progress Report (No. 4)	Japan and Vietnam	Japanese and English
26.	Work Completion Report (2nd Year)	Japan and Vietnam	Japanese

Fiscal 2008 (Third Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Various training materials for technology transfer in building GMP implementation system (including quality assurance manual and contractor supervision procedure)	Japan	
2.	Training materials for technical guidance in bulk production and final production processes	Japan and Vietnam	Mainly in Japan
3.	Various training materials relating to Medium Preparation	Japan	
4.	Various training materials relating to quality control	Japan	
5.	Regular PQ and MFT (PST) and integrated production (bulk) PV work plans for guidance in bulk production and final production processes	Japan and Vietnam	Mainly in Japan
6.	Regular PQ and revised MFT and integrated production (formulation) PV work plans for guidance in final production process	Japan and Vietnam	Mainly in Japan
7.	Common and individual SOPs for departments	Japan and Vietnam	Japanese/Vietnamese
8.	List of equipment, list of spares and consumables (revised edition)	Vietnam	Japanese/Vietnamese
9.	List of SOPs for equipment operation, maintenance and calibration	Vietnam	Japanese/Vietnamese
10.	Training materials for guidance in retrospective validation	Japan and Vietnam	Mainly in Japan
11.	Training materials for filing method and documentation management	Japan	
12.	List of training materials	Japan	
13.	Table of Educational Guidance	Vietnam	Japanese/Vietnamese
14.	Education/Training Completion Report (Certificate)	Vietnam	Japanese/Vietnamese
15.	Materials for project management (schedule management, problem solution schemes, documentation rules, etc.)	Vietnam	English/Japanese/ Vietnamese
16.	Materials for management of facilities and equipment	Vietnam	English/Japanese/ Vietnamese
17.	Materials relating to environmental pollution, procurement and risk management	Japan and Vietnam	English/Japanese/ Vietnamese
18.	Minutes of 4th Meeting of Joint Coordination Committee (JCC)	Vietnam	English/Japanese/ Vietnamese
19.	Minutes of weekly meetings with POLYVAC (No.086-No.132)	Vietnam	English
20.	Minutes of meetings in Japan No.16 - No.22	Japan	Japanese
21.	Work Schedule	Japan and Vietnam	Japanese
22.	Project Progress Report (No. 5)	Japan and Vietnam	Japanese and English
23.	Vaccine Production Scale-up Work Plan	Japan and Vietnam	Japanese and English
24.	Report on Integrated Production Technology Transfer	Japan and Vietnam	Japanese and English
25.	Project Progress Report (No. 6)	Japan and Vietnam	Japanese and English
26.	Work Completion Report (3rd Year)	Japan and Vietnam	Japanese

Fiscal 2009 (Fourth Year)

No.	Name of Output	Place of Preparation	Remarks
1.	Various training materials for GMP capacity improvement	Japan and Vietnam	Mainly in Japan
2.	Training materials for technical guidance in bulk production and final production processes	Japan and Vietnam	Mainly in Japan
3.	Training materials for quality control-related guidance	Japan and Vietnam	Mainly in Japan
4.	Development-related documents including design document for heat-resistant measles vaccine prescription	Japan	
5.	Document for operating conditions for freezing and drying technology transfer	Japan	
6.	Samples of change validation protocols	Japan and Vietnam	Mainly in Japan
7.	Common and individual SOPs for departments	Japan and Vietnam	Japanese/Vietnamese
8.	List of equipment, list of spares and consumables (revised edition)	Vietnam	Japanese/Vietnamese
9.	List of SOPs for equipment operation, maintenance and calibration	Vietnam	Japanese/Vietnamese
10.	List of training materials	Japan	
11.	Table of Educational Guidance Achievements	Vietnam	Japanese/Vietnamese
12.	Education/Training Completion Report (Certificate)	Vietnam	Japanese/Vietnamese
13.	Materials for project management (including schedule management, problem solution schemes and documentation rules)	Vietnam	Japanese/Vietnamese
14.	Materials for management of facilities and equipment	Japan and Vietnam	English, Japanese and Vietnamese
15.	Minutes of meetings of 8 working groups	Vietnam	English, Japanese and Vietnamese
16.	Minutes of 5th meeting of Joint Coordination Committee (JCC)	Vietnam	English, Japanese and Vietnamese
17.	Minutes of weekly meetings with POLYVAC No.133 - No.183	Vietnam	English
18.	Minutes of meetings in Japan No.23 - No.26	Japan	Japanese
19.	Work Schedule	Japan and Vietnam	Japanese
20.	Project Progress Report (No. 7)	Japan and Vietnam	Japanese and English
21.	Report on Preparatory Survey of Terminal Evaluation	Japan and Vietnam	Japanese and English
22.	Project Progress Report (No. 8)	Japan and Vietnam	Japanese and English
23.	Work Completion Report (4th Year)	Japan and Vietnam	Japanese
24.	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.

The training materials relating to the production of these documents cannot be attached here in their entirety as outputs of this Project, because the training materials are bulky volumes. In addition, these materials contain the know-how and expertise relating to measles vaccine production accumulated to date by the Kitasato Institute, and it is not desired that these materials should be disclosed publicly.

(9) List of Counterparts

List of Counterpart

Updated: 31, August, 2009

No	Name in full	Position	Note
Quality Control Dept			
1	Nguyen Nu Anh Thu	Manager	
2	Ngo Thu Huong	Biological group	
3	Pham Anh Thu	Biological group	
4	Vu Thi Huong	Biological group	
5	Ngo Thi Thanh Huong	Biology control	
6	Nguyen Thi Mai Huong	Biological group	
7	Nguyen Minh Phuc	Biological group	
8	Le Van Duy	Animal group	
9	Nguyen Thi Nga	Animal group	
10	Le Trung Dung	Animal test group	
11	Tran Thi Bich Hanh	Immunology group	
12	Dang Mai Dung	Manager -Chemical group	
13	Nguyen Thi Nguyet	Chemical group	
14	Nguyen Thi Mai Huong	Chemical group	
15	Le Thi Huong	Chemical group	
16	Nguyen Anh Tuyet	Chemical group	
17	Cao Xuan Ngoc	Staff	New
Quality Assurance Dept			
1	Nguyen Thuy Huong	Manager	
2	Le Thu Nga	Documentation group	
3	Hoang Thi Lan	Documentation group	
4	Le Thi Hoa	Documentation & change control group	
5	Nong Thi Thanh Van	Pro. Release group	
6	Tran Thi Phuong	Validation Deviation & Self inspection group	
7	Hoang Thi Phuong Thu	Validation Deviation & Self inspection group	
8	Pham Thi Phuong Thao	Registration, training group	

Production Management Dept			
1	Tran Thi Hong Thuy	Manager	
Medium Preparation Dept			
1	Le Tuan Anh	Manager	
2	Nguyen Phuong Lan	Measles Medium Preparation Group	
3	Le Thi Oanh	Measles Medium Preparation Group	
4	Nguyen Thai Hoc	Measles Medium Preparation Group	
5	Nguyen Danh Binh	Measles Medium Preparation Group	
6	Pham Huu Manh	Measles Medium Preparation Group	
Measles Bulk Production Dept			
1	Nguyen Xuan Hoa	Head of Measles Bulk Production Dept	
2	Lai Quynh Mai	Cell culture Group	
3	Le Van Dung	Washing & Sterilize Group Materials control Group	
4	Vu Thi Mai	Prepare tools & materials Group	
5	Ha Hoang Phuong	Documentation Group CAL & VAL Group	
6	Pham Van Khoi	Environment monitoring Group	
7	Pham Thanh Truong	Virus culture Group	
8	Nguyen Thi Khuyen	Cleaning & sanitation Group	
9	Pham Le Tuan	Washing & Sterilize Group	
Final Production Dept			
1	Le Quoc Hung	Head of Final Production Dept	
2	Nguyen Thi Thanh Van	Final bulk composition group	
3	Nguyen Luong Ngoc Thanh	Environmental monitoring group	
4	Nguyen Binh Nguyen	Vial washing and sterilizing group &	
5	Ta Kim Quoc	Filling group	
6	Nguyen Dang Quynh	Freeze – Drying group	
7	Nguyen Manh Hien	Capping group	
8	Tran Minh Toan	Labeling group	
9	Nguyen Huy Truong	Filling group	
10	Dam Van The	Vial washing and sterilizing group	

Main & Tech Dept			
1	Nguyen Dang Anh	Head of Main & Tech Dept	
2	Dang Anh Tuan	Head of Official equipment and manufacturing machine group	
3	Nguyen Tuan Dung	Official equipment and manufacturing machine group	
4	Vu Van Dung	Official equipment and manufacturing machine group	
5	Nguyen Manh Dung	Head of Centre air conditioner, steam, air compressor system group	
6	Luu Van Chien	Centre air conditioner, steam, air compressor system group	
7	Nguyen Quoc Phong	Water supply system- waste water treatment system group	
8	Cao Minh Duc	Head of water supply system- waste water treatment system group	
9	Le hoang Nam	Head of Electrical system, extinguish fire system group	
10	Tran Cong Thang	Electrical system, extinguish fire system group	
GMP Supporting Dept			
Administration and Personnel Department			
1	Nguyen Thi Hai Thanh	Head of Administration and Personnel Dept	
2	Dao Ngoc Dien	Deputy Head of Administration and Personnel Dept	
3	Cao Hai Anh	Staff	
Financial Dept			
1	Nguyen Thi Thanh Mai	Head of Financial Dept	
2	Dang Bich Lien	Staff	
Material and Planning Dept			
1	Nguyen Thanh Thuy	Head of Material and planning Dept	
2	Nguyen Manh Khue	Deputy Head of Material and planning Dept	
3	Tran Trong Hai	Staff	
4	Nguyen Duc Thang	Driver	

(10) Table of Technology Transfer Management Results and List of Certificates Issued

Achievement of Education and Training from 2006 to 2009 for Final Production

Dept.: FINAL PRODUCTION **Trained by: Mr. Miygawa**

Classification	Code	Items	Trained staffs of POLYVAC and level achieved												
			HUNG	KIM	NGUYEN	QUOC	VAN	HA	THANH	THUY	QUYNH	HIEN	TOAN	TRUONG	THE
1. Machine of washing room and steam sterilizer		Method of writing production training records.	B: 4	C: 0	A: 4	B: 4	C: 3	C: 3	C: 3	B: 3	C: 3	–	–	3	3
		Prepare and start machines.	B: 2	C: 4	A: 4	B: 4	C: 2	C: 2	C: 2	B: 3	C: 3	–	–	3	3
		Automatic operation of machine	B: 2	C: 4	A: 4	B: 4	C: 2	C: 2	C: 2	B: 3	C: 3	–	–	3	3
		Machine operation by manual	B: 2	C: 4	A: 4	B: 4	C: 2	C: 2	C: 2	B: 3	C: 3	–	–	3	3
		Stop machine and put everything in order	B: 2	C: 4	A: 4	B: 4	C: 2	C: 2	C: 2	B: 3	C: 3	–	–	3	3
		Disassemble and assemble	B: 2	C: 3	A: 4	B: 4	C: 2	C: 2	C: 2	B: 3	C: 3	–	–	3	3
		Wash, sterilization and dry.	B: 2	C: 3	A: 4	B: 4	C: 2	C: 2	C: 2	B: 3	C: 3	–	–	3	3
		Troubleshooting procedure	B: 2	C: 3	A: 4	B: 4	C: 1	C: 1	C: 1	B: 3	C: 3	–	–	3	3
		Maintenance procedure	B: 2	C: 3	A: 4	B: 4	C: 1	C: 1	C: 1	B: 2	C: 3	–	–	–	–
		Procedure/ frequency of equipment and consumed tool replacement v.v.	B: 2	C: 3	A: 4	B: 4	C: 1	C: 1	C: 1	B: 2	C: 3	–	–	–	–
		Operate cooling machine such as UF and WFI	B: 2	B: 2	A: 4	B: 4	B: 3	B: 3	B: 3	B: 3	C: 4	3	3	3	3
		General evaluation	2	2	4	4	2	2	2	3	3	–	–	3	3
2. Vial washing and sterilization process		Method of writing production training records.	B: 4	B: 2	A: 4	–	C: 2	C: 1	C: 2	B: 4	–	–	B: 4	1	3
		Prepare and start machine	B: 2	B: 3	A: 4	–	C: 2	C: 1	C: 2	B: 4	–	–	B: 4	2	2
		Operate machine Automatically	B: 2	B: 3	A: 4	–	C: 2	C: 1	C: 2	B: 4	–	–	B: 4	2	2
		Operate machine by manual.	B: 2	B: 3	A: 4	–	C: 2	C: 1	C: 2	B: 4	–	–	B: 3	2	2
		Stop machine and put everything in order	B: 2	B: 3	A: 4	–	C: 2	C: 1	C: 2	B: 4	–	–	B: 4	2	2
		Disassemble and assemble	B: 2	B: 3	A: 4	–	C: 2	C: 1	C: 2	B: 4	–	–	B: 3	2	2
		Clean and sterilize machine	B: 2	B: 3	A: 4	–	C: 2	C: 1	C: 2	B: 4	–	–	B: 3	2	2
		Procedure of troubleshooting	B: 1	B: 3	A: 4	–	C: 2	C: 1	C: 2	B: 4	–	–	B: 3	2	2
		Maintenance procedure	B: 1	B: 2	A: 4	–	C: 1	C: 1	C: 1	B: 3	–	–	B: 2	2	2
		Procedure/ frequency of equipment and consumed tool replacement v.v.	B: 1	B: 2	A: 4	–	C: 1	C: 1	C: 1	B: 3	–	–	B: 2	2	2
		General evaluation	2	2	4	–	2	2	2	3	–	–	3	2	2
3. Final bulk preparation process		Method of writing production training records.	A: 4	–	–	B: 3	A: 4	B: 3	B: 3		C: 3	–	–	–	–
		Prepare implement used to produce bulk	A: 4	–	–	B: 4	A: 4	B: 2	B: 3	–	C: 3	–	–	–	–
		Preparation	A: 4	–	–	B: 4	A: 4	B: 2	B: 3	–	C: 4	–	–	–	–
		Preparation (Real production grade)	A: 4	–	–	B: 2	A: 4	B: 2	B: 3	–	C: 1	–	–	–	–
		Disassemble and assemble	A: 4	–	–	B: 2	A: 4	B: 2	B: 3	–	C: 1	–	–	–	–
		Wash, sterilize/ disinfect and dry.	A: 4	–	–	B: 4	A: 4	B: 2	B: 2	–	C: 1	–	–	–	–
		Procedure of troubleshooting	A: 4	–	–	B: 2	A: 4	B: 2	B: 2	–	C: 0	–	–	–	–
		Procedure/ frequency of replacement of equipment and consumed implement v.v.	A: 4	–	–	B: 3	A: 4	B: 2	B: 2	–	C: 0	–	–	–	–
		General evaluation	4	–	–	3	4	2	3	–	1	–	–	–	–
4. Filling, capping and tray loading process		Method of writing production training records.	A: 4	–	–	A: 4	B: 4	B: 3	B: 2	–	C: 4	1	–	–	–
		Prepare implement for filling	A: 4	–	–	A: 4	B: 2	B: 2	B: 2	C: 2	C: 4	2	–	–	–
		Prepare and start machine	B: 3	C: 1	C: 1	A: 4	B: 3	B: 2	B: 2	–	C: 4	2	–	–	–
		Operate machine automatically	B: 3	C: 1	C: 1	A: 4	B: 3	B: 2	B: 2	–	C: 4	2	–	–	–
		Operate machine by manual	B: 3	C: 1	C: 1	A: 4	B: 3	B: 2	B: 2	–	C: 4	2	–	–	–
		Stop machine and put everything in order	B: 3	C: 1	C: 1	A: 4	B: 3	B: 3	B: 3	–	C: 4	2	–	–	–
		Disassemble and assemble	B: 3	C: 1	C: 1	A: 4	B: 2	B: 2	B: 2	–	C: 4	2	–	–	–
		Wash, sterilize/ disinfect and dry.	B: 3	–	C: 1	A: 4	B: 3	B: 3	B: 3	C: 3	C: 4	2	–	–	–
		Procedure of troubleshooting	B: 3	–	–	A: 4	B: 1	B: 1	B: 1	–	C: 4	2	–	–	–
		Maintenance procedure	B: 3	–	–	A: 4	B: 0	B: 0	B: 0	–	C: 4	1	–	–	–
		Procedure/ frequency of replacement of equipment and consumed implement v.v.	B: 3	–	–	A: 4	B: 0	B: 0	B: 0	–	C: 4	1	–	–	–
		General evaluation	3	–	–	4	3	2	2	–	4	2	–	–	–
5. Freeze drying process		Method of writing production training records.	C: 4	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	1	–
		Prepare and start machine	C: 2	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	1	–
		Operate machine automatically	C: 2	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	1	–
		Operate machine by manual	C: 2	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	1	–
		Stop machine and put everything in order	C: 2	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	1	–
		Disassemble and assemble	C: 2	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	1	–
		Wash, sterilize/ disinfect and dry	C: 2	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	1	
		Procedure of troubleshooting	C: 2	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	1	–
		Maintenance procedure	C: 2	A: 4	–	B: 4	–	–	–	–	A: 4	–	–	–	–
		Procedure/ frequency of replacement of equipment and consumed implement v.v.	C: 2	A: 4	–	B: 3	–	–	–	–	A: 4	–	–	–	–
		General evaluation	2	4	–	4	–	–	–	–	4	–	–	1	–
6. Filling process		Method of writing production training records.	B: 4	C: 0	C: 3	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Prepare and start machine	B: 4	C: 0	C: 4	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Operate machine automatically	B: 4	C: 0	C: 4	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Operate machine by manual	B: 4	C: 0	C: 4	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Stop machine and put everything in order	B: 4	C: 0	C: 4	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Disassemble and assemble	B: 4	C: 0	C: 4	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Wash, sterilize/ disinfect and dry	B: 4	C: 0	C: 4	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Procedure of troubleshooting	B: 4	C: 0	C: 3	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Maintenance procedure	B: 3	C: 0	C: 3	A: 4	–	–	–	–	C: 2	B: 4	–	–	2
		Procedure/ frequency of replacement of equipment and consumed implement v.v.	B: 3	C: 0	C: 3	A: 4	–	–	–	–	C: 2	B: 3	–	–	2
		General evaluation	4	–	3	4	–	–	–	–	2	4	–	–	2
7. Other work	7-1	Operation of filling, supplying and filtration of WFI	B: 2	–	A: 4	A: 4	–	–	–	C: 0	C: 4	–	–	–	–
	7-2	Wash 70L pooling tank and electricity converter for stirrer	B: 2	–	C: 2	A: 4	C: 2	C: 2	C: 2	C: 1	C: 4	–	–	–	–
	7-3	Use 70L pooling tank	B: 2	–	B: 3	A: 4	C: 1	C: 1	C: 1	C: 0	C: 4	–	C: 3	2	–
	7-4	Check foreign agent	A: 4	–	B: 3	B: 4	A: 4	B: 4	B: 4	B: 4	C: 4	C: 3	C: 3	C: 3	–
	7-5	Control temperature of cold room	A: 4	B: 2	B: 3	B: 3	B: 3	B: 3	B: 3	B: 3	C: 3	B: 3	B: 3	–	–
	7-6	Control air-conditioner	A: 4	B: 2	B: 3	B: 3	B: 3	B: 3	B: 3	B: 3	C: 3	B: 3	B: 3	–	–
	7-7	Integrity test of filter.	A: 4	–	A: 3	A: 3	B: 3	C: 2	C: 2	C: 2	C: 2	–	C: 3	–	–
	7-8	Particle counter in clean room	B: 2	–	A: 4	A: 4	C: 1	B: 0	C: 3	C: 0	C: 3	–	–	–	–
	7-9	Bacterium in clean room and count particle in air	B: 2	–	–	C: 3	C: 0	A: 4	C: 4	–	C: 0	–	–	–	–
8. General items	8-1	Procedure of formalin fumigation in clean room (Bulk production)	HOA: A: 4											–	–
	8-2	Procedure of formalin fumigation (Final production)	QUOC: A: 4											–	–
	8-3	Procedure of formalin fumigation in clean room (QC)	THU: A: 4											–	–
	8-4	Procedure of formalin fumigation in clean room (Air-conditioner operation)	DUNG: A: 4											–	–
9. Validation technique	9-1	CAL sensor for validation (Mr. Ihara)	–	–	A: 4	C: 2	–	–	–	–	B: 3	–	–	–	–
	9-2	Validation relating to autoclave (Mr. Ihara)	B: 3	C: 0	A: 4	C: 3	–	–	–	C: 2	–	–	–	–	3
	9-3	Validation of washing equipment by hands	B: 4	–	C: 2	A: 4	C: 2	C: 2	C: 2	C: 2	C: 2	–	–	–	–
	9-4	Validation of vial washing effect	B: 3	C: 0	A: 4	–	–	–	–	C: 3	C: 1	–	3	2	–
	9-5	Validation of confirmation of filling volume and initial flow loss	B: 3	–	–	A: 4	C: 2	C: 2	C: 2	–	C: 2	–	–	–	–
	9-6	Validation of washing freeze drying machine	A: 4	B: 3	–	B: 4	–	–	–	–	C: 4	–	–	–	–
	9-7	Confirmation of temperature and humidity measurement	A: 4	–	C: 2	B: 4	–	–	–	–	C: 2	–	–	–	–
	9-8	Confirmation of vial sterilization effect	A: 4	–	A: 4	C: 3	–	–	–	B: 3	C: 2	–	3	–	–
	9-9	Confirmation of formalin fumigation effect	A: 4	–	–	A: 4	–	–	–	–	B: 3	–	–	–	–
	9-10	Confirmation that changing procedure passes	A: 4	–	C: 2	B: 4	A: 4	C: 3	C: 3	C: 3	C: 2	3	2	–	–
	9-11	Confirmation that in-transportation procedure passes	A: 4	–	–	B: 3	C: 4	C: 4	C: 4	B: 4	C: 2	–	–	–	–
	9-12	Confirm elements of water of rubber stopper	A: 4	–	–	B: 3	–	–	–	–	–	–	–	–	–
	9-13	Condition of keeping sterilized things	A: 4	–	–	B: 4	C: 1	C: 1	C: 1	–	C: 1	–	–	–	–
	9-14	Environment monitoring (Control during operation and at static condition)	A: 4	–	–	B: 4	C: 4	B: 4	C: 3	–	C: 2	–	–	–	–
	9-15	Confirm that confirmation of in whole process passes	A: 4	B: 4	B: 4	B: 4	B: 3	B: 3	B: 3	B: 3	B: 3	–	–	–	–
	9-16	Leak test of HEPA filter	C: 2	–	A: 4	C: 3	–	–	–	B: 3	C: 1	3	3	2	–
	9-17	Measure wind flow of HEPA filter	C: 2	–	A: 4	C: 3	–	–	–	B: 3	C: 1	3	3	2	–
	9-18	Measure dust of HEPA filter of sterilization cellar	C: 2	–	A: 4	C: 3	–	–	–	B: 3	C: 1	3	3	2	–
	9-19	Measure temperature of vial in sterilization cellar	C: 2	–	A: 4	C: 2	–	–	–	B: 3	C: 1	–	3	–	–
	9-20	Medium filling test (vial washing and sterilization)	B: 1	–	A: 4	–	–	–	–	A: 4	–	–	B: 3	–	–
	9-21	Medium filling test (To produce final bulk)	A: 4	–	–	–	A: 4	B: 3	B: 3	–	–	–	–	–	–
	9-22	Medium filling test (Medium test)	C: 1	–	–	B: 3	A: 1	A: 4	A: 4	–	–	–	–	–	–
	9-23	Medium filling test (Filling and capping)	B: 4	–	–	A: 4	B: 3	B: 2	B: 2	–	A: 4	–	–	–	–
	9-24	Medium filling test (freeze drying)	C: 2	A: 4	–	A: 4	–	–	–	–	A: 4	–	–	–	–
	9-25	Medium filling test (loading)	A: 4	–	–	A: 4	B: 2	B: 1	B: 2	–	C: 3	–	–	–	–
	9-26	Medium filling test (Capping)	A: 4	–	A: 4	A: 4	–	–	–	–	–	B: 3	–	–	–
	9-27	Medium filling test (check by eyes)	B: 4	–	B: 3	B: 4	A: 4	B: 4	B: 4	A: 4	C: 4	C: 3	C: 3	C: 2	–
Package	10-1	Labeling	C: 3	–	C: 3	C: 3	–	–	–	–	A: 3	–	A: 3	–	3
	10-2	Package of product	A: 4	–	3	3	B: 3	–	3	–	3	B: 3	3	3	3
	10-3	Release	A: 4	–	2	2	2	–	2	–	2	3	2	2	2
	10-4														

Category of Trainee

A: Subject trained about technical transfer by Kitasato experts (person in charge of processes)…level 4 targeted

B: Subjects are process assistants recommended by Kitasato experts (more than level 3 targeted by Polyvac)

C: Trained subjects have prospect for production in the future recommended by Kitasato expert (more than level 3 targeted by Polyvac)

- : Management board of Polyvac will be in charge.

Achievement level of trainee

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

Level 2: Capable of performing assigned work under the instruction of supervisors. Also exhibits some knowledge.

Level 3: Capable of performing his/her assigned work on his/her own. Also exhibits knowledge in level, but unable to provide training for other staffs adequately.

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

Level achieved in 2007

Level achieved in 2007 (continue the year of 2006

Level achieved in 2008 (continue the year of 2007)

Level achieved in 2009 (continue the year of 2008)

List of Certificates Issued (F2006〜F2009)

F2006〜F2009 Final Prodcution Department Name of Expert; Mr. K. Miyagawa

	Name of Process	As of 19 Jan. 2007		As of 9 Mar. 2007		As of 12 Mar. 2007						As of 19 Oct. 2007								As of 22 Oct. 2008	As of 16 Jan. 2009						As of 30 Oct. 2009									
Final Production related	Washing room machine and Autoclave	NGUYEN				QUOC						THUY	QUYNH														TRUONG	THE								
	Procedure of vial washing and sterilization	NGUYEN										THUY									TOAN															
	Procedure of final bulk preparation	HUNG	VAN																		QUOC						THANH									
	Procedure of filling, capping and tray loading	QUOC										HUNG	QUYNH								QUYNH						VAN									
	Aluminum capping procedure	QUOC				HUNG						NGUYEN									HIEN						HIEN									
	Freeze drying procedure	KIM										QUOC								QUYNH															
	Procedure of checking foreign agent	HUNG	VAN			NGUYEN	QUOC	VAN	HA	TAINH	THUY										QUYNH						QUOC	HA	THANH	THUY	QUYNH	HIEN	THUONG			
	Use WFI filtration and supplying system	NGUYEN										QUOC	QUYNH																						
	Disassemble and wash 70L pooling tank and operation of electricity converter of stirrer	QUOC										QUYNH									QUYNH														
	Operation of 70L pooling tank	QUOC				NGUYEN						QUYNH									QUYNH						TOAN									
	Integrity test of filter					QUOC						HUNG	NGUYEN	VAN							TOAN															
	Measure bacterium adhering and bacterium in air of clean room					HA						QUOC	VAN	THANH							HA	THANH														
	Check temperature of cold keeping room	HUNG				NGUYEN	QUOC	VAN	HA	TAINH	THUY	QUYNH									HIEN	TOAN														
	Check air-conditioner	HUNG				NGUYEN	QUOC	VAN	HA	TAINH	THUY	QUYNH									HIEN	TOAN														
	Particle counter in Clean rm	QUOC	NGUYEN									VAN	HA	THANH													QUYNH									
	Validation of washing equipment and tool by hand											HUNG	QUOC																						
	Validation of vial washing effect			NGUYEN								HUNG	THUY														TOAN									
	Validate to check filling volume and initial flow loss											HUNG	QUOC														QUYNH									
	Validation of CIP for freeze drying machine											HUNG	KIM	QUOC																					
	Measure temperature and humidity											HUNG	QUOC																						
	Effect of vial sterilization											HUNG	NGUYEN	THUY													QUOC	TOAN								
	Effect of Formalin fumigation											HUNG	QUOC	QUYNH																					
	Check the suitability of changing procedure											HUNG	QUOC	VAN													HIEN									
	Check suitability of entry											HUNG	QUOC	VAN	HA	THANH	THUY																		
	Check element of water of rubber stopper											HUNG	QUOC																						
	Condition to keep sterilized things											HUNG	QUOC																						
	Environment monitoring (Control at active and static condition)											HUNG	QUOC	VAN	THANH																				
	Check suitability of procedure by confirmation of in whole process											HUNG	KIM	NGUYEN	QUOC	VAN	HA	THANH	THUY	QUYNH															
	Leakage test of HEPA filter											NGUYEN	QUOC	THUY													HIEN	TOAN								
	Measure wind of HEPA filter											NGUYEN	QUOC	THUY													HIEN	TOAN								
	Measure dust of HEPA filter of sterilization cellar											NGUYEN	THUY														QUOC	HIEN	TOAN							
	Measure temperature in sterilization cellar											NGUYEN	THUY																						
	Medium filling test (Vial washing and sterilization)											NGUYEN	THUY								TOAN														
	Medium filling test (bulk preparation)											HUNG	VAN								HA	THANH													
	Medium filling test (Check medium)											QUOC	VAN	THANH							HA														
	Medium filling test (Filling and capping)											HUNG	QUOC	QUYNH							VAN														
	Medium filling test (Freeze drying)											KIM	QUOC								QUYNH														
	Medium filling test (Loading)											HUNG	QUOC								QUYNH														
	Medium filling test (CAPPING)											HUNG	NGUYEN	QUOC							HIEN														
	Medium filling test (Check by eyes)											HUNG	NGUYEN	VAN	THANH	THUY					QUOC	HA	THANH	QUYNH	HIEN	TOAN	HUNG	QUOC	QUYNH						
																											HUNG	NGUYEN	QUOC	QUYNH	TOAN	THE				
																											HUNG	NGUYEN	QUOC	VAN	THANH	QUYNH	HIEN	TOAN	TRUONG	THE
																											HUNG	HIEN								
	Procedure of Formalin fumigation in working rooms (Bulk production)											NGUYEN															HUNG	QUOC	THE							
Common	Procedure of Formalin fumigation in working rooms (Bulk production)			HOA (BP)																															
	Formalin fumigation of working room (Final product)			QUOC(FP)																															
	Formalin fumigation procedure in working room (QC)			THU (QC)																															
	Formalin fumigation procedure in working room (Air-conditioner: Engineering)			DUNG(ENG)																															