Annex 11. List of Equipment and Materials Supplied by Vietnamese side

List of equipment bought by inland capital

1. Specialized equipment			
No.	**Name**	**Counting unit**	**Quantity**
1	Labeller and label	Set	2
2	ELISA system includes:		
2.1	*ELISA washing machine*	Unit	1
2.2	*ELISA reader*	Unit	1
2.3	*ELISA thermorstar*	Unit	1
3	Nitrogent supplying system includes:		
3.1	*Super-clean nitrogent cylinder(41 litres/cylinder)*	Unit	2
3.2	*Pressure-gauge*	Unit	2
3.3	*Desiccation set for nitrogent*	Set	2
4	Automatic hand washer	Unit	2
5	Egg cutter	Unit	1
6	Centrifuge	Unit	1
7	Magnetic stirrer and magnets:	Unit	1
7.1	7cm magnetic stirrer	Unit	20
7.2	4cm magnetic stirrer	Unit	20
7.3	2,5cm magnetic stirrer	Unit	20
8	Water filtration equipment	Unit	5
9	Automatic alcohol sprayer	Unit	3
10	Hoover used in sterilized rooms	Unit	3
11	Vacuum pump/high capacity pressure	Unit	1
12	Thermometer of water	Unit	1
13	Desiccation machine	Unit	1
14	2,100g electronic balance	Unit	3
15	Technical electronic balance	Unit	1
Total			**94**

Annex 12. Budget Allocation by POLYVAC

OPERATION EXPENSES IN 2008-2009 (ESTIMATED)

No.	Expenses detail	In cash (VND)		In cash (USD)	
		2008	2009	2008	2009
A	**Expenses for personnel**	**2,820,000,000**	**2,820,000,000**	**176,250**	**176,250**
1	*Wages for personnel*	*2,520,000,000*	*2,520,000,000*	*157,500*	*157,500*
2	*Deducted items according to wage*	*300,000,000*	*300,000,000*	*18,750*	*18,750*
B	**Expenses for material**	**7,077,204,000**	**13,147,204,000**	**442,325**	**830,700**
1	*Chicken egg*	*100,000,000*	*300,000,000*	*6,250*	*18,750*
2	*Medium and chemicals*	*1,500,000,000*	*3,000,000,000*	*93,750*	*187,500*
3	*Vial*		*3,750,000,000*	-	*243,375*
4	*Consumed material + implement*	*3,490,112,000*	*3,490,112,000*	*218,132*	*218,132*
5	*Chemical for water treatment*	*1,907,092,000*	*1,907,092,000*	*119,193*	*119,193*
6	*Expenses for package*	*80,000,000*	*700,000,000*	*5,000*	*43,750*
C	**Expenses for utility charge**	**8,091,000,000**	**8,091,000,000**	**505,688**	**505,688**
1	*Electricity*	*3,672,000,000*	*3,672,000,000*	*229,500*	*229,500*
2	*Petroleum*	*4,284,000,000*	*4,284,000,000*	*267,750*	*267,750*
3	*Water*	*135,000,000*	*135,000,000*	*8,438*	*8,438*
D	**Expenses for maintenance, validation and calibration**	**1,181,821,000**	**1,181,821,000**	**73,864**	**73,864**
1	*Maintenance*	*971,821,000*	*971,821,000*	*60,739*	*60,739*
2	*Validation and calibration*	*210,000,000*	*210,000,000*	*13,125*	*13,125*
E	**Spare parts for air conditioning system, compressor and boiler**	**5,120,581,000**	**5,120,581,000**	**320,036**	**320,036**
F	**Management expenses**	**2,384,000,000**	**3,200,000,000**	**149,000**	**200,000**
1	*Administration tasks (Guard, sanitation and other administration works)*	*800,000,000*	*1,000,000,000*	*50,000*	*62,500*
2	*Verification expenses*	*84,000,000*	*700,000,000*	*5,250*	*43,750*
3	*Clinical trial*	*1,500,000,000*	*1,500,000,000*	*93,750*	*93,750*
TOTAL		**26,674,606,000**	**33,560,606,000**	**1,667,163**	**2,106,538**

Annex 13. Summary of Education and Training Activities

Achievement of Education and Training in 2006 and 2007

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

Final Production Dept.

Experts: Mr. Miyagawa Kazunori, Ihara Nobuyuki, Baba Shuuichi and other experts
Implementation time: 14/7/2006 ~ 19/10/2007 Total implementation days: 206 days

Classification	Items	Trained staffs of POLYVAC and level achieved										
		FP1	FP2	FP3	FP4	FP5	FP6	FP7	FP8	FP9	FP10	FP11
Machine of washing room and steam sterilizer	Method of writing production training records.	B : 4	C : 0	A : 4	B : 4	C : 2	C : 2	C : 2	B : 3	C : 3	–	–
	Prepare and start machines.	B : 2	C : 4	A : 4	B : 4	C : 2	C : 2	C : 2	B : 3	C : 3	–	–
	Automatic operation of machine	B : 2	C : 4	A : 4	B : 4	C : 2	C : 2	C : 2	B : 3	C : 3	–	–
	Machine operation by manual	B : 2	C : 4	A : 4	B : 4	C : 2	C : 2	C : 2	B : 3	C : 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	–	–
	Disassemble and assemble	B : 2	C : 3	A : 4	B : 4	C : 2	C : 2	C : 2	B : 3	C : 3	–	–
	Wash, sterilization and dry.	B : 2	C : 3	A : 4	B : 4	C : 2	C : 2	C : 2	B : 3	C : 3	–	–
	Troubleshooting procedure	B : 2	C : 3	A : 4	B : 4	C : 1	C : 1	C : 1	B : 3	C : 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 : 3	–	–
	General evaluation	2	2	4	4	2	2	2	3	3	–	–
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	C : 1	–	–
	Prepare and start machine	B : 2	B : 3	A : 4	–	C : 2	C : 1	C : 2	B : 4	C : 2	–	–
	Operate machine Automatically	B : 2	B : 3	A : 4	–	C : 2	C : 1	C : 2	B : 4	C : 2	–	–
	Operate machine by manual.	B : 2	B : 3	A : 4	–	C : 2	C : 1	C : 2	B : 4	C : 2	–	–
	Stop machine and put everything in order	B : 2	B : 3	A : 4	–	C : 2	C : 1	C : 2	B : 4	C : 2	–	–
	Disassemble and assemble	B : 2	B : 3	A : 4	–	C : 2	C : 1	C : 2	B : 4	C : 2	–	–
	Clean and sterilize machine	B : 2	B : 3	A : 4	–	C : 2	C : 1	C : 2	B : 4	C : 2	–	–
	Procedure of troubleshooting	B : 1	B : 3	A : 4	–	C : 2	C : 1	C : 2	B : 4	C : 2	–	–
	Maintenance procedure	B : 1	B : 2	A : 4	–	C : 1	C : 1	C : 1	B : 3	C : 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	C : 2	–	–
	General evaluation	2	2	4	–	2	2	2	3	2	–	–
Final bulk preparation process	Method of writing production training records.	A : 4	–	–	B : 2	A : 4	B : 2	B : 2		C : 0	–	–
	Prepare implement used to produce bulk	A : 4	–	–	B : 3	A : 4	B : 2	B : 2	–	C : 1	–	–
	Preparation	A : 4	–	–	B : 3	A : 4	B : 2	B : 2	–	C : 1	–	–
	Preparation (Real production grade)	A : 4	–	–	B : 2	A : 4	B : 2	B : 2	–	C : 1	–	–
	Disassemble and assemble	A : 4	–	–	B : 2	A : 4	B : 2	B : 2	–	C : 1	–	–
	Wash, sterilize/ disinfect and dry.	A : 4	–	–	B : 2	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 : 2	A : 4	B : 2	B : 2	–	C : 0	–	–
	General evaluation	4	–	–	2	4	2	2	–	1	–	–
Filling, capping and tray loading process	Method of writing production training records.	A : 4	–	–	A : 4	B : 3	B : 3	B : 2	–	C : 3	–	–
	Prepare implement for filling	A : 4	–	–	A : 4	B : 2	B : 2	B : 2	C : 2	C : 3	–	–
	Prepare and start machine	B : 3	C : 1	C : 1	A : 4	B : 3	B : 2	B : 2	–	C : 3	–	–
	Operate machine automatically	B : 3	C : 1	C : 1	A : 4	B : 3	B : 2	B : 2	–	C : 3	–	–
	Operate machine by manual	B : 3	C : 1	C : 1	A : 4	B : 3	B : 2	B : 2	–	C : 3	–	–
	Stop machine and put everything in order	B : 3	C : 1	C : 1	A : 4	B : 3	B : 3	B : 3	–	C : 3	–	–
	Disassemble and assemble	B : 3	C : 1	C : 1	A : 4	B : 2	B : 2	B : 2	–	C : 3	–	–
	Wash, sterilize/ disinfect and dry.	B : 3	–	C : 1	A : 4	B : 3	B : 3	B : 3	C : 3	C : 3	–	–
	Procedure of troubleshooting	B : 3	–	–	A : 4	B : 1	B : 1	B : 1	–	C : 3	–	–
	Maintenance procedure	B : 3	–	–	A : 4	B : 0	B : 0	B : 0	–	C : 3	–	–
	Procedure/ frequency of replacement of equipment and consumed implement v.v.	B : 3	–	–	A : 4	B : 0	B : 0	B : 0	–	C : 3	–	–
	General evaluation	3	–	–	4	2	2	2	–	3	–	–
Freeze drying process	Method of writing production training records.	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Prepare and start machine	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Operate machine automatically	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Operate machine by manual	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Stop machine and put everything in order	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Disassemble and assemble	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Wash, sterilize/ disinfect and dry	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Procedure of troubleshooting	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Maintenance procedure	C : 0	A : 4	–	B : 4	–	–	–	–	C : 2	–	–
	Procedure/ frequency of replacement of equipment and consumed implement v.v.	C : 0	A : 4	–	B : 3	–	–	–	–	C : 2	–	–
	General evaluation		4	–	4	–	–	–	–		–	–
Filling process	Method of writing production training records.	B : 4	C : 0	C : 3	A : 4	–	–	–	–	C : 2	–	–
	Prepare and start machine	B : 4	C : 0	C : 4	A : 4	–	–	–	–	C : 2	–	–
	Operate machine automatically	B : 4	C : 0	C : 4	A : 4	–	–	–	–	C : 2	–	–
	Operate machine by manual	B : 4	C : 0	C : 4	A : 4	–	–	–	–	C : 2	–	–
	Stop machine and put everything in order	B : 4	C : 0	C : 4	A : 4	–	–	–	–	C : 2	–	–
	Disassemble and assemble	B : 4	C : 0	C : 4	A : 4	–	–	–	–	C : 2	–	–
	Wash, sterilize/ disinfect and dry	B : 4	C : 0	C : 4	A : 4	–	–	–	–	C : 2	–	–
	Procedure of troubleshooting	B : 4	C : 0	C : 3	A : 4	–	–	–	–	C : 2	–	–
	Maintenance procedure	B : 3	C : 0	C : 3	A : 4	–	–	–	–	C : 2	–	–
	Procedure/ frequency of replacement of equipment and consumed implement v.v.	B : 3	C : 0	C : 3	A : 4	–	–	–	–	C : 2	–	–
	General evaluation	4	–	3	4	–	–	–	–		–	–

Other works	7-1	Operation of filling, supplying and filtration of WFI.	B : 2	–	A : 4	A : 3	–	–	–	C : 0	C : 3	–	–
	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 : 3	–	–
	7-3	Use 70L pooling tank	B : 2	–	B : 3	A : 4	C : 1	C : 1	C : 1	C : 0	C : 3	–	–
	7-4	Check foreign agent	A : 4	–	B : 3	B : 3	A : 4	B : 3	B : 3	B : 3	C : 2	–	–
	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	–	–
	7-6	Control air-conditioner	A : 4	B : 2	B : 3	B : 3	B : 3	B : 3	B : 3	B : 3	C : 3	–	–
	7-7	Integrity test of filter.	A : 4	–	A : 3	A : 3	B : 3	C : 2	C : 2	C : 2	C : 2	–	–
	7-8	Particle counter in clean room	B : 2	–	A : 4	A : 4	C : 3	B : 3	C : 3	C : 1	C : 1	–	–
	7-9	Bacterium in clean room and count particle in air	B : 2	–	–	C : 3	C : 3	A : 4	C : 3	–	C : 0	–	–
General items	8-1	Procedure of formalin fumigation in clean room (Bulk production)	BP1:A:4										
	8-2	Procedure of formalin fumigation (Final production)	FP4:A:4										
	8-3	Procedure of formalin fumigation in clean room (QC)	QC1:A:4										
	8-4	Procedure of formalin fumigation in clean room (Air-conditioner operation)	EG2:A:4										
Validation technology	9-1	Prepare sensor for validation (Ihara)	–	–	A : 3	C : 2	–	–	–	–	B : 3	–	–
	9-2	Validation relates to sterilization of autoclave (Ihara)	B : 3	C : 0	A : 4	C : 3	–	–	–	C : 3	–	–	–
	9-3	Validation of washing equipment by	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	–	–
	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	A : 4	B : 3	–	B : 4	–	–	–	–	C : 2	–	–
	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 : 1	–	–	–	B : 3	C : 2	–	–
	9-9	Confirmation of formalin fumigation	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	–	–
	9-11	Confirmation that in-transportation procedure passes	A : 4	–	–	B : 3	C : 3	C : 3	C : 3	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 : 3	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	–	–
	9-17	Measure wind flow of HEPA filter	C : 2	–	A : 4	C : 3	–	–	–	B : 3	C : 1	–	–
	9-18	Measure dust of HEPA filter of sterilization cellar	C : 2	–	A : 4	C : 2	–	–	–	B : 3	C : 1	–	–
	9-19	Measure temperature of vial in sterilization cellar	C : 2	–	A : 4	C : 2	–	–	–	B : 3	C : 1	–	–
	9-20	Medium filling test (vial washing and sterilization)	B : 1	–	A : 4	–	–	–	–	A : 4	–	–	–
	9-21	Medium filling test (To produce final	A : 4	–	–	–	A : 4	B : 0	B : 2	–	–	–	–
	9-22	Medium filling test (Medium test)	C : 1	–	–	B : 3	A : 3	A : 0	A : 4	–	–	–	–
	9-23	Medium filling test (Filling and capping)	B : 3	–	–	A : 4	B : 1	B : 0	B : 1	–	A : 4	–	–
	9-24	Medium filling test (freeze drying)	C : 1	A : 4	–	B : 3	–	–	–	–	B : 3	–	–
	9-25	Medium filling test (loading)	A : 4	–	–	A : 4	B : 1	B : 0	B : 1	–	C : 2	–	–
	9-26	Medium filling test (Capping)	A : 4	–	A : 4	A : 4	–	–	–	–	–	–	–
	9-27	Medium filling test (check by eyes)	B : 3	–	B : 3	B : 2	A : 4	B : 0	B : 3	A : 4	C : 0	–	–

Medium Production Dept.

Expert: Mr. NAOI Mitsuo Implementation time: from July 2006 to October 2007 Total implementation days (dispatch days) : 148

Category	Items	Trained staffs of POLYVAC and level achieved										
		MP1	MP2	MP3	MP4	MP5						
Water production system for vaccine production	SIP process for WFI, UFW production system	A : 4	B : 4	• : 2	C : 3	–						
	User point SIP process for WFI, UFW production system	A : 4	B : 3	• : 2	C : 3	–						
	WFI, UFW sampling process	A : 4	B : 3	• : 3	C : 3	–						
	Sampling for water quality control test	A : 4	B : 4	• : 2	C : 3	–						
Basic operation	Chemical quality control	A : 4	B : 3	• : 2	C : 2	–						
	Sanitation and disinfection procedure for operation room	A : 4	B : 2	• : 2	C : 2	–						
Open system filtration procedure	Equipment sterilization preparation	A : 3	B : 3	• : 3	C : 3	–						
	Entry process	A : 3	B : 3	• : 3	C : 3	–						
	Mixture procedure	A : 3	B : 3	• : 2	C : 2	–						
	Open system filtration	A : 3	B : 2	• : 2	C : 2	–						
	Wash, dry equipments	A : 3	B : 2	• : 2	C : 2	–						
	Troubleshooting process	A : 3	B : 2	• : 2	C : 2	–						
Close system filtration procedure	Equipment sterilization preparation	A : 4	B : 3	• : 3	C : 3	–						
	Entry process					–						
	Mixture procedure					–						
	Close system filtration					–						
	wash, dry equipments					–						
	Troubleshooting process					–						
Diluted vaccine solution production procedure	Equipment sterilization preparation	A : 4	B : 3	• : 3	C : 3	–						
	Entry process					–						
	Mixture procedure					–						
	Close system filtration					–						
	Troubleshooting process					–						
Medium production procedure for QC	Equipment sterilization preparation	A : 4	B : 3	• : 2	C : 2	–						
	Entry process					–						
	Mixture procedure					–						
	Close system filtration					–						
	Troubleshooting process					–						

Others	Medium preparation for quality control	A : 4	B : 2	• : 2	C : 2	—							
Equipment operation	Operate electronic scale, Combics1	A : 4	B : 2	• : 3	C : 2	—							
	Operate electronic scale, LE2202S	A : 4	B : 2	• : 3	C : 2	—							
	Operate electronic scale, CP16001S	A : 4	B : 2	• : 3	C : 2	—							
	Operate p H meter	A : 4	B : 2	• : 3	C : 2	—							
	Operate stirrer	A : 4	B : 3	• : 3	C : 3	—							
	Operation in clean bench	A : 4	B : 2	• : 3	C : 2	—							
	Operate No.4 Integrity test machine	A : 4	B : 3	• : 4	C : 2	—							
	Operate Lowstar integrity test machine	A : 4	B : 3	• : 4	C : 2	—							
	Control pressure difference between rooms	A : 4	B : 2	• : 2	C : 3	—							
	Control cold room for keeping chemical	A : 4	B : 2	• : 2	C : 3	—							
PQ	Water System monitoring	—	B : 4	—	C : 3	—							
	Washing of equipments	A : 4	—	—	C : 3	—							
	Pre-environment monitoring (At static condition)	A : 4	B : 3	—	—	—							
	Environment monitoring	A : 4	B : 3	—	—	—							
	Bringing substances into diff. grade rm	A : 4	B : 3	—	C : 3	—							
	Quality of Vaccine diluted solution	A : 4	B : 3	• : 3	C : 3	—							
	Quality of SCD broth solution	A : 4	B : 3	• : 3	C : 3	—							
	Formalin Fumigation	A : 4	B : 3	—	—	—							

Bulk Production Dept.

Expert: Mr. Sato Training time : From 14th May to 14th Training days in total : 6 2
Expert: Mr. Katsuda Training time : From 14th May to 16th Training days in total : 3 4 days

Classification	Contents	Trained staffs of POLYVAC and level achieved											
		BP1	BP2	BP3	BP4	BP5	BP6						
Basic operation	Wash, prepare and keep implement	A : 4	B : 3	C : 3	C : 3	C : 3	B : 3						
	Prepare medium	A : 4	B : 3	C : 3	—	—	—						
	Operation with medium roux	A : 4	B : 3	C : 2•	C : 3	C : 2•	B : 3						
	Operation with virus	A : 4	B : 3	C : 3	—	—	B : 2						
	Inactivate serum	A : 4	B : 3	—	—	C : 3	—						
	Inactivate virus	A : 4	B : 3	C : 3	C : 2	—	B : 3						
Procedure to receive and incubate SPF eggs	Receive and sterilize SPF eggs	A : 4	C : 3	B : 3	B : 4	C : 3	C : 3						
	SPF eggs break, do not have embryo and die in the womb	A : 4	C : 3	B : 3	B : 4	C : 3	C : 3						
	Incubate and transport S.P.F eggs	A : 4	C : 3	B : 3	B : 4	C : 3	C : 3						
Sterilization process	Wash and sterilize embryo	A : 4	B : 3	C : 2	—	C : 2	B : 2						
	Prepare and dispense cell	A : 4	B : 3	C : 2	—	—	B : 2•						
	Calculate cells after centrifugal	A : 4	—	—	—	—	B : 3						
	Culture roux	A : 4	B : 3	C : 2	—	C : 3	B : 3						
Infection process	Follow culture cells	A : 4	B : 2•	C : 1	—	C : 1	B : 2•						
	Infect virus and make virus adhesive	A : 4	B : 3	C : 2•	C : 3	C : 2•	B : 3						
	Prepare and add solution for culture	A : 4	B : 3	C : 2	—	C : 1	B : 2•						
	Culture roux	A : 4	B : 3	C : 2	—	C : 2	B : 2						
Process to change solution to keep cell	Follow virus roux	A : 4	B : 2•	C : 1	—	C : 1	B : 1						
	Prepare and add solution for culture	A : 4	B : 3	C : 2•	—	C : 2•	B : 2						
	Culture roux	A : 4	B : 3	C : 2	—	C : 2	B : 2						
Process to wash virus infected cells	Follow roux	A : 4	B : 2•	C : 1	—	C : 1	B : 1						
	Prepare solution for culture	A : 4	B : 3	C : 2•	—	C : 2•	B : 2•						
	Wash virus infected cell and add solution for culture	A : 4	B : 3	C : 2	—	C : 2	B : 2						
Process to keep at 5 ℃	Follow roux of virus infected cell	A : 4	B : 2•	C : 1	—	C : 1	B : 2						
	Keep roux of virus infected cell at cold	A : 4	B : 3	C : 3	—	C : 3	B : 3						
Harvesting process	Harvest virus mixture and add stability agent	A : 4	B : 3•	C : 2•	—	C : 2•	B : 2•						
Purification process	Filtrate virus mixture separately	A : 4	B : 3•	C : 1•	—	C : 1•	B : 2•						
Dispensing process	Solution after filtration	A : 4	B : 3	C : 2	—	C : 2	B : 2						
General items	Use centrifuge	C : 2	C : 2	—	B : 3	—	A : 4						
	Use Autoclave Dry oven	C : 2	B : 1	—	B : 4	—	A : 4						
	Use supply system of WFI	C : 2	C : 1	—	B : 4	—	A : 4						
	Use clean bench	B : 4	B : 2	—	—	—	A : 4						
	Use particle counter	B : 3	B : 2	—	C : 4	—	A : 4						
	Adhesive bacteria	B : 4	B : 2	—	—	—	A : 4						
	Use air sampler	B : 4	B : 2	—	C : 4	—	A : 4						
	Use integrity testing machine	B : 2	C : 2	—	B : 3	—	A : 4						
	Use formalin fumigator	A : 4	B : 2	C : 2	B : 3	C : 2	C : 3						

Expert: Mr. Katsuda Training time : From 14th May to 16th Training days in total : 3 4 days

Classification	Content	Trained staffs of POLYVAC and level achieved											
		BP1	BP2	BP3	BP4	BP5	BP6	BP7	BP8				
Autoclave	Prepare implement for PQ	—	B : 2	—	B : 4	—	A : 4	—	—				
	Opoeration to check machines for use	—	B : 1	—	B : 4	—	A : 4	—	—				
	Real operation and data collection	—	B : 2	—	B : 4	—	A : 4	—	—				
	Make and keep working report	—	B : 1	—	B : 3	—	A : 4	—	—				
	Complete work and tidy up implement	—	B : 2	—	B : 4	—	A : 4	—	—				
Dry Oven	Prepare implement for PQ	—	B : 2	—	B : 4	—	A : 4	—	—				
	Opoeration to check machines for use	—	B : 1	—	B : 4	—	A : 4	—	—				
	Real operation and data collection	—	B : 2	—	B : 4	—	A : 4	—	—				
	Make and keep working report	—	B : 1	—	B : 3	—	A : 4	—	—				
	Complete work and tidy up implement	—	B : 2	—	B : 4	—	A : 4	—	—				

Expert : Mr. Sato Training time : From 13th August 2007 to 8th Sept. Days in total: 27 days

Incubator	Prepare implement for PQ	—	B : 2	—	B : 4	—	A : 4	—	—				
	Opoeration to check machines for use	—	B : 1	—	B : 4	—	A : 4	—	—				
	Real operation and data collection	—	B : 2	—	B : 4	—	A : 4	—	—				
	Make and keep working report	—	B : 1	—	B : 3	—	A : 4	—	—				
	Complete work and tidy up implement	—	B : 2	—	B : 4		A : 4						
Cold rm	Prepare implement for PQ	—	B : 2	—	B : 4	—	A : 4	—	—				
	Opoeration to check machines for use	—	B : 1	—	B : 4	—	A : 4	—	—				
	Real operation and data collection	—	B : 2	—	B : 4	—	A : 4	—	—				
	Make and keep working report	—	B : 1	—	B : 3	—	A : 4	—	—				
	Complete work and tidy up implement	—	B : 2	—	B : 4	—	A : 4	—	—				

Egg Incubator	Prepare implement for PQ	—	B : 2	—	B : 4	—	A : 4	—	—			
	Opoeration to check machines for use	—	B : 1	—	B : 4	—	A : 4	—	—			
	Real operation and data collection	—	B : 2	—	B : 4	—	A : 4	—	—			
	Set up and keep working report	—	B : 1	—	B : 3	—	A : 4	—	—			
	Complete work and tidy up implement	—	B : 2	—	B : 4	—	A : 4	—	—			
Inactivate virus (at 7 0℃)	Purpose of inactivating virus	A : 4	B : 4	—	—	—	B : 4	—	—			
	Preprare implement before inactivating	A : 4	B : 4	—	—	—	B : 4	—	—			
	Inactivated order	A : 4	B : 4	—	—	—	B : 4	—	—			
	Set up and keep working reports	A : 4	B : 4	—	—	—	B : 4	—	—			
	After completion, report to persons in charge of Dept.	A : 4	B : 4	—	—	—	B : 4	—	—			
Temperature and humidity	Prepare implement for PQ	—	B : 2	—	B : 4	—	A : 4	—	—			
	Opoeration to check machines for use	—	B : 1	—	B : 4	—	A : 4	—	—			
	Real operation and data collection	—	B : 2	—	B : 4	—	A : 4	—	—			
	Make and keep working report	—	B : 1	—	B : 3	—	A : 4	—	—			
	Complete work and tidy up implement	—	B : 2	—	B : 4	—	A : 4	—	—			
Entry order	Prepare implement for PQ	A : 3	B : 2	—	—	—	B : 2	—	—			
	Opoeration to check machines for use	A : 3	B : 2	—	—	—	B : 2	—	—			
	Real operation and data collection	A : 3	B : 2	—	—	—	B : 2	—	—			
	Make and keep working report	A : 3	B : 2	—	—	—	B : 2	—	—			
	Complete work and tidy up implement	A : 3	B : 2	—	—	—	B : 2	—	—			
Number of sterilization keeping days	Prepare implement for PQ	—	—	—	—	—	—	—	—			
	Opoeration to check machines for use	—	—	—	—	—	—	—	—			
	Real operation and data collection	—	—	—	—	—	—	—	—			
	Make and keep working report	—	—	—	—	—	—	—	—			
	Complete work and tidy up implement	—	—	—	—	—	—	—	—			
Quality of product of thawing solution	Prepare implement for PQ	—	—	—	—	—	—	—	—			
	Opoeration to check machines for use	—	—	—	—	—	—	—	—			
	Real operation and data collection	—	—	—	—	—	—	—	—			
	Make and keep working report	—	—	—	—	—	—	—	—			
	Complete work and tidy up implement	—	—	—	—	—	—	—	—			
Clothes changing	Purpose of changing clothes	A : 4	B : 4	C : 3	C : 4	C : 3	B : 4	C : 3	C : 3			
	Prepare implement for PQ	A : 4	B : 4	C : 3	C : 4	C : 3	B : 4	C : 3	C : 3			
	Changing order	A : 4	B : 3	C : 3	C : 4	C : 3	B : 4	C : 3	C : 3			
	handle troubles	A : 4	B : 3	C : 3	C : 4	C : 3	B : 4	C : 3	C : 3			
Count bacteria in air (before working)	Prepare implement before operation	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
	Operation to check machines for use	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
	Real operation and data collection	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
	Make and keep working report	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
	Complete work and tidy up implement	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
Count particle in air (Before operation)	Prepare implement before operation	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
	Operation to check machines for use	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
	Real operation and data collection	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
	Make and keep working report	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
	Complete work and tidy up implement	B : 4	B : 3	—	C : 4	—	A : 4	—	—			
Fumigation	Prepare implement before operation	A : 4	B : 3	—	C : 3	—	B : 3	—	—			
	Operation to check machines for use	A : 4	B : 3	—	C : 3	—	B : 3	—	—			
	Real operation and data collection	A : 4	B : 3	—	C : 3	—	B : 3	—	—			
	Make and keep working report	A : 4	B : 3	—	C : 3	—	B : 3	—	—			
	Complete work and tidy up implement	A : 4	B : 3	—	C : 3	—	B : 3	—	—			

QC Dept.-Chemical

Expert: Mr. Kenichi Baba Performance period: 2006.7～11(Performance date: 77)

Categoly	Items	Trained staffs of POLYVAC and level achieved										
		QCC1	QCC2	QCC3								
Basic analysis Operation	Washing and drying for utensils	A : 4	A : 4	C : 3								
	Weighing/Records	A : 4	A : 4	C : 3								
	Pippet operation	A : 4	A : 4	C : 3								
	Procedure regarding water	A : 4	A : 4	C : 3								
pH	Preaparation	A : 4	A : 4	—								
	Calibration/Inspection of measuring instrument	A : 4	A : 4	—								
	Measurement method/Records	A : 4	A : 4	—								
	trouble shooting	A : 2	A : 2	—								
	Procedure/frequency of exchanging instrument parts and comsumables	A : 2	A : 2	—								
Moisture Contents	Preaparation	A : 4	A : 4	—								
	Calibration/Inspection of measuring instrument	A : 4	A : 4	—								
	Measurement method/Records	A : 4	A : 4	—								
	trouble shooting	A : 3	A : 3	—								
	Procedure/frequency of exchanging instrument parts and comsumables	A : 3	A : 3	—								
Osmosis	Preaparation	A : 4	A : 4	—								
	Calibration/Inspection of measuring instrument	A : 4	A : 4	—								
	Measurement method/Records	A : 4	A : 4	—								
	trouble shooting	A : 2	A : 2	—								
	Procedure/frequency of exchanging instrument parts and comsumables	A : 3	A : 3	—								
Microparticle	Preaparation	A : 4	A : 4	—								
	Calibration/Inspection of measuring instrument	A : 4	A : 4	—								
	Measurement method/Records	A : 4	A : 4	—								
	trouble shooting	A : 2	A : 2	—								
	Procedure/frequency of exchanging instrument parts and comsumables	A : 1	A : 1	—								
Propeties	Preaparation	A : 4	A : 4	—								
	Inspection method/Records	A : 4	A : 4	—								
	trouble shooting	A : 2	A : 2	—								
Weight deviation	Preaparation	A : 4	B : 0	—								
	Calibration/Inspection of measuring instrument	A : 4	B : 0	—								
	Measurement method/Records	A : 2	B : 0	—								
	trouble shooting	A : 1	B : 0	—								
	Procedure/frequency of exchanging instrument parts and comsumables	A : 2	B : 0	—								
Inspection of foreign particles	Preaparation	A : 3	B : 0	—								
	Inspection method/Records	A : 3	B : 0	—								
	trouble shooting	A : 1	B : 0	—								

P.W	Preaparation	A : 4	A : 4	B : 3									
	Inspection method/Records	A : 4	A : 4	B : 3									
	trouble shooting	A : 4	A : 4	B : 2									
W.F.I	Preaparation	A : 2	A : 2	—									
	Inspection method/Records	A : 2	A : 2	—									
	trouble shooting	A : 2	A : 2	—									
TOC	Preaparation	A : 2	B : 0	—									
	Calibration/Inspection of measuring instrument	A : 2	B : 0	—									
	Measurement method/Records	A : 2	B : 0	—									
	trouble shooting	A : 2	B : 0	—									
	Procedure/frequency of exchanging instrument parts and comsumables	A : 2	B : 0	—									
Endtoxin	Preaparation	A : 3	B : 0	—									
	Calibration/Inspection of measuring instrument	A : 3	B : 0	—									
	Measurement method/Records	A : 3	B : 0	—									
	trouble shooting	A : 2	B : 0	—									
	Procedure/frequency of exchanging instrument parts and comsumables	A : 1	B : 0	—									
Electric conductivity	Preaparation	A : 1	A : 1	—									
	Calibration/Inspection of measuring instrument	A : 1	A : 1	—									
	Measurement method/Records	A : 1	A : 1	—									
	trouble shooting	A : 1	A : 1	—									
	Procedure/frequency of exchanging instrument parts and comsumables	A : 1	A : 1	—									
Specification ofRubber stopper	Preaparation	A : 2	A : 2	—									
	Calibration/Inspection of measuring instrument	A : 2	A : 2	—									
	Measurement method/Records	A : 2	A : 2	—									
	trouble shooting	A : 2	A : 2	—									
	Procedure/frequency of exchanging instrument parts and comsumables	A : 2	A : 2	—									
Vial	Preaparation	A : 4	A : 3	—									
	Inspection method/Records	A : 4	A : 3	—									
	trouble shooting	A : 2	A : 2	—									
Almicap	Preaparation	A : 1	A : 1	—									
	Inspection method/Records	A : 1	A : 1	—									
	trouble shooting	A : 1	A : 1	—									
Rubber stopper appearance	Preaparation	A : 1	A : 1	—									
	Inspection method/Records	A : 1	A : 1	—									
	trouble shooting	A : 1	A : 1	—									
Vial appearance	Preaparation	A : 1	A : 1	—									
	Inspection method/Records	A : 1	A : 1	—									
	trouble shooting	A : 1	A : 1	—									
25 raw materiales	Preaparation	A : 0	A : 0	—									
	Inspection method/Records	A : 0	A : 0	—									
	trouble shooting	A : 0	A : 0	—									
making up of SOP	SOP for analysis instruments	A : 2	A : 2	—									
	SOP for analysis operations	A : 3	A : 2	—									

QC Dept.-Biological1

Expert: Mr. Fumio Yoshida Implementation time: XX/1/2007- 28/11/2007 Total implementation days: 170 days

Classification	Items	Trained staffs of POLYVAC and level achieved											
		QCB1	QCB2	QCB3	QCB4	QCB5	QCB6						
sterility test	Preparation for materials	A : 4	B : 4	B : 2	C : 2	C : 2	—						
	Prepare test medium	A : 4	B : 4	B : 2	C : 2	C : 2	—						
	Stenlity filtration	A : 4	B : 4	B : 2	C : 2	C : 2	—						
	Observation of test medium	A : 4	B : 4	B : 2	C : 2	C : 2	—						
	Judge of test medium	A : 4	B : 4	B : 2	C : 2	C : 2	—						
	Clean and disposal after judge	A : 4	B : 4	B : 2	C : 2	C : 2	—						
Mycoplasma test	Preparation for materials	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Sterilization of medium	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Preparation and filling	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Aseptic filtration	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Cell line	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Observation of test medium	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Judge of test medium	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Clean and disposal after judge	A : 4	B : 4	B : 4	C : 2	C : 2	—						
test of Virus concentration and Virus concentration	Preparation for materials	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Dispensing and Trypsinization	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Preparation of agar and culture solution	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Dilution and inoculation	A : 4	B : 3	B : 3	C : 2	C : 2	—						
	ABC Staining test	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Plaque counts	A : 4	B : 2	B : 2	C : 2	C : 2	—						
	Judge and calculation	A : 4	B : 2	B : 2	C : 2	C : 2	—						
	Clean and disposal after judge	A : 4	B : 4	B : 4	C : 2	C : 2	—						
Cell line	Preparation for materials	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Preparation for Trypsin and medium	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Trypsinization	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Centrifugation	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Filling and cell line	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Count and calculation of cell	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Incubation at 37°C incubator	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Clean and disposal after judge	A : 4	B : 4	B : 4	C : 2	C : 2	—						
Water quality test	Preparation for materials	A : 4	B : 4	B : 4	C : 3	C : 2	—						
	Preparation and sterilization of agar	A : 4	B : 4	B : 4	C : 3	C : 2	—						
	Dispensing agar medium	A : 4	B : 4	B : 4	C : 3	C : 2	—						
	Aseptic filtration	A : 4	B : 4	B : 3	C : 3	C : 2	—						
	Observation	A : 4	B : 4	B : 4	C : 3	C : 2	—						
	Judge	A : 4	B : 4	B : 4	C : 3	C : 2	—						
	Clean and disposal after judge	A : 4	B : 4	B : 4	C : 3	C : 2	—						
Identity test	Preparation for materials	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Dispensing and trypsinization	A : 4	B : 4	B : 4	C : 2	C : 2	—						
	Dilution and inoculation	A : 4	B : 4	B : 3	C : 1	C : 1	—						
	Washing and fixing and staining	A : 4	B : 2	B : 3	C : 1	C : 1	—						
	Judge	A : 4	B : 2	B : 3	C : 1	C : 1	—						
	Clean and disposal after judge	A : 4	B : 4	B : 4	C : 1	C : 1	—						

E. coli	Preparation for materials	A : 4	B : 1	B : 3	C : 1	C : 1	—					
	Preparation and sterilization of medium	A : 4	B : 1	B : 3	C : 1	C : 1	—					
	Incubation at 37℃ incubator	A : 4	B : 1	B : 1	C : 1	C : 1	—					
	Observation	A : 4	B : 1	B : 1	C : 1	C : 1	—					
	Judge	A : 4	B : 1	B : 1	C : 1	C : 1	—					
	Clean and disposal after judge	A : 4	B : 1	B : 1	C : 1	C : 1	—					
Preparation for antibody of measles immunity	Preparation for materials	A : 4	B : 3	B : 3	C : 2	C : 2	—					
	Trypsinization	A : 4	B : 4	B : 4	C : 2	C : 2	—					
	Dilution and inoculation of virus	A : 4	B : 2	B : 3	C : 1	C : 1	—					
	Cell line and inoculation of virus	A : 4	B : 2	B : 2	C : 1	C : 1	—					
	Observation of CPE	A : 4	B : 2	B : 2	C : 1	C : 2	—					
	Harvest	A : 4	B : 1	B : 1	C : 1	C : 2	—					
	Operation of centrifuge machine	A : 4	B : 3	B : 3	C : 2	C : 2	—					
	Safekeeping of virus	A : 4	B : 2	B : 2	C : 1	C : 1	—					
	Clean and disposal after judge	A : 4	B : 3	B : 3	C : 2	C : 2	—					
Observation	Preparation for materials	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Cell observation	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Sample pool and dispensing	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Washing and preparation of Haemadsorbing virus	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Cell washing and haemadsorbing virus	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Test for haemadsorbing virus	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
Test of inoculation in simian cell culture-1	Preparation for materials	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Cell observation, trypsinization, and dispensing	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Inoculation	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Observation and medium change	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
Test of inoculation in human tissue cell culture-1	Preparation of sterilization for materials	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Cell observation, trypsinization, and dispensing	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Inoculation and inoculation of cell line	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Observation and medium change	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
Test of inoculation in primary tissue cultures of embryonic chick cell-1	Preparation of sterilization for materials	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Trypsinization, cell count and dispensing	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Inoculation and inoculation of cell line	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Observation and medium change	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Test for haemadsorbing virus	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
Virus test (identification)-1	Preparation of sterilization for materials	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Aseptic distribution of virus for each tests	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after distribution	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
Test of inoculation in simian cell culture-2	Preparation for materials	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Cell observation, trypsinization, and dispensing	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Sample neutralization	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Inoculation	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Observation and medium change	A : 4	B : 3	B : —	C : 2	C : 2	C :					
	Judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
Test of inoculation in human tissue cell culture-2	Preparation of sterilization for materials	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Cell observation, trypsinization, and dispensing	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Neutralization for samples	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Inoculation and inoculation of cell line	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Observation and medium change	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
Test of inoculation in primary tissue cultures of embryonic chick cell-1	Preparation of sterilization for materials	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Cell observation, trypsinization, and dispensing	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Sample neutralization	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Inoculation and inoculation of cell line	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Observation and medium change	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
	Judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 3	B : —	C : 2	C : 2	C : 1					
Virus test (identification)-1	Preparation of sterilization for materials	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Cell observation, trypsinization, and dispensing	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Sample dilution neutralization	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Virus dilution inoculation	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	C P E observation and addition to medium	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
Distribution/Filling test	Temperature adjustment and operation	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Observation	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Identification of bacteria and Fungi	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Date of changing temperature	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Clean and disposal after judge	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
	Efficiency test	A : 4	B : 2	B : —	C : 2	C : 2	C : 1					
R S V|1,2 virus growth	Preparation of sterilization for materials	A : 2	B : 2	B : —	C : 2	C : 2	C : -					
	Operation of temperature and hygrometer in egg incubator	A : 2	B : 2	B : —	C : 2	C : 2	C : -					
	Candling egg	A : 2	B : 2	B : —	C : 2	C : 2	C : -					
	Identification of non-fertilized egg and dead egg	A : 2	B : 2	B : —	C : 2	C : 2	C : -					
	Virus dilution and inoculation	A : 2	B : 2	B : —	C : 2	C : 2	C : -					
	Identification of life and death and	A : 2	B : 2	B : —	C : 2	C : 2	C : -					
	Clean and disposal after harvest	A : 2	B : 2	B : —	C : 2	C : 2	C : -					

QC Dept.-Biological2

Expert: Mr. Chiharu Yoshino Training time: From 29th May to 13th June 2007 Training days: 18 days

Classification	Content	Trained staffs of POLIOVAC and level achieved
		QCB21
Egg infection test (Egg Yolk sac)	Could prepare implement, material and reagent or not	B : 3
	Could prepare (neutralize) reagent and material for test or not.	B : 3
	Could use machines and implement or	B : 3
	Could carry out test according to regulated order or not	B : 3
	Could evaluate or not	B : 3
	Could treat material suitably after having evaluation or not	B : 3
Egg infection test (Allantoic fluid)	Could prepare implement, material and reagent or not	B : 3
	Could prepare (neutralize) reagent and material for test or not.	B : 3
	Could use machines and implement or	B : 3
	Could prepare red blood cell or not	B : 3
	Could carry out test according to regulated order or not	B : 3
	Could evaluate or not	B : 3
	Could treat material suitably after having evaluation or not	B : 3

QC Dept.-Animal

Expert: Mr. Urayama Shigenobu Trainning time: From 29th May to 13th June 2007 Trainning days: 18Days

Classification	Content	Trained staffs of POLYVAC and level achieved		
		QCA1	QCA2	QCA3
Basic operation	Sterilized operation	4 : A	4 : A	—
	Measure and take note	4 : A	4 : A	—
	Operation with pipet	4 : A	4 : A	
Toxicity test	①Prepare implement and material	3 : A	3 : A	—
	②Prepare sample for test	3 : A	4 : A	—
	③When take animal into Lab (follow and mark)	3 : A	3 : A	3 : C
	④Before test (Weight and follow)	3 : A	3 : A	3 : C
	⑤Select animal for test	3 : A	3 : A	—
	⑥Inject animal	3 : A	3 : A	—
	⑦Stablize animal	4 : A	4 : A	—
	⑧During test, follow and weight animal	3 : A	3 : A	2 : C
	⑨Accuracy of testing operation	3 : A	3 : A	—
	⑩Quick operation of test	3 : A	3 : A	—
	⑪Write record for each work	3 : A	3 : A	—
	⑫Evaluation	4 : A	4 : A	—
	⑬Contact and report	3 : A	3 : A	—
	⑭Grasp content and process of test throughly	4 : A	4 : A	—
Adnormal toxicity test(Mouse)	①Prepare implement and material	3 : A	3 : A	—
	②Prepare sample for test	3 : A	4 : A	—
	③When take animal into Lab (follow and mark)	3 : A	3 : A	3 : C
	④Before test (Weight and follow)	3 : A	3 : A	3 : C
	⑤Select animal for test	3 : A	3 : A	—
	⑥Inject animal	4 : A	4 : A	—
	⑦Stablize animal	4 : A	4 : A	—
	⑧During test, follow and weight animal	3 : A	3 : A	2 : C
	⑨Accuracy of testing operation	3 : A	3 : A	—
	⑩Quick operation of test	3 : A	3 : A	—
	⑪Write record for each work	3 : A	3 : A	—
	⑫Evaluation	4 : A	4 : A	—
	⑬Contact and report	3 : A	3 : A	—
	⑭Grasp content and process of test throughly	4 : A	4 : A	—
Adnormal toxicity test (Guinea pig)	①Prepare implement and material	3 : A	3 : A	—
	②Prepare sample for test	3 : A	4 : A	—
	③When take animal into Lab (follow and mark)	3 : A	3 : A	3 : C
	④Before test (Weight and follow)	3 : A	3 : A	3 : C
	⑤Select animal for test	3 : A	3 : A	—
	⑥Inject animal	3 : A	3 : A	—
	⑦Stablize animal	4 : A	4 : A	—
	⑧During test, follow and weight animal	3 : A	3 : A	2 : C
	⑨Accuracy of testing operation	3 : A	3 : A	—
	⑩Quick operation of test	3 : A	3 : A	—
	⑪Write record for each work	3 : A	3 : A	—
	⑫Evaluation	4 : A	4 : A	—
	⑬Contact and report	3 : A	3 : A	—
	⑭Grasp content and process of test throughly	4 : A	4 : A	—
General items				
Other problem	Standard of animal			
Equipment, implement and spare parts	Equipment calibration (Such as scale)	—	—	—

Annex 14. Summary of Issued Certificate

Name of Department / Year	Date of Issued	Nos. of Processes or	Nos. of Issued	Nos. of Certified Persons	Remarks
1. Final Production					
1.1 FY 2006	14 Jan. 2007	13	16	5	
	9 Mar. 2007	5	5	5	
	12 Mar. 2007	10	25	8	
1.2 FY 2007	19 Oct. 2007	40	102	14	
2. Medium Preparation					
2.1 FY 2006	14 Mar. 2007	16	16	5	
2.2 FY 2007	6 Jul. 2007	4	4	1	
	9 Jul. 2007	5	10	3	
	12 Jul. 2007	4	7	3	
	16 Jul. 2007	2	4	2	
	3 Oct. 2007	33	46	4	
3. Quality Control					
3.1 FY 2006 for Biological	23 Oct. 2006	6	10	3	
	22 Dec. 2006	2	3	2	
	16 Mar. 2007	2	3	2	
3.2 FY 2007 for Biological	24 Aug. 2007	10	10	1	
3.3 FY 2006 for Chemical	20 Nov. 2006	12	104	2	
	24 Nov. 2006	5	33	3	
	6 Dec. 2007	1	20	1	
	7 Dec. 2007	1	8	1	
	8 Dec. 2007	9	36	1	
	1 Feb. 2007	2	28	2	
3.4 FY 2007 for Chemical	27 Apr. 2007	1	2	1	
	3 May 2007	1	11	2	
	4 May 2007	1	9	1	
	12 May 2007	2	19	1	
	15 May 2007	1	20	1	
	16 May 2007	6	12	1	
	17 May 2007	8	38	2	
	18 May 2007	4	8	1	
	22 May 2007	6	26	3	
	15 Jun. 2007	5	20	1	
	31 Jul. 2007	4	5	2	
3.5 FY 2007 for Animal-1	13 Jun. 2007	2	2	1	
3.6 FY 2007 for Animal-2	13 Jun. 2007	3	6	2	
4. Bulk Production					
4.1 FY 2006	-	-	-	-	
4.2 FY 2007	14 Jun. 2007	10	2	2	
	15 Jun. 2007	10	2	2	
	29 Jun. 2007	10	20	2	
	3 Jul. 2007	8	22	4	
	6 Jul.2007	2	5	5	
	12 Jul. 2007	5	10	2	
	14 Jul. 2007	9	19	4	
	23 Jul. 2007	5	10	3	
	6 Sep. 2007	6	9	2	
	12 Sep. 2007	14	37	4	

Annex 15. List of Training Manuals

Department	Prepared number of volumes	
	2006	2007
Quality Control	44	39
Final Production	138	28
Media Preparation	40	15
Bulk Production	20	21
Total	242	103

Annex 16. List of Working Groups

LIST OF WORKING GROUP

Rev.-1

Prepared by: Nguyen Thanh Hai - QA
Approved by: Nguyen Thuy Huong QA
Date: 10 May 2007

No.	Code	Name	POLYVAC		KITASATO		Member					
			Leader	Sub Leader	Leader	Sub Leader	BP	MP	FP	QA	QC	Eng
1	WG-1	Calibration/ Valibration	Nguyen Dang Anh	Nguyen Thuy Huong	Katsuda	Nakashima	Nguyen Xuan Hoa Ha Hoang Phuong Le Van Dung	Tran Hong Thuy Le Anh Tuan Bui Van Hoang	Le Quoc Hung Nguyen Dinh Kim Nguyen Binh Nguyen Ta Kim Quoc Le Thi Thuy	Nguyen Thuy Huong Tran Thi Phuong	Nguyen Nu Anh Thu Le Trung Dung Ngo Thi Thanh Huong	Nguyen Dang Anh Dang Anh Tuan Nguyen Manh Dung Cao Minh Duc
2	WG-2	Formalin Fumigation	Nguyen Xuan Hoa	Tran Thi Phuong	Sato	Nakashima	Nguyen Xuan Hoa Ha Hoang Phuong	Nguyen Quy Duong	Nguyen Binh Nguyen Ta Kim Quoc	Nguyen Thuy Huong Tran Thi Phuong	Nguyen Nu Anh Thu Le Trung Dung Nguyen Thi Nga Vu Thi Huong Ngo Thi Thanh Huong	Nguyen Manh Dung Cao Minh Duc Le Quoc Hung
3	WG-3	Environmental Pollution Control	Nguyen T. Mai Huong	Tran Thi Phuong	Baba K	Ishikawa	Lai Quynh Mai	Tran Hong Thuy	Le Thi Thuy	Nguyen Thuy Huong	Nguyen T. Mai Huong	Nguyen Manh Dung
4	WG-4	Environmental Monitoring	Nguyen Nu Anh Thu	Tran Thi Phuong	Yoshida	Nakashima	Ha Hoang Phuong	Tran Hong Thuy	Dang Ngan Ha	Nguyen Thuy Huong Tran Thi Phuong	Nguyen Nu Anh Thu Le Trung Dung	Nguyen Quoc Phong
5	WG-5	Procurement Control	Tran Trong Hai	Le Thu Nga	Miyagawa	Ishikawa	Nguyen Thanh Tung	Tran Hong Thuy	Nguyen Binh Nguyen	Nguyen Thuy Huong Le Thu Nga	Ngo Thu Huong B	Cao Minh Duc

Annex 17. List of GMP Documents

1. LIST OF GMP DOCUMENTS

Rev.-0

As of 19 October 2007

No.	Name of Documents	Doc. No	Priority	Preparing progress	QA Approval	Remarks
1) Standard document						
1	Production control	SD-01	1	100%	Approval	
2	Sanitation control	SD-02	1	100%	Approval	
3	Quality control	SD-03	1	100%	Approval	
4	Validation	SD-04	1	100%	Approval	Expert will check after PV.
5	Revision control	SD-05	1	100%	Approval	
6	Release control	SD-06	1	100%	Approval	
7	Education and Training	SD-07	1	100%	Approval	
8	Handling abnormal and deviation	SD-08	1	100%	Approval	
9	Change control	SD-11	1	100%	Approval	
10	Policy for training new staffs	SD-07-01	1	100%	Approval	
11	Policy for self inspection	SD-10	2	100%	Approval	
12	Policy for product recall	SD-13	2	100%	Approval	
13	Policy for market supervision	SD-14	2	100%	Approval	
14	Policy for line communication	SD-15	2	0%	—	
15	Policy for authorizing communication and approval	SD-16	2	50%	—	
16	Policy for environment monitoring	SD-09	2	50%	—	
17	Policy for trend analysis	SD-17	2	100%	Approval	
18	Policy for retraining about professional skills	SD-07-02	2	0%	—	
19	Policy for checking of hearth and immunization	SD-12	2	30%	—	
2) MF						
1	MF - Measles	M01-MF	1	100%	Approval	
3) Manuals						
1	Quality Manual	01-QM	2	100%	Approval	
2	Material manual for measles vaccine production	M01-MM	2	100%	Approval	
3	Manual for measles equipments	M01-EM	2	50%	—	

Annex 18. List of SOPs

2. LIST OF SOPs

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
				preparing	non preparing	due date	
BULK PRODUCTION DEPARTMENT							
1	Changing in grade C	M03-SOP-01-01	X				
2	Changing in grade D	M03-SOP-01-02	X				
3	Wash hand and wear gloves	M03-SOP-01-03		X		30 Oct. 2007	
4	Sanitation of grade A, B, C	M03-SOP-02-01		X		30 Oct. 2007	
5	Sanitation of grade D	M03-SOP-02-02		X		30 Oct. 2007	
6	Sterilization procedure by Formalin fumigation	M03-SOP-02-03	X				
7	Environment monitoring	M03-SOP-03-01		X		30 Oct. 2007	
8	Follow deviation in pressure, temperature, humidity of clean rooms	M03-SOP-03-02		X		30 Oct. 2007	
9	Particle counting	M03-SOP-03-03		X		30 Oct. 2007	
10	Bacterium sampling in air	M03-SOP-03-04		X		30 Oct. 2007	
11	Surface sampling	M03-SOP-03-05		X		30 Oct. 2007	
12	Procedure for gowning	M03-SOP-03-06	X				
13	SPF egg receipt	M03-SOP-04-01	X				
14	Keep SPF egg	M03-SOP-04-02	X				
15	Incubate SPF egg	M03-SOP-04-03	X				
16	Check egg	M03-SOP-04-04	X				
17	Wash and sterilize SPF egg shell	M03-SOP-04-05	X				
18	Cut and collect SPF chicken embryo	M03-SOP-04-06	X				
19	M1.1. - trypsination medium preparation	M03-SOP-04-07	X				
20	M1.2. Trypsination of chicken embryo cell	M03-SOP-04-08	X				
21	M1.3. Dispense and centrifuge	M03-SOP-04-09	X				
22	M1.4. Collect cell after centrifuge	M03-SOP-04-10	X				
23	M1.5. sample cell counting	M03-SOP-04-11	X				
24	M1.6. Cell counting	M03-SOP-04-12	X				
25	M1.7. Prepare and dispense cell suspension in culture roux	M03-SOP-04-13	X				
26	M2.1. Infected virus suspension preparation	M03-SOP-05-01		X		30 Oct. 2007	
27	M2.2.Virus infection	M03-SOP-05-02		X		30 Oct. 2007	
28	M2.3. M199 addition	M03-SOP-05-03		X		30 Oct. 2007	
29	M3.1. M199 preparation (1)	M03-SOP-05-04		X		30 Oct. 2007	
30	M3.2.Medium replacement (1)	M03-SOP-05-05		X		30 Oct. 2007	
31	M4.1. Hanks and M199 preparation (2)	M03-SOP-05-06		X		30 Oct. 2007	
32	M4.2. Wash Hanks and replace medium (2)	M03-SOP-05-07		X		30 Oct. 2007	
33	Virus suspension virus	M03-SOP-05-08		X		30 Oct. 2007	
34	CGI-CPE evaluation	M03-SOP-05-09		X		30 Oct. 2007	
35	Mixture of virus suspension and add table agent into 70L Tank	M03-SOP-06-01		X		30 Oct. 2007	
36	Suspension filtration	M03-SOP-06-02		X		30 Oct. 2007	
37	Dispense Bulk into 10l tank	M03-SOP-06-03		X		30 Oct. 2007	
38	Freeze Bulk quickly	M03-SOP-06-04		X		30 Oct. 2007	
39	Keep bulk in deep freezer	M03-SOP-07-01		X		30 Oct. 2007	
40	Thaw Bulk	M03-SOP-07-02		X		30 Oct. 2007	
41	Prepare implement for trypsination	M03-SOP-08-01	X				
42	Prepare implement for infection	M03-SOP-08-02	X				
43	Prepare implement for medium replacement (1)	M03-SOP-08-03	X				
44	Prepare implement for medium replacement (2)	M03-SOP-08-04	X				
45	Prepare implement for filtration-mixture	M03-SOP-08-05		X		30 Oct. 2007	
46	Prepare clothes	M03-SOP-08-06	X				
47	Order and receive medium	M03-SOP-08-07		X		30 Oct. 2007	
48	Environment monitoring	M03-SOP-08-08		X		30 Oct. 2007	
49	Dispense NaHCO3 and EK	M03-SOP-08-09		X		30 Oct. 2007	
50	Medium preparation	M03-SOP-08-10		X		30 Oct. 2007	
51	Iod alcohol preparation	M03-SOP-08-11		X		30 Oct. 2007	
52	Make calf serum inactive	M03-SOP-08-12		X		30 Oct. 2007	
53	Check integrity of filtration membrane- Integrity test	M03-SOP-08-13		X		30 Oct. 2007	
54	Wash implement	M03-SOP-08-14		X		30 Oct. 2007	
55	Treat virus infected implement	M03-SOP-10-01	X				
56	Handle with new roux	M03-SOP-10-02		X		30 Oct. 2007	
57	Handle rubber stopper	M03-SOP-10-03		X		30 Oct. 2007	
58	Wash clothes of grades C, D	M03-SOP-10-04		X		30 Oct. 2007	
59	Sakura autoclave	M03-SOP-11-01	X				
60	AirTech dry oven	M03-SOP-11-02	X				
61	Operate incubation room	M03-SOP-11-03		X		30 Oct. 2007	
62	Operate cold room	M03-SOP-11-04		X		30 Oct. 2007	
63	Operate big electronic scale	M03-SOP-11-05		X		30 Oct. 2007	
64	Operate small electronic scale	M03-SOP-11-06		X		30 Oct. 2007	
65	Operate Clean bench	M03-SOP-11-07		X		30 Oct. 2007	
66	Operate Safety cabinet	M03-SOP-11-08		X		30 Oct. 2007	
67	Operation of use point UFW - 3	M03-SOP-11-09	X				
68	Operate FW4 using point	M03-SOP-11-10		X		30 Oct. 2007	

69	Operate WFI6 using point	M03-SOP-11-11		X		30 Oct. 2007	
70	SIP use point UFW - 3	M03-SOP-11-12	X				
71	SIP use point WFI - 6	M03-SOP-11-13	X				
72	SIP use point UFW - 3	M03-SOP-11-14	X				
73	SIP use point system UFW - 4	M03-SOP-11-15	X				
74	SIP use point system WFI - 6	M03-SOP-11-16	X				
75	Operate As One TR-4 thermal regulator	M03-SOP-11-17		X		30 Oct. 2007	
76	Operation of use point WFI - 6	M03-SOP-11-18	X				
77	Operate Olympus microscope	M03-SOP-11-19		X		30 Oct. 2007	
78	Operate dispenser	M03-SOP-11-20	X				
79	Operate Toyo-10 dispenser	M03-SOP-11-21		X		30 Oct. 2007	
80	Operate sterilization bag stamping machine	M03-SOP-11-22	X				
81	Operate particle counter	M03-SOP-11-23	X				
82	Operate washing machine	M03-SOP-11-24	X				
83	Operate integrity test machine	M03-SOP-11-25		X		30 Oct. 2007	
84	Operate stirrer	M03-SOP-11-26		X		30.Oct. 2007	
85	Operate clothes drying machine	M03-SOP-11-27		X		30 Oct. 2007	
86	Operation of air sampling machine	M03-SOP-11-28	X				
87	Operate centrifuge	M03-SOP-11-29	X				
88	Operate Formalin neutralizing machine	M03-SOP-11-30		X		30 Oct. 2007	
89	Operate Formalin fumigator	M03-SOP-11-31		X		30 Oct. 2007	
90	Operate egg incubator	M03-SOP-11-32		X		30 Oct. 2007	
91	Operate egg keeping cabinet	M03-SOP-11-33	X				
92	Operate MDF-U72V deep freezer	M03-SOP-11-34	X				
93	Operate MDF-U537D deep freezer	M03-SOP-11-35	X				
94	Operate MDF-U581 deep freezer	M03-SOP-11-36	X				
95	SOP for setting and collecting sensor and BI in PQ Autoclave	M03-SOP-12-01	X				
96	SOP for setting and collecting sensor and BI in PQ Dry Oven	M03-SOP-12-02	X				
97	SOP for setting and collecting sensor in PQ of incubation room and cold room	M03-SOP-12-03	X				
98	SOP for setting up and collecting BI in PQ of fumigation	M03-SOP-12-04	X				
99	SOP for setting and collecting sensor in PQ of egg incubator	M03-SOP-12-05	X				
100	SOP for setting up, collecting BI in fumigation PQ	M03-SOP-12-06		X		30 Oct. 2007	
101	SOP for implement transportation	M03-SOP-12-07		X		30 Oct. 2007	
			47				
FINAL PRODUCTION DEPARTMENT							
1	Clothes changing to enter D grade area	M04-SOP-01-01	X				
2	Clothes changing to enter measles production area	M04-SOP-01-02	X				
3	Clothes changing to enter formulation and filling room	M04-SOP-01-03	X				
4	Washing and aseptic the hand	M04-SOP-01-04		Completed			submitted to QA, waiting for approval
5	Sanitation of clean room of grade D	M04-SOP-02-01	X				
6	Sanitation of ungraded area	M04-SOP-02-03	X				
7	SIP UFW system	M04-SOP-02-04	X				
8	Sanitation of clean room of grade A, B	M04-SOP-02-05	X				
9	SIP UFW-2	M04-SOP-02-06	X				
10	SIP WFI system	M04-SOP-02-08	X				
11	SIP WFI-2	M04-SOP-02-09	X				
12	SIP WFI-3	M04-SOP-02-10	X				
13	Room sterilization by formalin fumigation	M04-SOP-02-12	X				
14	Sample bacteria in the air	M04-SOP-03-01	X				
15	Count particle in the air in clean room	M04-SOP-03-02	X				
16	Monitoring tempt. Humidity and pressure of clean room	M04-SOP-03-03	X				
17	Monitoring temperature of cold room	M04-SOP-03-04	X				
18	Sample bacteria on surface	M04-SOP-03-05	X				
19	Conformable changing clothes	M04-SOP-03-06		Completed			submitted to QA, waiting for approval
20	Freeze dry vaccine	M04-SOP-05-01		x			
21	Inspection for vaccine product	M04-SOP-05-02	X				
22	Inspection for WFI product	M04-SOP-05-03	X				
23	Receiving vial,	M04-SOP-07-01	X				
24	Receiving rubber stopper	M04-SOP-07-02	X				
25	Receiving aluminum stopper	M04-SOP-07-03	X				
26	Storage vial, rubber stopper, aluminum stopper	M04-SOP-07-04	X				
27	Receive semi-final vaccine	M04-SOP-07-05	X				
28	Receive medium for diluting vaccine	M04-SOP-07-06	X				
29	Storage vaccine product after label sticking	M04-SOP-07-07		x		26-Oct-07	
30	Storage WFI product after label sticking	M04-SOP-07-08		x		26-Oct-07	
31	Release vaccine (WFI)	M04-SOP-07-09		x		23-Oct-07	
32	Sampling the raw material	M04-SOP-07-10		x		23-Oct-07	
33	Preparation for vaccine packing	M04-SOP-08-01		x		30 Nov. 07	
34	Washing equipment for vaccine preparation	M04-SOP-08-02	x				
35	Wrapping for sterilization of equipment for vaccine preparation	M04-SOP-08-03	x				
36	Prepare implement for Measles vaccine preparation	M04-SOP-08-04	X				
37	Wash filling implement of Final vaccine	M04-SOP-08-05	X				
38	Wrapping for sterilization of equipment for filling	M04-SOP-08-06	X				
39	Preparation equipment for filling	M04-SOP-08-07	X				
40	Washing 70L tank	M04-SOP-08-08	X				

41	Preparation aluminum stopper for capping	M04-SOP-08-09		Completed			submitted to QA, waiting for approval
42	Wash filling implement of WFI	M04-SOP-08-10	X				
43	Prepare filling implement for WFI	M04-SOP-08-12	X				
44	Prepare filling implement of WFI for sterilization	M04-SOP-08-13	X				
45	Preparation instrument for capping	M04-SOP-08-14		x		23 Oct. 07	
46	Preparation rubber stopper for filling	M04-SOP-08-15		Completed			submitted to QA, waiting for approval
47	Prepare sterilized clothes for grade D	M04-SOP-08-16	X				
48	Wetting the filter	M04-SOP-08-17	X				
49	Handle implement and clothes after filling	M04-SOP-08-18	X				
50	Check integrity of air membrane	M04-SOP-08-19	X				
51	Check integrity of WFI membrane	M04-SOP-08-20	X				
52	Prepare to operate washing machine and vial sterilization machine	M04-SOP-09-01(1)	X				
53	Operate vial washing and sterilization machine	M04-SOP-09-01(2)	X				
54	Sanitation vial washing and sterilization room	M04-SOP-09-01(4)	X				
55	Use vaccine filling machine	M04-SOP-09-03 (2)		Completed			submitted to QA, waiting for approval
56	Sanitation filling machine	M04-SOP-09-03(4)	X				
57	Problem handling for filling machine	M04-SOP-09-03(7)	X				
58	Operate tray loading machine	M04-SOP-09-04(2)	X				
59	Problem handling for tray loading machine	M04-SOP-09-04(3)	X				
60	Sanitation tray loading machine	M04-SOP-09-04(4)	X				
61	Operate aluminum stopper capping machine	M04-SOP-09-05 (2)	X				
62	Sanitation for aluminum stopper capping machine	M04-SOP-09-05 (4)	X				
63	Problem handling for aluminum stopper capping machine	M04-SOP-09-05 (3)	X				
64	Use labeling machine	M04-SOP-09-06 (2)		x		23 Oct. 07	
65	Sanitation for labelling machine	M04-SOP-09-06 (4)		x		23 Oct. 07	
66	Use freeze dryer	M04-SOP-09-07		x			
67	Operate autoclave	M04-SOP-09-08(2)	X				
68	Sanitation for autoclave	M04-SOP-09-08(4)	X				
69	Maintenance for autoclave	M04-SOP-09-08(7)		x		30 Nov.07	do after PV
70	Use auto alcohol sprayer	M04-SOP-09-09	X				
71	Use sterilized- bag sticker	M04-SOP-09-10		Completed			submitted to QA, waiting for approval
72	Use ice maker	M04-SOP-09-11				30 Nov.07	do after PV
73	Use air sampling machine	M04-SOP-09-13	X				
74	Use particle count in the air	M04-SOP-09-14	X				
75	Use Formalin fumigation machine	M04-SOP-09-15	X				
76	Use Formalin neutralization machine	M04-SOP-09-16	X				
77	Operator and clean bench	M04-SOP-09-17	X				
78	Operate to check integrity of membrane	M04-SOP-09-18	X				
79	Operation of WFI-2	M04-SOP-09-20	X				
80	Operation of WFI-3	M04-SOP-09-21	X				
81	Operation of water supply system UFW-2	M04-SOP-09-22	X				
82	Operation of water supply system UFW-5	M04-SOP-09-23	X				
83	Usage computer system for filling environment	M04-SOP-09-25		Completed			submitted to QA, waiting for approval
84	Use electronics balance	M04-SOP-09-29	X				
85	Set up and collect sensor in sterilizing rubber stopper	M04-SOP-10-01	X				
86	Set up and collect BI in sterilizing rubber stopper	M04-SOP-10-02	X				
87	Set up and collect sensor in sterilizing aluminum stopper and implement	M04-SOP-10-03	X				
88	Set up and collect BI in sterilizing aluminum stopper and implement	M04-SOP-10-04	X				
89	Set up and collect sensor in sterilizing clothes and sanitation implement	M04-SOP-10-05	X				
90	Set up and collect BI in sterilizing clothes and sanitation implement	M04-SOP-10-06	X				
91	Set up and collect sensor in freeze drying structure	M04-SOP-10-07	X				
92	Set up and collect BI in sterilizing	M04-SOP-10-08	X				
93	Set up and collect BI in fumigating formalin	M04-SOP-10-09	X				
94	Assemble and collect sensor in sterilizing vial	M04-SOP-10-10	X				
95	Assemble and collect Endotoxin rinsing vial in vial sterilizing	M04-SOP-10-12	X				
96	Handle drop vial during MFT	M04-SOP-10-13	X				
97	Sample water after rinsing implement	M04-SOP-12-01	X				
98	Sample by cleaning implement for vaccine preparation after washing	M04-SOP-12-02	X				
99	Sample by cleaning components of filling machine after washing	M04-SOP-12-03	X				
100	Sample after sampling water after rinsing components of filling machine	M04-SOP-12-04	X				
101	Check volume of filling solution	M04-SOP-12-05	X				
102	Adjust for filling volume	M04-SOP-12-06	x				
103	Sample by cleaning chamber of freeze drying machine	M04-SOP-12-07	X				
104	Sample vial during washing process	M04-SOP-12-08	X				
105	Sample rubber stopper after sterilizing and drying	M04-SOP-12-09	X				
			86				

MEDIUM PRODUCTION DEPARTMENT							
1	Changing to enter area of grade C	M05-SOP-01-01	X				
2	Changing to enter area of grade D	M05-SOP-01-02	X				
3	*Sanitation non-graded area(chemical keeping room)*	*M05-SOP-02-01*		*Completed*			submitted to QA, waiting for approval
4	Sanitation clean room of grade D	M05-SOP-02-02	X				
5	Sanitation clean area of grade C	M05-SOP-02-03	X				
6	Sterilize room by fumigating Formalin	M05-SOP-02-04	X				
7	Environment monitoring of airborne microorganisms	M05-SOP-03-01	X				
8	Environment monitoring of airborne particles	M05-SOP-03-02	X				
9	Environment monitoring of surface microorganism	M05-SOP-03-03	X				
10	Follow temperature, humidity and pressure deviation of Medium reparation area	M05-SOP-03-04	X				
11	Operation of PH meter	M05-SOP-04-01	X				
12	Operate 300 kg electronics scale	M05-SOP-04-02	X				
13	Operate CP 16001S electronics scale (16 kg)	M05-SOP-04-03	X				
14	Operate LE2202S electronics scale	M05-SOP-04-04	X				
15	Use Formalin neutral machine	M05-SOP-04-05	X				
16	Use Formalin fumigation machine	M05-SOP-04-06	X				
17	Use remaining concentration meter of Formalin	M05-SOP-04-07	X				
18	Operate heat creation stirrer	M05-SOP-04-08	X				
19	Operate vertical stirrer (stirrer)	M05-SOP-04-09	X				
20	Operate surface thermometer	M05-SOP-04-10		X		22-Oct-07	
21	Operate checking machine of integrity	M05-SOP-04-12	X				
22	Use clean bench E	M05-SOP-04-13	X				
23	Use clean bench C	M05-SOP-04-14	X				
24	Use A-2 autoclave	M05-SOP-04-15	X				
25	Use dry oven	M05-SOP-04-16	X				
26	Operate air sampling	M05-SOP-04-17	X				
27	Operate medium dispenser	M05-SOP-04-18	X				
28	Operate vacuum pump	M05-SOP-04-19		X			do after PV
29	Operate deep freezer -30 deg. C	M05-SOP-04-20	X				
30	Operate Pall integrity tester	M05-SOP-04-22	X				
31	Operator refrigerator 4 deg. C	M05-SOP-04-23	X				
32	Washing of tools for medium preparation	M05-SOP-05-01	X				
33	Prepare and pack implement for open filtration system	M05-SOP-05-02	X				
34	Prepare and pack implement for close filtration system	M05-SOP-05-03	X				
35	Wash and pack 4 inch and 10 inch filters	M05-SOP-05-04	X				
36	Wash and pack Tank	M05-SOP-05-05		completed			submitted to QA, waiting for approval
37	Sterilize implement	M05-SOP-05-07	X				
38	Sterilize solution	M05-SOP-05-08	X				
39	Sterilize Tank	M05-SOP-05-09	X				
40	Filtration of closed system	M05-SOP-06-01	X				
41	Open system filter	M05-SOP-06-02	X				
42	Check integrity of solution membrane	M05-SOP-06-03	X				
43	Preparation for 7% phenol red	M05-SOP-06-04					
44	Alcohol sterilization filter	M05-SOP-06-05	X				
45	Receiving raw material, chemical	M05-SOP-07-01	X				
46	Storage chemical	M05-SOP-07-02	X				
47	Manage chemical usage	M05-SOP-07-03	X				
48	Medium delivery	M05-SOP-08-01		X		22-Oct-07	
49	Cancel rejected medium	M05-SOP-08-03	X				
50	Number lot and write label	M05-SOP-08-04	X				
51	Operate WFI using point	M05-SOP-09-01 (2)	X				
52	Operate UFW using point	M05-SOP-09-02 (2)	X				
53	Procedure of water sampling in points of WFI system	M05-SOP-10-01	X				
54	Procedure of water sampling in points of UFW system	M05-SOP-10-02	X				
55	Sampling procedure of clean water sampling	M05-SOP-10-03	X				
56	Sampling water after equipment rinsing	M05-SOP-10-04	X				
57	Water sampling after rinsing tools	M05-SOP-10-04	X				
58	Sampling by swapping equipment	M05-SOP-10-05	X				
59	Swab sampling of equipment	M05-SOP-10-05	X				
60	SIP by WFI	M05-SOP-10-06		completed			submitted to QA, waiting for approval
61	SIP using UFW	M05-SOP-10-07		completed			submitted to QA, waiting for approval
62	Set up and collect thermal sensor (sterilize implement)	M05-SOP-11-01	X				
63	Set up and collect BI (sterilize implement)	M05-SOP-11-02	X				
64	Set up and collect thermal sensor (sterilize implement)	M05-SOP-11-03	X				
65	Set up and collect BI (sterilize solution)	M05-SOP-11-04	X				
66	Set up and collect BI (dry oven)	M05-SOP-11-05	X				
67	Set up and collect thermal sensor (dry oven)	M05-SOP-11-06	X				
68	Set up and collect BI of Formalin fumigation	M05-SOP-11-07	X				
			60				

QC DEPARTMENT							
(BIOLOGICAL)							
1	Exit and entrance procedure of quality control area	M02-SOP-01-01	X				
2	Output and Input process of raw material in the area	M02-SOP-01-02		X			prepare after PV
3	Output and Input process of equipment after sterilizing	M02-SOP-01-03		X			prepare after PV
4	Output and Input process of waste material and dirty tool	M02-SOP-01-04		X			prepare after PV
5	Sanitize non- grade area	M02-SOP-02-01		X			prepare after PV
6	Sanitize clean area of grade C	M02-SOP-02-02	X				
7	Sanitize clean area of grade B	M02-SOP-02-03	X				
8	Sterilize room by Formalin fumigation	M02-SOP-02-04	X				
9	Sanitize store for putting freezer	M02-SOP-02-05		X			prepare after PV
10	Sanitize normal store	M02-SOP-02-06		X			prepare after PV
11	Sanitize cold room 4oC	M02-SOP-02-07		X			prepare after PV
12	Sanitize incubation room 37oC keeping cell	M02-SOP-02-08		X			prepare after PV
13	Sanitize store for putting incubator	M02-SOP-02-09		X			prepare after PV
14	Particle counting procedure in air	M02-SOP-03-01	X				
15	Microorganism counting procedure in air	M02-SOP-03-02	X				
16	Surface microorganism counting procedure	M02-SOP-03-03	X				
17	Check suitability of changing clothes	M02-SOP-03-04		X		30. Oct.07	
18	Check temperature, pressure difference	M02-SOP-03-05		X			prepare after PV
19	Micro-organism test of water	M02-SOP-04-01				30.Nov.07	prepare after PV
20	Principle for sampling, supervision process for importing raw material	M02-SOP-04-02		X			prepare after PV
21	Check sensitivity of medium for stenlity test	M02-SOP-04-03		X			prepare after PV
22	Check sensitivity of medium for detecting Mycoplasma	M02-SOP-04-04		X			prepare after PV
23	Check toxic of rubber stopper on mouse	M02-SOP-04-05		X		30.Nov.07	prepare after PV
24	Check blood thawing of rubber stopper	M02-SOP-04-06		X		30.Nov.07	prepare after PV
25	Process for receiving final sample	M02-SOP-05-01		X		22.Oct.07	
27	Process for receiving bulk sample	M02-SOP-05-02		X		15Nov. 07	prepare after PV
28	Check control cell	M02-SOP-05-03		X		30 Nov. 07	prepare after PV
29	Receive and dispense sample at bulk period (CEC, MVV, MVN)	M02-SOP-05-04		X		30 Nov. 07	prepare after PV
30	Erythrocyte adsorption	M02-SOP-05-05		X		30 Nov. 07	prepare after PV
31	Sterility test	M02-SOP-05-06	X				prepare after PV
32	Mycoplasma test	M02-SOP-05-07	X				
33	Test for freedom from extraneous viruses on FL cell	M02-SOP-05-08		X		30Nov. 07	prepare after PV
34	Test for freedom from extraneous viruses on Vero cell	M02-SOP-05-09		X		30Nov. 07	prepare after PV
35	Test for freedom from extraneous viruses on CEC cell	M02-SOP-05-10		X		30Nov. 07	prepare after PV
36	Potency of Measles vaccine	M02-SOP-05-11	X				
37	Identification test	M02-SOP-05-12		X		22 nov.07	
38	Thermal-stability test	M02-SOP-05-13	X				
39	Gram dye test	M02-SOP-05-14		X		30Nov. 07	prepare after PV
40	Test for detecting Leucosis virus	M02-SOP-05-15		X		31-Dec-07	prepare after PV
41	Test for detecting Adeno virus	M02-SOP-05-16		X		31-Dec-07	prepare after PV
42	Egg injection (Allantoic)	M02-SOP-07-01		X		22 Oct. 07	prepare after PV
43	Egg injection (Yolk sac)	M02-SOP-07-02		X		22 Oct. 07	prepare after PV
44	Common safety on guinea- pig	M02-SOP-07-03		X		22 Oct. 07	
45	Common safety on mice	M02-SOP-07-03		X		22 Oct. 07	prepare after PV
46	Keep media at 4oC	M02-SOP-08-01				X	prepare after PV
47	Keep samples, chemicals at -30oC	M02-SOP-08-02				X	prepare after PV
48	Keep samples, chemicals at -70oC	M02-SOP-08-03				X	prepare after PV
49	Keep cells at -196 ^{o}C (Nitrogen vessel)	M02-SOP-08-04		X			
50	Principle for keeping material in normal store	M02-SOP-08-05		X		31-Dec-07	prepare after PV
51	Principle for keeping material in cold room 4oC	M02-SOP-08-06		X		31-Dec-07	prepare after PV
52	Principle for keeping material in cold room	M02-SOP-08-07		X		31-Dec-07	prepare after PV
53	Procedure of FL cell separation	M02-SOP-09-01	X				
54	Procedure of Vero cell separation	M02-SOP-09-02	X				
55	Process for counting CEC for producing bulk	M02-SOP-09-03		X		30 nov. 07	prepare after PV
56	Procedure of GM growing medium preparation	M02-SOP-10-01	X				
57	Medium preparation procedure to maintain MM	M02-SOP-10-02	X				
58	Sterilized steam of medium used for verification	M02-SOP-10-03	X				
59	Operate Autoclave B	M02-SOP-13-01(2)	X				
60	Use CO2 incubator	M02-SOP-13-04	X				
61	Use A incubator	M02-SOP-13-11	X				
62	Use B incubator	M02-SOP-13-12	X				
63	Use C incubator	M02-SOP-13-13	X				
64	Use D incubator	M02-SOP-13-14	X				
65	Use nitrogen bottle to keep cell	M02-SOP-13-36	X				
66	Operate dry oven	M02-SOP-13-61(2)	X				
67	Set up and collect thermal sensor	M02-SOP-14-01	X				
68	Assemble and collecting BI Autoclave B	M02-SOP-14-02		X		31-Dec-07	prepare after PV
69	Set up and collect thermal sensor for A, B, C, D incubator	M02-SOP-14-03	X				
70	Process for receiving and keeping BI for Autoclave	M02-SOP-14-04		X		31-Dec-07	prepare after PV
71	Set up and collect BI for Formalin fumigation	M02-SOP-14-06	X				
72	Assembly and collecting sensor Autoclave B	M02-SOP-14-07		X		31-Dec-07	prepare after PV
73	Procedure of measuring CO2 concentration (CO2 incubator)	M02-SOP-14-08	X				
74	Check accuracy of pipette	M02-SOP-14-09		X		30 nov.07	prepare after PV
75	Set up and collect thermal sensor for incubator	M02-SOP-14-10	X				

76	Set up and collect thermal sensor for Autoclave	M02-SOP-14-12	X				
77	Treat dirty implement	M02-SOP-15-01	X				
78	Wash implement	M02-SOP-15-02	X				
79	Prepare tool for autoclave	M02-SOP-15-03		X		15-Dec-07	prepare after PV
80	Prepare tool for dry oven	M02-SOP-15-04		X		15-Dec-07	prepare after PV
			32				
(CHEMICAL)							
1	Test for measles vaccine description	M02-SOP-06-01		completed			submitted to QA, waiting for approval
2	Remaining humidity test for freeze dried vaccine	M02-SOP-06-02	X				
3	PH test of measles vaccine	M02-SOP-06-03		completed			submitted to QA, waiting for approval
4	Particle counting for freeze dried vaccine and WFI	M02-SOP-06-04	X				
5	Test of quantity deviation for freeze dried vaccine	M02-SOP-06-05	X				
6	osmosis test for freeze dried vaccine	M02-SOP-06-06	X				
7	Test of acid level and alkali for WFI	M02-SOP-06-07	X				
8	Chloride test for WFI	M02-SOP-06-08	X				
9	Sulfate test for WFI	M02-SOP-06-09	X				
10	Nitrogen test from Nitrate for WFI	M02-SOP-06-10	X				
11	Nitrogen test from Nitrite for WFI	M02-SOP-06-11		completed			submitted to QA, waiting for approval
12	Ammonium test for WFI	M02-SOP-06-12	X				
13	Heavy metal test for WFI	M02-SOP-06-13	X				
14	KMnO4 test for WFI	M02-SOP-06-14		X		26-Oct-07	
15	Remaining scale after evaporation for WFI	M02-SOP-06-15	X				
16	Check capacity of WFI	M02-SOP-06-16		X		26-Oct-07	
17	Unthaw foreign agent test of WFI	M02-SOP-06-17		X		26-Oct-07	
18	Endotoxin test for WFI	M02-SOP-06-18		X		26-Oct-07	
19	Test for unthaw particle for WFI	M02-SOP-06-19		X		26-Oct-07	
20	Test of supervising condition of clean water	M02-SOP-06-20	X				
21	Test of checking acid and alkali for clean water	M02-SOP-06-21	X				
22	Chloride test for clean water	M02-SOP-06-22	X				
23	Sulfate test for clean water	M02-SOP-06-23	X				
24	Nitrogen test from Nitrate for clean water	M02-SOP-06-24	X				
25	Nitrogen test for Nitrite for clean water	M02-SOP-06-25	X				
26	Ammonium test for clean water	M02-SOP-06-26	X				
27	Test of heavy metal for clean water	M02-SOP-06-27	X				
28	$KMnO_4$ test for clean water	M02-SOP-06-28	X				
29	Residual test after evaporation for clean water	M02-SOP-06-29	X				
30	TOC test for clean water	M02-SOP-06-30	X				
31	Endotoxin test for clean water	M02-SOP-06-31	X				
32	Test for unthaw particle for DW, UF	M02-SOP-06-32		X		26-Oct-07	
33	Check acid and base of vaccine dispensing vial	M02-SOP-06-33		completed			submitted to QA, waiting for approval
34	Nitrogen test from Nitrite of vaccine vial	M02-SOP-06-34		completed			submitted to QA, waiting for approval
35	Check rubber stopper perceptibly	M02-SOP-06-35		X		26-Oct-07	
36	Check foaming of rubber stopper	M02-SOP-06-36		X		26-Oct-07	
37	PH test of rubber stopper	M02-SOP-06-37		completed			submitted to QA, waiting for approval
38	KMnO4 test of rubber stopper	M02-SOP-06-38		completed			submitted to QA, waiting for approval
39	Chloride test for rubber stopper	M02-SOP-06-39	X				
40	Nitrogen test from Nitrite of rubber stopper	M02-SOP-06-40		X		26-Oct-07	
41	Conductivity test	M02-SOP-06-41	X				
42	Moisture content test after evaporating for rubber stopper	M02-SOP-06-42		X		26-Oct-07	
43	Moisture content test for rubber stopper	M02-SOP-06-43		X		26-Oct-07	
44	BSA test	M02-SOP-06-47	X				
45	Remaining residual for rubber stopper	M02-SOP-06-48	X				
46	Measuring alcohol concentration	M02-SOP-06-51		completed			submitted to QA, waiting for approval
47	Operation procedure of pH meter(PP-15)	M02-SOP-13-06	X				
48	Operate Endotoxin machine, computer and printer for Endotoxin test	M02-SOP-13-16(2)	X				
49	Use of Autoclave E	M02-SOP-13-18	X				
50	Operate Vacuum drying Oven	M02-SOP-13-20	X				
51	Operation procedure of electronics balance (LE 2202S and LE 224S)	M02-SOP-13-42	X				
52	Operate Pipette washing machine	M02-SOP-13-44	X				
53	Operation procedure of TOC meter (Phoenix 8000)	M02-SOP-13-50	X				
54	Set up and collect thermal sensor for vacuum drying oven	M02-SOP-14-05	X				
			35				

ENGINEERING DEPARTMENT							
1	Operate water production system	M06-SOP-WSO-01	x				
2	Operate filtration system	M06-SOP-WSO-02	x				
3	Operate system for shortening and active coal	M06-SOP-WSO-04	x				
4	Operate deionizer system	M06-SOP-WSO-07	x				
5	Operate ultra filtered water production system	M06-SOP-WSO-08	x				
6	Operate ultra filtered water distribution system	M06-SOP-WSO-09	x				
7	Operate WFI production system	M06-SOP-WSO-11	x				
8	Operate WFI distribution system	M06-SOP-WSO-12	x				
9	Operate clean steam production system	M06-SOP-WSO-16	x				
10	Chemical preparation and transfusion	M06-SOP-WSO-08		x		15-Dec-07	
11	Operate neutral system of waste water of production water system	M06-SOP-WSO-05		x		15-Dec-07	
12	Operate UFW distribution equipment for CIP	M06-SOP-WSO-10		x		15-Dec-07	
13	Trouble shooting	M06-SOP-WSO-13		x		15-Dec-07	
14	Operate Cooling tower 1	M06-SOP-WSO-14		x		15-Dec-07	
15	Operate Cooling tower 2	M06-SOP-WSO-15		x		15-Dec-07	
16	Operate boiler	M06-SOP-PSO-01		x		15-Dec-07	
17	Operate Chiller	M06-SOP-PSO-02		x		15-Dec-07	
18	Operate air compressor	M06-SOP-PSO-05		x		15-Dec-07	
19	Operate water system for activities	M06-SOP-PSO-06		x		15-Dec-07	
20	Operate waste treatment system	M06-SOP-DrWSO-01		x		15-Dec-07	
21	Operate fire-fighting system	M06-SOP-FireHydS-01		x		15-Dec-07	
22	Operate central air-condition system	M06-SOP-HVACO-01		x		15-Dec-07	
23	Operate electric generator	M06-SOP-ESO-01		x		15-Dec-07	
24	Operation and maintenance for pressure calibrator	M06-SOP-CALEQ-01		Completed			submitted to QA, waiting for approval
25	Operation and maintenance for temperature calibrator	M06-SOP-CALEQ-02		Completed			submitted to QA, waiting for approval
26	Operation and maintenance for particle counter	M06-SOP-CALEQ-03		x		30 Nov. 07	
27	Operation and maintenance for aerosol generator	M06-SOP-CALEQ-04		x		30 Nov. 07	
28	Operation and maintenance for thermal recorder	M06-SOP-CALEQ-05		Completed			submitted to QA, waiting for approval
29	Operation and maintenance for low temperature water bath	M06-SOP-CALEQ-06		Completed			submitted to QA, waiting for approval
30	Operation and maintenance for hybrid recorder	M06-SOP-CALEQ-07		Completed			submitted to QA, waiting for approval
31	Operation and maintenance for vibration meter	M06-SOP-CALEQ-08			x		
32	Operation and maintenance for sound level meter	M06-SOP-CALEQ-09			x		
33	Operation and maintenance for mist generator	M06-SOP-CALEQ-10			x		
34	Operation and maintenance for cap torque meter	M06-SOP-CALEQ-11			x		
35	Operation and maintenance for spectrophotometer meter	M06-SOP-CALEQ-12			x		
36	Operation and maintenance for digital stroboscope	M06-SOP-CALEQ-13			x		
37	Operation and maintenance for electro balance	M06-SOP-CALEQ-14			x		
38	Operation and maintenance for digital surface thermometer	M06-SOP-CALEQ-15			x		
39	Operation and maintenance for standard thermometer	M06-SOP-CALEQ-16			x		
40	Operation and maintenance for hygrometer meter	M06-SOP-CALEQ-17			x		
41	Operation and maintenance for multifunction calibrator	M06-SOP-CALEQ-18			x		
			9				

Annex 19. Summary Results Table of PQ, MFT and PV performances

Summary Results Table of PQ, MFT and PV performances

Department	Machine Name & PQ Items	PQ content	Summary of PQ condition	Number of times	Evaluation		Judgment
					Acceptance Criteria	Results	
QC	CO_2 Incubator A	Temperature distribution	Temp.:37℃	1 time	37±2℃	Min:36.1℃ Max:37.1℃	Pass
			CO_2:5%		5± 1 %	Min:5.4% Max:5.6%	
	CO_2 Incubator B		Temp.:37℃	1 time	37±2℃	Min: 36.3℃ Max: 38.0℃	Pass
			CO_2:5%		5± 1 %	Min:4.5% Max:5.2%	
	CO_2 Incubator C		Temp.:37℃	1 time	37±2℃	Min:36.1℃ Max:36.9℃	Pass
			CO_2:5%		5± 1 %	Min:4.5% Max:5.2%	
	Egg Incubator	Temp.& Humid.distribution	Temp : 37℃	1 time	37±2℃	Min:36.8℃ Max:37.4℃	Pass
			Humid: 62%		60±10%	Min:63% Max:67%	
	Lab. Autoclave E for Chemical lab	Temperature distribution	Loading Pattern 1 (Set parameter) Temp.:121℃,Time: 1hour	3 times	121±2℃	Min:119.7℃ Max122.2℃	Pass
						Min:119.4℃ Max122.6℃	
						Min:120.6℃ Max:122.8℃	
	Lab. Autoclave D for Biological lab	Effect of sterilization	Loading Pattern 1 (Set parameter) Temp.:123℃,Time:20m	3 times	BI:(-), Temp.&Time:≧121℃,≧12min.F0≧12	BI(3/3:-), Temp.&time : ≧121℃,14min, F0 : Min21.1,Max22.3	Pass
						BI(3/3:-), Temp.&time : ≧121℃,13min, F0 : Min20.0,Max21.9	
						BI(3/3:-), Temp.&time : ≧121℃,14min, F0 : Min20.3,Max22.9	
	Dry Oven	Effect of sterilization	Loading Pattern 1 (Set parameter) Temp.: 240℃, Time: 70m	3 times	BI:(-), Temp.&Time:≧190℃,≧20min	BI(10/10:-), Temp.&Time : ≧190℃, 28min.	Pass
						BI(10/10:-), Temp.&Time : ≧190℃, 28min.	
						BI(10/10:-), Temp.&Time : ≧190℃, 30min.	
	Formalin Fumigation	Effect of sterilization	Grade: A,B,C	1 time	BI:≧3 log reduction, Formalin residual of 3rd time: ≦0.1ppm	BI (Grade B : 12/12: - , Grade C : 18/18: -)	Pass
						Formalin residual : Non detect	
	Environmental Monitoring	Confirmation of environmental condition	Grade: A,B,C (at static)	3 times	Microorganism: Airborne organism, settling plate, Contact plate Microparticle:≦5μm,＞5μm	1st: Airborne: Ok; Setting plate: Ok; Contact plate: Ok; Particle count: Ok	Pass
						2nd: Airborne: Ok; Setting plate: Ok; Contact plate: Ok; Particle count: Ok	
						3rd: Airborne : Ok; Setting plate: Ok; Contact plate: Ok; Particle count: Ok	
	Gowning Validation	Confirmation of qualificated person	4 persons	3 times	Microorganism (Contact Plate)	1st: OK	Pass
						2nd: OK	
						3rd: Ok	
Final Production	Washing of Equipments	Effect of washing	By manual	3 times	Rinse solution:≦500ppb (TOC) Swab: same as control (TOC)	Rinse (3 Locations) : 0,0,0 Swab (1Location) : same as control (Both data≦500ppb)	Pass
						Rinse (3 Locations) : 70,90,120 Swab (1Location) : same as control (Both data≦500ppb)	
						Rinse (3 Locations) : 70,130,120 Swab (1Location) : same as control (Both data≦500ppb)	
	Autoclave (Tray of F.D)	Effect of sterilization	Loading Pattern 1	3 times	BI:(-) Temp.&Time:≧121℃,≧20min. Dev.temp.:±2℃, F0:≧12	BI:(12/12:-), Temp.:OK, F0:46.67	Pass
						BI:(12/12:-), Temp.:OK, F0:46.99	
						BI:(12/12:-), Temp.: OK, F0:43.72	
	Washing of Freeze Dryer	Effect of washing	CIP	3 times	Swab; same as control (TOC) ≤ 500ppb	Samples (16 Locations): Min150, Max 250. Control (16 locations) : Min110, Max430	Pass
						Samples (16 Locations): Min30, Max170. Control (16 locations) : Min110, Max430	
						ok	
	Quality of rubber stopper received	Confirmation of supplier's certification	-	1 time	≤ 6000particle/vial	Rubber stopper for WFI: Particle count: ok; Endotoxin: ok	Pass
					≤ 0.25 EU/ml	Rubber stopper for Vaccine: Particle count: ok; Endotoxin: ok	
	Moisture content of rubber stopper after drying by Autoclave	Qualification of drying Time	(Set Parameter) Vacuum dry time:90min Hot Dry time:90min.	3 times	Rubber Stopper for WFI:≦0.5% Rubber Stopper for Freeze Dry:≦0.3%	For WFI : 0.18～0.25%, For Freeze Dry : 0.20～0.24%	Pass
						For WFI : 0.20～0.31%, For Freeze Dry : 0.18～0.28%	
						For WFI : 0.13～0.26%, For Freeze Dry : 0.18～0.22%	
	Tunnel Sterilizer	Effect of de-endotoxin	(Set Parameter) Hot zone temp.: 320℃ Belt Speed:137mm/min	3 times	Endotoxin: ≧3 log reduction Max Temp.:≧300℃,	Endotoxin (9Locations : ≧6 Log reduction, Max temp. (9 sensors) 300.3℃ ~319.4 ℃	Pass
						Endotoxin (9Locations : ≧5 Log reduction, Max temp. (9sensors): 301.8 ℃ ~319.9 ℃	
						Endotoxin (9Locations : ≧5 Log reduction, Max temp.(9 sensors) :300.0 ℃ ~312.3 ℃	
	Measuring of Temp.& Humid.	Confirmation of environmental condition	Grade: A,B,D	5days	Temp.:22±4℃ Humi.:50±20%	Disinfection Rm.&Vial washing Rm :1day⇒Humidity : Out of Criteria => Solution: attach the handle deviation report with PQ report All of another data : within Criteria	Pass
	Formalin Fumigation	Effect of sterilization	Grade: A,B	3 times	BI:≧3 log reduction, Formalin residual in 3rd time:≦0.1ppm	1st: BI (18/18:-): OK; Formalin residual: non detect	Pass
						2nd: BI (18/18:-): OK; Formalin residual: non detect	
						3rd: Formalin residual: non detect	
	Pre-environmental Monitoring	Confirmation of environmental condition	Grade: A,B,D (at static)	1 time	Microorganism: Airborne organism, settling plate, Contact plate Microparticle:≦5μm,＞5μm	Air born: Ok; Settling plate: Ok; Contact plate: Ok; Particle count: Ok	Pass
	Environmental Monitoring	Confirmation of environmental condition	Grade: A,B,D (at dynamic)	3 times	Microorganism: Airborne organism, settling plate, Contact plate Microparticle:≦5μm,＞5μm	1st: OK	Pass
						2nd: Ok	
						3rd: Ok	
	Gowning Validation	Confirmation of qualificated person	6 persons	3 times	Microorganism (Contact Plate)	1st: one person is out of criteria => instruction => already implement again and result OK; others: OK	Pass
						2nd: Ok	
						3rd : Ok	
	Validation Bringing substance into room	Qualification of SOP	(Rout) NC→D, D→B, B→A	3 times	Microorganism (Contact Plate)	1st: Ok	Pass
						2nd: Ok	
						3rd: Ok	
	Storage of sterilized substance	Decision of storage period in Sterilize room	Storage Location: Grade B	1 time	Microorganism (Contact Plate)	3rd day: Ok; 5th day: Ok; 7th day: Ok	Pass
						14th day: Ok	
	Confirmation of all process for Virus manufacturing		Same as normal production	1 time	Process control items Lot uniformity	All results: within criteria	Pass
	Confirmation of all process for WFI manufacturing		Same as normal production	1 time	Process control items Lot uniformity	All results: within criteria	Pass
	MFT		Same as normal production	3 times	No contamination for all lots	No contamination for all 3 lots	Pass
	PV		Same as normal production	3 times	Meet all criteria for measles vaccine in: Identity test, Sterility test, potency and thermo stability test, General safety test, Residual moisture content and Inspection of final container	QC tests are in progress of implementing.	
Medium	Washing of Equipments	Effect of washing	By manual	3 times	Rinse solution:≦500ppb Swab: same as control	Rinse(3 Locations) :360,500,270, Swab (3 Locations) : Same as control (All data≦500ppb)	Pass
						Rinse(3 Locations) : 140,130,140, Swab (3Locations) : Same as control (All data≦500ppb)	
						Rinse(3 Locations) : 150,170,150, Swab (3Locations) : Same as control (All data≦500ppb)	
	Dry Oven	Effect of sterilization	Loading Pattern 1 (Set parameter) Temp.: 240℃,Time:30min.	3 times	BI:(-), Temp.&Time:≧190℃,≧30min.,	BI(4/4 : -), Temp.&Time : ≥219.3 ℃; 30m	Pass
						BI(4/4 : -), Temp.&Time : ≥218.5 ℃; 30m	
						BI(4/4 : -), Temp.&Time : ≥219.7 oC; 30m	
	Measuring of Temp.& Humid.	Confirmation of environmental condition	Grade: B,C,D	2days	Temp.:22±4℃ Humi.:50±20%	1 Room :1day ⇒ Temperature : Out of Criteria => Solution: attach the handle deviation report with PQ report All of another data : within Criteria	Pass
	Formalin Fumigation	Effect of sterilization	Grade: B,C	3 times	BI:≧3 log reduction, Formalin residual in 3rd time:≦0.1ppm	BI (15/15 : -); formalin residue: 0.18ppm; 0.135ppm; 0.09ppm	Pass
						BI (15/15 : -), formalin residue: none detect	
						BI (15/15 : -), Formalin residue: non detect	
	Pre-environmental Monitoring	Confirmation of environmental condition	Grade: B,C,D (at static)	1 time	Microorganism: Airborne organism, settling plate, Contact plate Microparticle:≦5μm,＞5μm	Airborne: Ok; Settling plate: Ok; Contact plate: Ok; Particle count: Ok	Pass
	Environmental Monitoring	Confirmation of environmental condition	Grade: B,C,D (at dynamic)	3 times	Microorganism: Airborne organism, settling plate, Contact plate Microparticle:≦5μm,＞5μm	B grade: Airborne: Ok; Settling plate: Ok; Contact plate: Ok; Particle count: Ok	Pass
						C grade: Contac plate: 1 point out => instruction => implement 3 times again. Others: OK	
						C grade: reimplementation: OK	
	Gowning Validation	Confirmation of qualificated person	5 persons	3 times	Microorganism (Contact Plate)	1st: OK	Pass
						2nd: OK	
						3rd: Ok	
	Validation Bringing substance into room	Qualification of SOP	(Rout) NC→D, D→C, C→B	3 times	Microorganism (Contact Plate)	1st: OK	Pass
						2nd: Ok	
						3rd: Ok	
	Quality of Virus diluted solution	Confirmation of filtration process	Same as normal production	3 times	pH	within criteria	Pass
					Sterilized test		
Bulk	Autoclave (Cell solution)	Effect of sterilization	Loading Pattern 1,4	3 times	BI:(-) Temp.&Time:≧121℃,≧20min. Dev.temp.:±2℃, F0:≧12	P.1:(BI:15/15:-),Temp&time:OK F0:42.83P.4:(BI:14/14:-),Temp&Time:OK,F0:47.25	Pass
						P.1:(BI:15/15:-),Temp&time:OK F0:43.98P.4:(BI:14/14:-),Temp&Time:OK,F0:48.14	
						P.1:(BI:15/15:-),Temp&time:OK F0:45.95P.4:(BI:14/14:-),Temp&Time:OK,F0:48.52	
	Autoclave (Virus Culture)	Effect of sterilization	Loading Pattern 2,3	3 times	BI:(-) Temp.&Time:≧121℃,≧20min. Dev.temp.:±2℃, F0:≧12	P.2:(BI:15/15:-),Temp&time:OK F0:45.5; P.3:(BI:14/14:-),Temp&Time:OK,F0:35.13	Pass
						P.2:(BI:15/15:-),Temp&time:OK F0:53.19;P.3:(BI:14/14:-),Temp&Time:OK,F0:37.3	
						P.2:(BI:15/15:-),Temp&time:OK F0:39.3;P.3:(BI:14/14:-),Temp&Time:OK,F0:39.3	
	Dry Oven (Cell Culture & Virus)	Effect of sterilization	Loading Pattern 1,2,3	3 times	BI:(-), Temp.&Time:≧190℃,≧30min.,	P.1:(BI:10/10:-), Temp.:OK,P.2:(BI:10/10:-),Temp.:OK,P.3:BI(7/7:-),Temp.:OK	Pass
						P.1:(BI:10/10:-), Temp.:OK,P.2:(BI:10/10:-),Temp.:OK,P.3:BI(7/7:-),Temp.:OK	
						P.1:(BI:10/10:-), Temp.:OK,P.2:(BI:10/10:-),Temp.:OK,P.3:BI(7/7:-),Temp.:OK	
	Incubator Room 1	Temperature distribution	Temp.: 37.5℃	1 time	Temp.:37.5±1℃	Min 36.5℃, Max38.0℃	Pass
	Incubator Room 2		Temp.: 32℃	1 time	Temp.: 32±1℃	Min 31.1℃, Max32.5℃	Pass
	Cold Room		Temp.:5℃	1 time	Temp: 3-8℃	Min 4.0℃, Max 8.0℃	Pass
	Revolving Type egg Incubator		Temp.: 37.6℃, Humi.:60%	1 time	Temp.:37.6±1℃, Humid.: 50-70%	Without egg inside: Temp. (Max: 38.6℃, Min:36.7℃) Humid.:(Max: 63%; Min: 52%) With egg inside: Temp. (Max: 38.10C, Min:36.80C) Humid.:(Max: 64%; Min: 61%)	Pass
	Measuring of Temp.& Humid.	Confirmation of environmental condition	Grade: B,C,D	3 times	Temp.:22±4℃ Humi.:50±20%	one time: out of specification due to Autoclave door open when measuring temp. and humidity => already implement again.	Pass
						Other result: Ok	
	Formalin Fumigation	Effect of sterilization	Grade: B,C	3 times	BI: ≧3 log reduction, Residual formalin in 3rd time:≦0.1ppm	1st: formalin residue: ok; BI: Ok	Pass
						2nd: formalin residue: ok; BI: Ok	
						3rd: formalin residue: ok; BI: Ok	
	Pre-environmental Monitoring	Confirmation of environmental condition	Grade: B,C,D (at static)	1 time	Microorganism: Airborne organism, settling plate, Contact plate Microparticle:≦5μm,＞5μm	Contact plate: ok	Pass
						Particle counter: Ok	
						Air sampler: Ok; settling plate: Ok	
	Environmental Monitoring	Confirmation of environmental condition	Grade: B,C,D (at dynamic)	3 times	Microorganism: Airborne organism, settling plate, Contact plate Microparticle:≦5μm,＞5μm	1st: Airborne: Ok; Settling plate: Ok; Contact plate: Ok; Particle count: Ok	
						2nd: Airborne: Ok; Settling plate: Ok; Contact plate: Ok; Particle count: Ok	
	Gowning Validation	Confirmation of qualificated person	9 persons	3 times	Microorganism (Contact Plate)	1st: Ok	Pass
						2nd: Ok	
						3rd: Ok	
	Validation Bringing substance into room	Qualification of SOP	(Rout) NC→D, D→C, C→B	3 times	Microorganism (Contact Plate)	1st: Ok	
						2nd: Ok	
	Storage of sterilized substance	Decision of storage period in Sterile room	Storage Location: Grade B	1time	Microorganism (Contact Plate)	1st: Ok	

Annex 20.Schedule of the Mid-term Evaluation Team

Schedule of Mid-term Evaluation for Measles Vaccine Production Project in Vietnam

	Date		Time	Activities
1	5-Dec	Wed	18:10 22:25	Narita - Hanoi (Ms. Kido)(VN959)
2	6-Dec	Thu	9:00	Meeting with JICA Office
			10:30	Meeting(Interview) with Japanese Experts
			13:30	Coutesy call and explanation of evaluation method and process to POLYVAC (Director)
			14:30	Explanation of project activities by experts and C/P , Observation of POLYVAC
			15:30	Meeting (Interview) with C/P (From 30min. to 50min. per person)
3	7-Dec	Fri	9:00	Meeting(Interview) with Japanese Experts
			11:00	Meeting (Interview) with C/P (From 30min. to 50min. per person)
			14:00	Meeting (Interview) with C/P (From 30min. to 50min. per person)
			17:00	Analysis of Studied Data, Drafting the Evaluation Report
4	8-Dec	Sat		Analysis of Studied Data, Drafting the Evaluation Report
			11:00 15:10	Narita - Hanoi (Dr. Murakami & Ms. Ibi)(VN955/JL5135)
5	9-Dec	Sun	9:00	Meeting with WHO
			12:00	Team Meeting
				Analysis of Studied Data, Drafting the Evaluation Report
6	10-Dec	Mon	9:00	Meeting with JICA Vietnam Office
			11:00	Meeting with WHO
			14:00	Coutesy call to MOH
			15:00	Coutesy call to POLYVAC
			15:30	Explanation of project activities by experts and C/P, technical observation of POLYVAC
			10:30	<Ms.Kido>Meeting(Interview) with Japanese Experts
			14:00	<Ms.Kido>Meeting (Interview) with C/P (From 30min. to 50min. per person)
				Analysis of Studied Data, Drafting the Evaluation Report
7	11-Dec	Tue	9:00	<Ms.Kido>Meeting (Interview) with C/P(if any), Drafting the Evaluation Report
			9:00	Meeting with WHO
			10:30	Meeting with NEPI
			14:30	Meeting with NICVB
8	12-Dec	Wed	9:00	Meeting with UNICEF
			10:00	Meeting (Interview) at QC department
			PM	Analysis of Studied Data, Drafting the Evaluation Report
9	13-Dec	Thu	8:30	Meeting at JICA office
				Drafting M/M and the Evaluation Report
10	14-Dec	Fri	10:00	Discussion with POLYVAC (PDM revision, review of achievement, evaluation by five criteria)
			13:30	Discussion with POLYVAC (Recommendations)
			17:30	Meeting at JICA Office

	Date		Time	Activities
11	15-Dec	Sat		Revising M/M and the Evaluation Report
12	16-Dec	Sun		Revising M/M and the Evaluation Report
13	17-Dec	Mon	9:00	Meeting with WHO
			14:00 - 16:00	Round Table Meeting with related department of MOH,NICVB, NIHE, POLYVAC, WHO, UNICEF, EOJ and JICA at WHO Office
14	18-Dec	Tue	AM	Revising M/M and the Evaluation Report
			14:00	Discussion with POLYVAC (Finalization of M/M and Evaluation Report)
15	19-Dec	Wed	AM	Revising M/M and the Evaluation Report
			14:00	Joint Coordinating Committee (JCC) (Confirmation of M/M and Evaluation Report)
			15:30	Sign on M/M
			23:55	Dept. Hanoi (VN958/JL752)
16	20-Dec	Thu	6:45	Arr. Narita

Annex 21. Major Interviewees by the Team

MOH

No.	Full Name	Department	Position
1	Dr. Tran Thi Giang Huong	Department of International Cooperation	Deputy Director
2	Dr. Ta Thanh Van	Department of Science and Training	Deputy Director
3	Dr. Do Minh Hung	Department of Drug Administration	Expert
4	Prof. Do Si Hien	National EPI	Director
5	Dr. Le Van Phung	NICVB	Director
6	Dr. Hoang Thi Hong	NICVB	Deputy Director
7	MA. Nguyen Hoang Tung	NICVB	Deputy Head of Quality Control Department

POLYVAC

No.	Full Name	Department	Position
1	Nguyen Dang Hien	Director board	Director
2	Le Thi Luan	Director board	Vice director-Quality system manager
3	Nguyen Thuy Huong	QA	Manager
4	Tran Thi Phuong	QA	staff
5	Nguyen Nu Anh Thu	QC	Manager
6	Dang Mai Dung	QC	Chemical Sup.
7	Le Quoc Hung	Final department.	Manager
8	Ta Kim Quoc	Final department.	Staff
9	Nguyen Xuan Hoa	Bulk department.	Manager
10	Phạm Thanh Tung	Bulk department.	Staff
11	Tran Thi Hong Thuy	Medium department.	Manager
12	Nguyen Dang Anh	Technical department.	Manager

Japanese Experts

1	Setsuo ARAI	Kitasato Institute	Project Manager
2	Shuzo ISHIKAWA	Kitasato Institute	D. PM/Engineering
3	Tomio LEE	Kitasato Institute	D. PM/Product Manager, Final Production
4	Takanori NAKASHIMA	Kitasato Institute	Final Production/ GMP/Validation
5	Fumitoshi SATO	Kitasato Institute	Bulk Production
6	Kazunori MIYAGAWA	Kitasato Institute	D. Product Manager/ Final Productio-1
7	Fumio YOSHIDA	Kitasato Institute	QC-2
8	Miki TAMURA	Kitasato Institute	Administration manager

WHO

No.	Full Name	Department	Position
1	Dr. Jean-Marc Olive	WHO Country Office for Viet Nam	Representative
2	Dr. Lokky Wai	WHO Country Office for Viet Nam	Senior Program Management Officer
3	Dr. Katsuyuki Tsukamoto	WHO Country Office for Viet Nam	EPI Medical Officer

UNICEF

No.	Full Name	Department	Position
1	Dr. Cao Tran Viet Hoa	Integrated Health & Nutrition Care, Health & Nutrition Section	Project Officer

Outstanding issues on vaccine regulation in Viet Nam: Towards WHO-accreditation of Viet Nam NRA

Hanoi, 17 Dec 2007

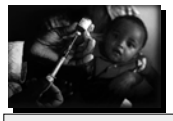
Hitoshi Murakami
JICA mid-term evaluation team for Polyvac measles vaccine production project

Future exportation of Vietnamese vaccines to region and the world

- Beneficial in terms of:
  - Global diversification of basic vaccines production
  - Regional vaccine security
  - Application of international quality standard →better quality of domestic vaccines and assurance of safety among Vietnamese children
  - Financial sustainability of manufacturers

Polyvac measles vaccine aims at WHO pre-qualification for possible export through UN.

- There are two requirements if Vietnamese vaccine to be WHO pre-qualified and exported through United Nations:
  1) National Regulatory Authority (NRA) for vaccines should be accredited by WHO for its 6 critical functions.
  2) Manufacturers meet the WHO pre-qualification requirement for the product

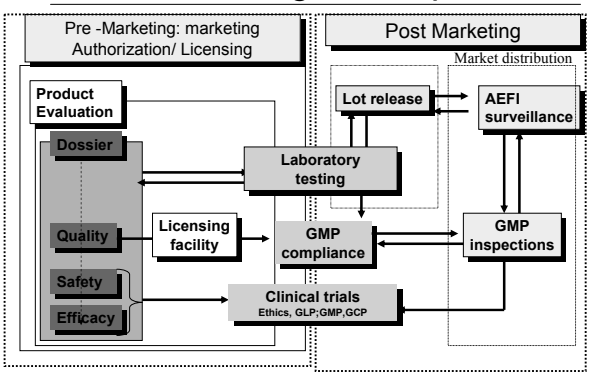


National Regulatory Functions depend on vaccine source

Regulatory functions	Source of vaccines: UN agency	Procure	Produce
Regulatory system	✓	✓	✓
Licensing	✓	✓	✓
Postmarketing: AEFI	✓	✓	✓
Lot release	Functions Undertaken by WHO on Behalf of UN agencies or producing countries	✓	✓
Laboratory access		✓	✓
GMP inspections		Functions undertaken By the producing country	✓
Supervision of clinical trials			✓

Regulatory functions

Ideal vaccine regulation process



Difference between biologicals and pharmaceuticals regulations

- Biological process, unlike chemical process, derives obvious fluctuation of product quality by each lot (e.g. wine fermentation) →lot by lot market release certification (lot release) by the National Regulatory Authority (NRA) is required.
- NICVB has been trained and is capable of undertaking the vaccine lot release.
- Lot (batch) release with quality assurance is primarily the responsibility of manufacturers in the case of pharmaceuticals.

Outstanding vaccine regulatory issues: 1. Technical issues

- In early 2006, Viet Nam NRA met only 2/6 WHO accreditation criteria. Only NICVB and National EPI (for post-marketing surveillance) has been assessed.

1)	GMP inspection	Passed
2)	Lot release	Passed
3)	Clinical trials supervision	Not passed yet
4)	Licensing	Not passed yet
5)	Laboratory access	Not passed yet
6)	Post-marketing surveillance	Not passed yet

- For current status, re-evaluation is needed.

Outstanding vaccine regulatory issues: 2. Organizational/institutional issues

- Following 3 conflicts of interest existing within the regulatory system addressed by Dr. Omi, Regional Director, WPRO-WHO in 2005:
  1) Having both state-owned vaccine manufacturers and NICVB report to the same department within MOH.
  2) Involvement of NIHE in the licensing board while the Institute held a manufacturer as part of it.
  3) Involvement of vaccine manufacturers in GMP inspection team (ref. Circular 19/2005/TT-BYT).

Our current understanding of the status of conflicts of interest addressed by Dr. Omi, WHO

Items	Current status	Actions needed
1) Manufacturers & NICVB report to same dpt.	Both still report to the same Dept of Drug admin.	Divert departments reported by manufacturers and regulatory body.
2) NIHE represents a manufacturer and sits in licensing board.	NIHE and manufacturer are organizationally and financially separated.	None (resolved!)
3) Involvement of vaccine manufacturers in GMP inspection team	Circular 19/2005/TT-BYT still in effect but under review.	Revise circular 19 and form GMP inspection team only by inspectors without any relation with manufacturer(s).

Further potential conflicts of interest

Items	Current status	Actions needed
Independence of science/ethical committees from manufacturers	New science/ethical committee members are yet to be determined.	Avoid inclusion of manufacturers in the science/ethical committees.
Clinical trials implementers	NIHE is considered to be contracted as an implementer of CT for Polyvac MV.	Appoint a new implementer not having seat in licensing /ethical boards.

Outstanding questions

- Which of the followings is the NRA in Viet Nam for vaccines?
  - NICVB?
  - Dept of Drug Administration, MOH?
  - Dept of Science and Training, MOH?
  - A combination or all of above?
- If a combination or all of above are to be the Viet Nam NRA, are they ready to be inspected for NRA accreditation by WHO?
- If not, when will NRA be ready for the WHO accreditation?

Particular concerns related with Polyvac measles vaccine project

- How can Polyvac ensure that their upcoming measles vaccine clinical trial (planned in Jan 2008) is accepted in future WHO pre-qualification assessment by selecting an implementer without any connection with clinical evaluation/ licensing process?
- Who will issue GMP certificate to Polyvac measles vaccine facility, NICBV (planning inspection in Dec 2007) or Dept of Drug Administration?
  - Certification must be essential for the product licensing of the measles vaccine.
- Can Polyvac measles vaccine be licensed according to the project schedule (vaccine from bulk in 2008 and that from the seed in 2009)?

Minutes of Vaccine Regulation Roundtable Meeting

Time and date: 14-16:00, 17 December 2007 (Monday)
Location: Conference room, WHO Viet Nam Office

Objective: To clarify the current status of the national regulatory system of vaccine in Viet Nam on the basis of the findings of the Japan International Cooperation Agency (JICA) mid-term evaluation team for the POLYVAC measles vaccine production project and discuss the outstanding constraints for the regulatory authority (NRA) to be accredited by the World Health Organization (WHO).

Participants:
Dr. Tran Thi Giang Huong, Department of International Cooperation, MOH
Dr. Dang Thi Minh Hang, Department of Drug Administration, MOH
Dr. Nguyen Xuan Tung, Vietnam Administration of Preventive Medicine, MOH
Dr. Dang Duc Anh, Deputy Director, NIHE (National Institute of Hygiene and Epidemiology)
Dr. Duong Thi Hong, National Expanded Programme on Immunization Office, NIHE
Dr. Hoang Thi Hong, Deputy Director, NICVB*
Dr. Nguyen Dang Hien, Director, POLYVAC
Mr. Hiroaki Nakagawa, Resident Representative, JICA** Viet Nam Office
Mr. Yosuke Kobayashi, Deputy Resident Representative, JICA Viet Nam Office
Ms. Kaori Takai, Assistant Resident Representative,JICA Viet Nam Office
Ms. Chu Xuan Hoa, Assistant Program Officer, JICA Viet Nam Office
Dr. Tomio Lee, Kitasato Institute
Mr. Shuzo Ishikawa, Kitasato Institute
Dr. Katsuyuki Tsukamoto, Medical Officer, WHO Viet Nam Office
Mr. Tomomi Ibi, Mid-term Evaluation Team Member (JICA Headquarters)
Ms. Chiaki Kido, Mid-term Evaluation Team Member (System Science Consultants Co. Ltd)
Dr. Hitoshi Murakami, Mid-term Evaluation Team Member (IMCJ***)

*National Institute for Control of Vaccines and Biologicals

**Japan International Cooperation Agency

***International Medical Center of Japan

Chairperson, Dr. Tsukamoto, the EPI Medical Officer, WHO Viet Nam Office officially commenced the meeting.

1. Address by Mr. Nakagawa, JICA Resident Representative to Viet Nam

He addressed the following key points:

1) JICA has been working on the POLYVAC measles vaccine production project since the beginning of 2006.
2) Initially the project intends to ensure a stable supply of measles vaccine in Viet Nam but eventually also assumes export to neighbouring countries to further ensure regional vaccine security to fundamentally contribute to the WPRO's measles elimination goal of 2012.
3) For Vietnamese vaccines to be exported through the United Nations, the NRA needs to be WHO-accredited.
4) For above, two conditions need to be met soon: first to establish a regulatory system without any conflict of interest within and second to upgrade its six critical regulatory functions up to the WHO-accreditation level.
5) JICA asks the relevant organizations in Vietnam, especially the Ministry of Health, to take the initiative in solving this issue. JICA also asks the WHO office for its continuous support.

2. Self-introduction of each participant

According to the chairperson's suggestion, each participant introduced him/herself.

3. Presentation on outstanding issues in the Viet Nam NRA in relation with the POLYVAC measles vaccine project proceedings

Dr. Murakami, a member of the JICA mid-term evaluation team for the POLYVAC measles vaccine production project, has presented conditions for vaccine export through the UN, WHO requirement of national regulatory authority (NRA) functions, its current status in Viet Nam and outstanding issues for the NRA to be WHO-accredited. The outstanding regulatory issues in Viet Nam addressed included the followings:

1) Manufacturers and NICVB, which is regarded as the main component of the Vietnam NRA, have been reporting to same MOH department (currently to Department of Drug Administration and formerly to Vietnam Administration of Preventive Medicine), constituting a fundamental conflict of interest.
2) Involvement of vaccine manufacturers in GMP (good manufacturing practice) inspection team as stipulated by the MOH Circular No. 19/2005/TT-BYT that is still in effect (but under review).

3) For clinical trials supervision, the Science and Technology Committee and Ethical Committee, both organized by the Department of Science and Training, Ministry of Health (MOH), do not have specified membership but rather the members are called upon on protocol-by-protocol basis. This arrangement does not ensure avoidance of the conflict of interest by itself unless additional regulation to ban such conflict is settled.
4) NIHE is considered to be contracted to be an implementer of the clinical trial of the POLYVAC measles vaccine that had been produced from an imported bulk. This constitutes a potential conflict of interest because NIHE is a member of the Licensing Committee organized by the Department of Drug Administration, MOH.

He also posed the following questions for discussion:

1) Which entity is ultimately the NRA in Viet Nam (NICVB, Department of Science and Training, Department of Drug Administration, or a combination or all of them)?
2) How can POLYVAC ensure that their upcoming measles vaccine clinical trial (planned in Jan 2008) is accepted in future WHO-prequalification assessment by selecting an implementer without any connection with clinical evaluation/ licensing process?
3) Who will issue GMP certificate to POLYVAC measles vaccine facility, NICBV (planning inspection in Dec 2007) or Department of Drug Administration (the certification must be essential for the product licensing of the measles vaccine)?
4) Can POLYVAC measles vaccine be licensed according to the project schedule (vaccine from bulk in 2008 and that from the seed in 2009)?

4. Comments from the WHO Viet Nam Office

Dr. Tsukamoto reiterated the following three principal WHO standpoints:

1) Lack of conflict of interest amongst the NRA, MOH and vaccine manufacturers is a prerequisite for the product prequalification and NRA accreditation by the WHO.
2) WHO requests MOH to clarify current structure of the Viet Nam NRA and issues related to the NRA system.
3) Based on above, WHO will provide supports in conducting re-assessment of the NRA and its accreditation if appropriate, as well as technical supports if needed.

5. Discussions

<u>Discussion on clinical trial of POLYVAC measles vaccine produced from bulk:</u>

(Dr. Duc Anh, NIHE) Clinical trial supervision is now regulated by the MOH Decision No. 01/2007/QD-BYT. It does not stipulate the fixed members of both the Science and Technology,

and the Ethical Committee. MOH is working on a document to further define the membership with an involvement of the Vice-Minister Dr. Tien. NIHE has not been and will not be involved in the clinical trial protocol approval of the POLYVAC measles vaccine, therefore does not have any conflict of interest. In the Licensing Committee, NIHE certainly holds a seat. However, the Institute has extensive experiences in clinical trials and also is GCP certified, therefore a suitable entity to conduct the clinical trial. The half million doses of measles vaccine produced from an imported bulk requires an urgent implementation of the clinical trial. The vaccine produced from a seed virus will eventually require a full set of clinical trial from phase one. It is not a big matter who conducts the clinical trial of the initial product from the bulk with limited amount because the eventual clinical trial of the vaccine from a seed is much more important and can be done by others.

(Ms. Ibi, JICA mid-term evaluation team) Can I reconfirm whether the members of the Science and Technology as well as the Ethical Committee are fixed or not?

(Dr. Anh Duc, NIHE) No, the membership is not fixed. As mentioned, NIHE surely sits in the Licensing Committee but it is quite experienced in conducting clinical trials. The clinical trial of the POLYVAC measles vaccine that was produced from the imported bulk should be done by NIHE according to the schedule without any delay.

(Dr. Lee and Mr. Ishikawa, JICA POLYVAC Project) We concern that the above arrangement suggested by Dr. Anh Duc might possibly undermine the credibility of the clinical evaluation of the measles vaccine that will eventually be produced from a seed virus because we assume to apply a bridging study between the one produced from the imported bulk and the one from the seed.

(Dr. Anh Duc, NIHE) Bridging study is not permitted because such method is not allowed according to the MOH Decision No. 1893/QD-BYT.

(Dr. Hien, POLYVAC) The document mentioned above needs to be later reviewed and point to be clarified. The bridging study, from scientific point of view, is considered enough to prove the effectiveness and safety of our measles vaccine produced from a seed virus, but different people seem to have different opinion on it. We are waiting for the quality certification of our measles vaccine produced from the imported bulk by the end of December 2007. We then need to submit the clinical trial protocol along with the quality certificate for the approval of the undertaking of the clinical trial of this vaccine by the Science and Technology Committee and the Ethical Committee. The acceptability of the planned bridging study is a critically matter. If it is not accepted, the JICA project time-frame collapses. The quality certificate currently

required by the Department of Science and Training as a condition to approve the clinical trial protocol is technically not needed.

(Dr. Hong, NICVB) The NICVB is authorized to issue the quality certificate according to the quality control tests conducted on the lot samples at the national reference laboratory. There is also a team for the clinical trial supervision and both will submit reports to the MOH. That, I understand, is the procedure.

Discussion on the party(s) in charge of the GMP inspection and certification:

(Dr. Hang, Department of Drug Administration) One significant difficulty in streamlining the vaccine regulatory system is that different regulatory functions are administered by different Vice-Ministers: VM Dr. Tien administers clinical trials supervision, VM Dr. Huan the Expanded Programme on Immunization (EPI) that actually implements the post-marketing surveillance of adverse events following immunization (AEFI), VM Dr. Quang licensing and VM Dr. Lien the POLYVAC project. In order to streamline the NRA issues, all VM need to work together. Currently, it is perceived that the Department of Drug Administration is officially in charge only of GMP inspection. The MOH Circular No.19/2005/TT-BYT is under review and will be amended soon. The Department is also planning to draft a new regulation on the GMP inspection separately from the Circular No. 19. Aside from the GMP, a new regulation on laboratory access is planned to be issued.

(Dr. Hong, NICVB) NICVB's terms of reference is stipulated by the MOH Decision No. 4268/2006/QD-BYT and accordingly involves all six critical vaccine regulatory functions. The Director of NICVB, Dr. Phung, will submit a new master plan very soon. Despite the above stipulations, the current regulatory functions and authorities entrusted to the NICVB is uncertain and ambiguous. For the GMP inspection, a lot of staff had been trained and participated in this activity. Likewise, the inspection on the POLYVAC measles vaccine facility is planned during 24-27 December 2007. Knowing that the Department of Drug Administration also assumes the responsibility in the GMP inspection, it is uncertain if a duplicated inspection might be conducted by the Department aside from the one already planned by NICVB in late December.

(Dr. Tung, Vietnam Administration of Preventive Medicine) The MOH Circular No. 19/2005/TT-BYT is still effective and according to it the final authorizer of the GMP status is the Vietnam Administration of Preventive Medicine (VAPM). Now that all regulatory responsibility held by the VAPM have been transferred to the Department of Drug Administration, the Department holds the final authority over the GMP issue.

(Dr. Hong, NICVB) As part of the comprehensive GMP inspections, the facility licensing of the POLYVAC measles vaccine facility that focused on the facility aspect of GMP has already been conducted by the NICVB. The inspection of the production process will commence by the planned inspection during 24-27 December 2007. All these undertakings need consistency among each other.

(Dr. Huong, Department of International Cooperation) Which of the six critical regulatory functions is the NICVB formally responsible for?

(Dr. Hong, NICVB) The MOH Circular No. 19/2005/TT-BYT lacks logical integrity in various aspects. It should be streamlined and will be amended next year.

Conclusive remarks:

(Dr. Huong, Department of International Cooperation) I understood of the overview of the problems lying in the vaccine regulatory system. I want the POLYVAC to later report the issues in more details to the MOH, and after considerations among the MOH, we will officially respond to the JICA. Probably, when POLYVAC is called upon and confer with the MOH, both WHO and JICA Viet Nam Offices will also be involved.

(Dr. Murakami, JICA evaluation team) For the implementer of the upcoming measles vaccine clinical trial (planned in Jan 2008), I propose myself and Dr. Tsukamoto to clarify with the WHO Headquarters whether it is acceptable for the future WHO-prequalification if NIHE, which is involved in the licensing process, actually conducts the clinical trial. For the issue of who the GMP inspector vis-à-vis the authorizer of the GMP certification should be, the planned amendment of the Circular No. 19 next year, drafting of other GMP related regulations and the discussion among POLYVAC and the MOH proposed by Dr. Huong are all very important and we will be anxiously and attentively waiting for the developments.

The chairperson, Dr. Tsukamoto, WHO Viet Nam Office thanked all participants for their active participation and officially closed the meeting.

6. Conclusions

The following actions are needed to follow up the roundtable discussions:

1) POLYVAC to report the outstanding regulatory issues related to its measles vaccine

production project.

2) The MOH to call upon POLYVAC, WHO and JICA to take up issues.
3) The MOH to provide official responses to the questions raised by the mid-term evaluation team.
4) Dr. Murakami and Dr. Tsukamoto to clarify with the WHO Headquarters if the NIHE's conducting of the clinical trial of the POLYVAC measles vaccine produced from the bulk may undermine the future WHO prequalification or not.
5) The acceptability of the bridging clinical study between the one produced from the imported bulk and the one from the seed need to be clarified as soon as possible by the relevant authority (the acceptance was once confirmed by NICVB already during the preliminary study of the JICA POLYVAC measles vaccine production project) since it may critically undermine the JICA project time-frame thus the achievement of the project purpose.

課 題	確 認 事 項	情 報 / 指 標	情報源/ 調査対象	調査結果
1. 妥当性				
1-1. ベトナム側のニーズは十分把握されていたか。	1) 案件目標はベトナム国の保健政策と一致しているか。	- 長期保健医療政策(2001-2010)		長期保健医療政策の目標である乳児死亡率25、5歳未満児死亡率出32(各出生1000対)を達成に向けて、麻疹ワクチンの2回接種の定着により、小児の主要死因である麻疹による死亡を減らすことが急務となっている。先進国がより高利潤のワクチン製造にシフトする中、麻疹ワクチンの安定供給に向けて、国内での生産体制の確立が必要となっており、本プロジェクトはベトナム国の保健政策に十分合致している。
	2) カウンターパートは麻疹ワクチン製造を担う機関として適していたか。		カウンターパート JICA 専門家	カウンターパートであるPOLYVACは1994年よりポリオワクチンの製造を行っており、国内需要を100%満たしている。本プロジェクトにおける麻疹ワクチンの生産課程の中心部分は生ワクチンの製造技術を有するスタッフが担っており、POLYVACはカウンターパート機関として最適であった。
1-2 協力計画の策定過程は妥当であったか。	1) アウトプット目標の設定は妥当であったか。		カウンターパート JICA 専門家	GMP 基準に適合した麻疹ワクチンの製造という点で、アウトプット目標の設定は妥当であった。
	2) 案件目標の設定は妥当であったか。		カウンターパート JICA 専門家	案件目標の一つ、「年間750万ドースの製造ペースで稼動」については、すでに各工程の基本的な生産技術が移転され、達成の見込みは十分であるが、もう一つの案件目標である「NRAによるGMP認証」については、現段階では十分なNRA機能が存在しないため、ベトナム政府による早急な体制整備が必要である。
	3) アウトプットの内容は案件目標を達成するための必要事項を全て含んでいたか。		カウンターパート JICA 専門家	必要事項は網羅されていた。
	4) ベトナム側の協力実施体制を把握していたか。		JICA 専門家	POLYVAC の体制とカウンターパートの技術レベルは十分に把握されていた。
	5) 計画策定過程は妥当であったか。	参加型の計画策定方式であったか。	カウンターパート JICA 専門家	北里研究所の専門家とベトナム側の協議に基づいて計画が策定された。
1-3 実施スケジュールの設定は妥当であったか。	1) それぞれの活動の期間は技術移転のために十分であったか。		カウンターパート JICA 専門家	GMPに適合した麻疹ワクチン製造のための技術移転を行う期間として、4年間という期間は非常にタイトであったが、綿密なスケジュール管理により効率的なプロジェクト運営がなされている。
1-4 我が国の援助政策に合致していたか。				JICA の国別事業実施計画においては、感染症対策支援プログラムの中で麻疹の抑制が位置づけられており、本プロジェクトは無償資金協力「麻疹ワクチン製造施設建設計画」の後を受ける技術協力プロジェクトとして実施されている。
2. 有効性				
2-1. アウトプット目標の達成状況はどれだけか。	1) プロジェクトに必要な施設・機材は整備されたか。	供与機材	供与機材リスト	主要な麻疹ワクチン生産施設および機材は無償資金協力により整備され、その他のバリデーション機材は本プロジェクトにより供与された。
	成果 1 2) POLYVAC スタッフは VN-GMP 基準に適合した麻疹ワクチン製造技術を習得できる見込みか。	- 各部門別の指導者レベルの技術者の人数 - 各部門別の責任者の職務に対する自信	- 中間評価準備調査報告書 - カウンターパート	GMP 基準に合致した麻疹ワクチンの製造技術に関して、基本的な技術移転は終了している。2008年12月24～26日に実施されるGMPインスペクションの結果をもって、「VN-GMP基準に適合しているかどうか」が判断される。
	活動 1	- 指導者レベルの技術者の人数	- 中間評価準備調査報	2007年10月、輸入ワクチン原液から最終製品を作る過程の基本的

課 題	確 認 事 項	情 報 / 指 標	情報源/ 調査対象	調査結果
	- 輸入ワクチン原液から最終製品を製造する過程を通して、最終バルク構成、充填、凍結乾燥技術を中心とした技術移転が行われたか	- 部門責任者の職務に対する自信	告書 - カウンターパート	な製造技術の移転がほぼ完了した。
	活動 2 - 種ウイルスからワクチン原液を製造する過程を通して、原液製造の技術移転は行われたか	- 指導者レベルの技術者の人数 - 部門責任者の職務に対する自信	- 中間評価準備調査報告書 - カウンターパート	2007 年 11 月までに試験バルク製造が 11 回行われ、基本的な技術移転はほぼ終了した。2008 年 10 月、最後の PV の実施をもって技術移転が完了する予定である。
	活動 3 - 年間 750 万ドースを定常的に製造するためのオペレーション、施設及び生産機材の維持管理、資機材の調達に関する技術移転が行われたか	- 指導者レベルの技術者の人数 - 部門責任者の職務に対する自信	- 中間評価準備調査報告書 - カウンターパート	2008 年 1 月中旬以降、種ウイルスから製造した原液を用いてスケールアップの実験を行う予定である。2008 年以降のフル稼働に向けて動線の検討、作業時間および資材の管理等のマネジメントの強化に向けて専門家による指導が行われる。
	活動 4 - ワクチンの品質管理に関する技術移転が行われたか	- 指導者レベルの技術者の人数 - 部門責任者の職務に対する自信	- 中間評価準備調査報告書 - カウンターパート	品質管理試験に関する必要な技術移転が行われ、QC 部門のスタッフにより PQ、PV 用の品質管理試験が実施された。今後は、すでに習得した技術の維持と、レベル4のスタッフからレベル 1、2 のスタッフへの技術指導が必要である。
	成果 2 3) 製造・品質管理が VN-GMP 基準に準拠したものとなる見込みか		- 保健省、WHO インタビュー	製造工程における GMP システムの構築は進んでおり、基本的な文書は整備された。今後は各スタッフに GMP の理念が定着するよう理解を深める必要がある。
	活動 1 - 原液から製造するワクチンについて稼動時適格性検証（PQ）、製造工程適格性検証（PV）が実施される見込みか	- 実施時期、回数、結果	- 中間評価準備調査報告書 - カウンターパート	2007 年 9 月までに PQ および 3 回の MFT が終了し、PV に関しては 3 バッチの生産が 2007 年 12 月の時点で終了しており、品質管理試験の部分を除き、ほぼ完了した。
	活動 2 - 一貫製造するワクチンについて PQ、PV が実施される見込みか	- 実施時期、回数、結果	- 中間評価準備調査報告書 - カウンターパート	主要な PQ は終了しており、2008 年 3 月までの MFT の実施と 2008 年度に予定されている 3 回の PV を待って完了する予定である。
	活動 3 - バリデーション（Validation）実施体制が整備され、実施技術が移転される見込みか	- 実施体制（責任者、組織） - 技術移転の状況	- 中間評価準備調査報告書 - カウンターパート	実施体制が構築され、技術移転はおおむね完了しているが、担当者が習得した技術を維持できるようフォローアップが必要である。
	活動 4 - VN-GMP に準拠した品質管理機能が整備され、実行される見込みか	- GMP 体制の確立に向けた活動の実施記録	- 中間評価準備調査報告書 - カウンターパート	文書作成、管理についての基礎的な部分の技術移転は完了し、QA 部門が GMP 文書の管理を行っている。今後はマネジャークラスには高度な GMP 体制構築に向けたモニタリングと追加指導を行うとともに、スタッフに対しては基礎的な GMP の理解を深めるための教育が実施される予定である。
	活動 5 - 製造工程、搬出入、保管等に関する SOP が作成され、運用され	- 作成された SOP の有無 - 運用状況	- 中間評価準備調査報告書 - カウンターパート	製造工程、搬出入、保管についての SOP は整備され、運用されている。施設、機材のメンテナンスに関する SOP の一部はまだ整備されておらず、今後作成される予定である。

課 題	確 認 事 項	情 報 / 指 標	情報源/ 調査対象	調査結果
	たか			
	活動 6 - VN-GMP 基準に準拠するために必要な関連書類の整備に関する技術移転が行なわれたか	- 作成された書類の種類 - 文書作成における技術移転の状況	- 中間評価準備調査報告書 - カウンターパート	基本的な GMP 書類の作成と技術移転は完了しているが、一部マネジャーの GMP 文書作成能力については引き続き強化が必要である。
	4) アウトプット目標の達成を促進/阻害した要因は何か。		カウンターパート JICA 専門家	特になし
2-2. 案件目標の達成は見込めるか。	1) 協力の結果、実施機関の能力は向上したか。		カウンターパート JICA 専門家	麻疹ワクチン製造に向けての技術移転は計画通り進んでおり、POLYVAC のキーパーソンたちの能力は着実に向上している。
	2) アウトプットが案件目標達成につながるのを促進/阻害した要因は何か。		カウンターパート JICA 専門家	NRA の 6 つの機能のうち、WHO のプレアセスメントをパスしたのは 2 つのみであり、残りの 4 つの機能については保健省による体制整備が必要である。マスタースケジュールにおいては、2008 年 8 月以降、許認可を得た後、20 万ドースの生産に入る予定であるが、許認可が得られない場合、スケジュールに遅延が生じる可能性もある。
2-3. 上位目標の達成は見込めるか。	1) 麻疹罹患率の低下は達成可能か。	- 2 回接種制の普及率	カウンターパート JICA 専門家	2006 年の MPV2 の接種率は 98%に達している。ただし、1 回目、2 回目の予防接種率 100%を達成しても、予防接種を受けていない世代においてアウトブレイクが発生する可能性は排除できない。
	2) アウトプットが上位目標達成につながるのを促進/阻害した要因は何か。		カウンターパート JICA 専門家	本プロジェクトは麻疹ワクチンの製造プロジェクトであり、麻疹罹患率の低下に貢献する要因の一つにはなりうるが、ワクチン生産活動が直接罹患率の低下をもたらすことはない。
3. 効率性				
3-1. 開発目標、案件目標に比較した協力規模は適正であったか。	1) 派遣された専門家の人数及びその期間は適正であったか。	アサイン	JICA カウンターパート JICA 専門家	2006 年度の投入は 49.5MM で計画通りに進んでおり、2007 年度も 52.4MM の投入計画が予定通り達成される見込みである。専門家は全員麻疹ワクチン製造過程における高度の専門性を有しており、投入量、投入期間とも適正であった。
	2) 供与機材の品目、数量、金額及びその管理状況は適正であったか。		JICA 専門家	一部不足している機材があり、2007 度中に投入予定である。その他の機材については数量、金額ともに適正で、定期的なメンテナンスがなされている。
	3) 日本への研修員受入れ人数及びその期間は適正であったか。	2 名	JICA 専門家 カウンターパート	2006 年度は QC 部門スタッフ 2 名を 2 ヶ月間派遣し、2007 年度は QA 部門長および QC 部門長の 2 名を 1 ヶ月間日本に派遣する予定であり、目的の成果を得た。人数、期間ともに適正であった。
	4) プロジェクトはスケジュール通り実施されたか。	2006 年 3 月～2010 年 2 月	カウンターパート JICA 専門家	マスタースケジュールに沿ってすべての活動が順調に実施されている。
	5) プロジェクトの総額予算は適正であったか。	日本側: 約 3 億 7,000 万円（予定額） ベトナム側: 運営・経常費用並びに維持管理費	カウンターパート JICA	中間評価の時点までは適正であった。今後の予算については中間評価の結果を踏まえて検討する必要がある。
	6) カウンターパートの人数は適正であったか。カウンターパートは常勤であったか。	カウンターパートの人数	カウンターパート JICA 専門家	カウンターパートはキーパーソンの 5 名を含む POLYVAC スタッフ全員 であり、全員フルタイムで勤務しており、体制として問題はなかった。
3-2. 協力実施のタイミングは適正であったか。	1) 専門家はタイミングよく派遣されたか。		カウンターパート JICA 専門家	原材料の到着時期に合わせて、現地派遣の調整が適宜行われたが、おおむね計画に沿ってタイミングよく派遣された。

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	2) 機材はタイミングよく供与されたか。	供与機材リスト及び供与スケジュール	カウンターパート JICA 専門家	機材調達に関してはベトナム政府による承認プロセスに時間を要し、必要時期に確保されないというトラブルがあったが、専門家がレンタルで持ち込み対応した。
	3) カウンターパートはタイミングよく日本での研修を受けたか。	本邦研修 2 名／年	カウンターパート JICA 専門家	2006 年度については、プロジェクトの進捗に応じてタイミングよく本邦研修が実施された。2007 年度についても同様にタイミングよく実施の見込みである。
	4) プロジェクトはタイミングよく実施されたか(総括的に)。		カウンターパート JICA 専門家	無償資金協力による2006 年 3 月の麻疹ワクチン製造施設の完成直後、同年 7 月から本プロジェクトの技術移転がスタートしており、タイミングよく実施された。
3-3. プロジェクトの支援体制は適正であったか。	1) 合同調整委員会は機能したか。	- 開催回数	カウンターパート JICA 専門家	JCC はこれまでに第 1 回(2006 年 9 月 28 日)、第 2 回(2007 年 9 月 20 日)の 2 回開催されている。このほか、毎週木曜日に開催される週例会議の結果を踏まえ、検討事項があれば適宜保健省等との意見交換が行われているため、関係機関との調整の点では問題はない。
	2) 関連機関からの支援は得られたか。	(a) ベトナム側 (b) 日本側	カウンターパート JICA 専門家 WHO	WHO は、国家検定機関の機能強化のための研修を実施してきた。
3-4. 他の協力形態とのリンケージは適正であったか。	1) 無償、第三国、国際援助機関による協力とのリンケージは良かったか。	(a) その他の JICA プロジェクト (b) 他国による援助プロジェクト	カウンターパート JICA 専門家	JICA 技プロの入っている NIHE とは適宜情報交換を行っており、技術者 1 名を POLYVAC に 1 ヶ月間受け入れ、無菌室におけるバリデーション技術の指導を行ったことがあるなど、良好な連携関係が保たれている。
4. インパクト				
4-1. プロジェクトの当該セクターの開発への貢献度はどれほどであったか。	1) プロジェクトの実施により当該セクターの社会経済的なレベルアップはどの程度みられるか。	- ワクチン製造基準整備の状況 - 国家検定体制整備の進捗状況	WHO 保健省、NICVB	本プロジェクトはベトナム初の GMP 基準適合ワクチン製造施設であり、国内のワクチン製造基準のレベルアップに貢献することが期待される。NRA 体制については、プロジェクト開始前から大きな変化は見られず、ベトナム政府による強いイニシアチブが必要である。
	2) プロジェクトが当該セクターの開発につながるのを促進/阻害した要因は何か。		カウンターパート その他関連機関	特になし
4-2 プロジェクトのその他の貢献度/マイナスの作用はどれほどあったか。	1) プロジェクトの実施により、その他のインパクトは生じたか。		JICA 専門家	日本語・英語教室の実施によるプロジェクト関係者間の連帯感の醸成およびスタッフのモチベーションの強化
5. 自立発展性				
5-1. 組織面での自立発展性はあるか。	1) カウンターパートはプロジェクト活動を継続する意欲があるか。		カウンターパート	POLYVAC は国内唯一の麻疹ワクチン生産施設であり、国内需要をカバーするため、十分に活動を継続する意欲を持っている。
	2) カウンターパートはプロジェクト活動を継続するために十分なスタッフを有するか。	スタッフ数	カウンターパート JICA 専門家	プロジェクト開始時のスタッフ数は 43 名、中間評価時点でのスタッフ数は 59 名であり、多忙ではあるものの数は充足されている。本格生産段階では70～80名程度のスタッフが必要になる見込みであり、時期をみて増員の予定である。
	3) カウンターパートに対する外部関係機関の支援はあるか。		その他関連機関(WHO、UNICEF、GAVI、ルクセンブルク)	WHO は NRA の強化に向けて、短期専門家を招聘し、MOH の関係者を対象とする GMP インスペクションのトレーニングを継続的に実施している。
5-2. 財務面での自立発展性はある	1) 麻疹ワクチン製造プロジェクトの		JICA 専門家	当初計画通り 2009 年からの一貫製造によるワクチンの販売が実現

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か。	独立採算性は見込めるか		カウンターパート	すれば、2009 年以降、独立採算が達成される見込みである。
	2) 保健省による必要予算確保の見込みはあるか。		保健省	2006 年、2007 年の予算は確保されており、2008 年以降も引き続き確保されることが見込まれる。
5-3. 技術的自立発展性はあるか。	1) 移転された技術は適切に使用されているか。	- マニュアル類	カウンターパート JICA 専門家	中間評価時点では基本的な技術移転はほぼ完了している。今後はすべてのスタッフがルールを遵守して生産活動に従事することが望まれる。
	2) 訓練された要員は適切に配置されているか。	- 要員配置計画	カウンターパート JICA 専門家	辞職や配置転換はなく、訓練を受けた要員は計画通りのポストで業務を継続している。
	3) 施設・機材は適切に管理されているか。	- 維持管理台帳	カウンターパート JICA 専門家	適切にバリデーションを含めたメンテナンスがなされている。
	4) カウンターパートから他の要員への技術移転はどのように行われるか。	- 訓練計画	カウンターパート	レベル 4 のスタッフからレベル 1、2 のスタッフに対して、業務の過程で必要に応じて指導が行われているが、QA 部門を除き、部門内で定期的なトレーニングを実施するまでには至っておらず、内部の技術移転の促進は今後の課題である。
6. 教訓と提言				
6-1. 協力期間の延長の必要性はあるか。	1) どの分野において延長が必要か。		JICA ベトナム事務所 JICA 専門家 カウンターパート	特に必要は認められない。
	2) 延長の期間はどのくらいか。		JICA ベトナム事務所 JICA 専門家	特に必要は認められない。
6-2. 技術協力の実施上、改善すべき事項は何か。	1) 本件に関する協力実施上の問題点及び改善点は何か。		JICA ベトナム事務所 JICA 専門家	前提条件である NRA 体制の早期整備が最大の課題である。
6-3. 制度的な改革が必要と考えられる事項は何か。	1) 日本側が協力実施改善のために必要な制度的改革は何か(組織・権限面・予算面等)。		JICA ベトナム事務所 JICA 専門家	特に必要は認められない。
	2) ベトナム側が協力実施改善のために必要な制度的改革は何か(組織・権限面・予算面等)。		JICA ベトナム事務所 JICA 専門家	NRA 体制の早期整備が必要である。
6-4. 教訓は何か。	1) プロジェクト目標達成を促進／阻害した要因は何か。		カウンターパート JICA 専門家	促進要因:朝礼、夕礼、週例会議の実施による緻密なスケジュール管理が行われたこと 阻害要因:特になし
6-5. 提言は何か。	1) 本プロジェクトに係る提言は何か。		カウンターパート JICA 専門家	・POLYVAC 内部における技術移転の促進、リスク対応能力の強化、GMP についての理解の促進、部門長のマネジメント能力の強化 ・保健省による POLYVAC 予算の確保 ・SPF 卵の輸入ルートの確保 ・GMP 審査、臨床試験、許認可の適切かつ遅滞のない実現 ・NRA 体制の早期整備

４．インタビュー用質問票

プロジェクトチームキーパーソン対象

クエスチョネア

評価分析担当
システム科学コンサルタンツ㈱　城戸千明

総括　荒井先生
副総括／ワクチン製造管理　李先生
組織管理　田村先生
品質管理　吉田先生

－今回の中間調査の趣旨について－

JICA 事業の評価は、事前・中間・終了時・事後の各段階において、プロジェクトをはじめとする協力事業の妥当性と協力効果を客観的な視点から判断することを目的としています。**今回実施される中間評価は、プロジェクトの中間地点で、計画の進捗状況を確認し、効果の発現に貢献した点や阻害要因を分析したうえで、評価結果を関係者間で共有することにより、プロジェクトの今後の展開を円滑化することが目的です。**評価という用語はプロジェクトを外部から一方的に批判するようなネガティブな印象を与えがちですが、そうした趣旨ではなく、**評価調査団が関係者の方のご協力を得ながら、成果の確認作業を共同で行うプロセス**だとお考えください。プロジェクトチームの方々のご理解をいただけますようお願いいたします。

なお、評価は「調査 5 項目（妥当性、有効性、効率性、インパクト、自立発展性)」の観点から行い、これに基づいて今後の「提言」の整理を行いますので、質問票もこの視点から整理を行っています。各項目の概要は以下の通りです。

妥　当　性：プロジェクト実施の必要性、妥当性について
有　効　性：プロジェクト目標や計画の達成度について
効　率　性：人材や機材等の投入の効率性について
インパクト：プロジェクトによる正負の効果について
自立発展性：協力期間終了後の自立発展性について

この 2 点は、中間評価においては十分に評価を行うことはできませんので、現時点での「見通し」を整理します。

提　　言：プロジェクトの関係者（プロジェクトチーム、ベトナム保健省、JICA など）に向けた提言について

次ページに質問項目を整理しています。

まず、プロジェクト全体についての質問です。

全体スケジュールについて

・ 全体のスケジュールは、作業計画書に基づいて予定通りに進捗している、という理解でよろしいでしょうか。スケジュール遵守の上でポイントになった活動やキーパーソンがいらっしゃいましたらお聞かせください。

妥当性について

・ NIHE の NEPI から POLYVAC に対して、ワクチン製造・出荷の早期実現を目指すよう要望が寄せられているとの記述がありますが、これは早期の販売許可取得の追い風とならないのでしょうか。

有効性について

・ 2 年目の半ばの時点で計画は予定通りに進行していると伺っています。大規模プロジェクトを計画通りに進めていらっしゃる背景には、①当初計画が十二分に練られたものであった、②徹底したマネジメント（調整会議や朝礼・夕礼）が行われた、の二点があると推察します。（他の要因についてもお聞かせください。）①および②の二点について、留意された点、工夫された点などを教えてください。他にも成果達成のために工夫されていることがあれば教えてください。

効率性について

・ プロジェクトの目標達成を図る上で、日本人専門家、カウンターパート（POLYVAC 職員）をはじめとする人材、薬品、機材のそれぞれについて効率的な投入が行われたと考えられますか？

インパクト

・ JCC への副大臣の参加、関係者による視察などベトナム側の関心が高く、今後のプロジェクト運営の円滑化に貢献すると見込まれています。TV、新聞等のメディアによって取り上げられた事例はありますか？
・ POLYVAC での日本語教室の開催は、他のプロジェクトにおいても参考となる好事例だと考えられます。スタートのきっかけを教えてください。
・ マイナスのインパクトはとくにないと伺っていますが、何かありましたら教えてください。

自立発展性

・ ベトナム国内での麻疹ワクチンの販売許可が早期に得られれば、事業は独立採算ベースに乗り、自立発展性は十分に見込めると考えられます。この理解でよろしいでしょうか。

成果の発現に貢献した要因について

- WHO-GMP の基準に準拠するために工夫された点はありますか。
- ここまでの過程で、大きな問題となった点はありますか。（供与機材調達の遅れが指摘されていましたが、ほかにもありますか。）
- 類似案件である「インドネシア共和国生ワクチン製造基盤技術プロジェクト」に関して、本プロジェクトの参考にされた点はありますか。

今後の提言

- 今後の提言として、「SPF 卵の自国生産に向けた MOH の取り組み強化」「MOH による麻疹ワクチンの承認の早期実現」を含めたいと考えています。このほかにありましたら教えてください。

教訓

- 今後、類似プロジェクトの教訓となる点がありましたら教えてください。

プロジェクト全体についての質問は以上です。

以下は、李先生、田村先生、吉田先生の**各ご担当分野について**、個別にお尋ねしたい質問です。

- ご担当分野の概要と、同一分野の専門家との業務の分担について教えてください。
- 全体の作業計画はほぼ予定通りに進んでいる、と理解していますが、ご担当分野の作業をスケジュール通りに進める上で、工夫された点や、苦心された点はありますか。
- 技術指導の上で工夫された点、留意された点の主なものについて教えてください。
- 技術指導の上で問題となった点はありますか。ありましたら、どのように解決したかを教えてください。
- 今後、解決すべき課題はありますか。

以上、お忙しいところお時間をいただきまして恐縮ですが、どうぞよろしくお願い申し上げます。

Questionnaire to the counterparts at POLYVAC
for the Mid-term Evaluation
of Measles Vaccine Production Project in Vietnam

The Director, Dr. Nguyen Dang Hien
Vice Director, Dr. Le Thi Luan

Please accept this questionnaire for the mid-term evaluation of Measles Vaccine Production Project in Vietnam, which will be held during December 5th to 19th, 2007. This is prepared for the information collection by the counterparts at POLYVAC, because all of you are the key persons being responsible of measles vaccine production in the future. I would like to request to the Director and your staffs to share some time for interview during my visit to POLYVAC during December 6th to 10th. I am grateful for your cooperation in advance.

Ms. Kido Chiaki, Evaluation Analysis

1. In general

- How do you evaluate the progress of the capacity building of your staff at POLYVAC since the beginning of the Project?
- What do you consider as the biggest factor of the steady progress of the Project so far?

2. Current situation

Technology transfer

- Currently POLYVAC has sufficient number of staffs to manage the activities of the Project?
- Do you consider that staffs at POLYVAC are confident enough to perform the required tasks at this moment? What is the expectation at the end of the Project?
- Are you satisfied with the process and contents of technology transfer by Japanese experts so far?

Finance

- Currently do you have sufficient budget for the operation of POLYVAC?

3. Difficulties or problems

- Do (or Did) you feel/ any difficulties or problems for the implementation of this project? If so, what are (or were) the main problems?
- Do (or Did) you feel any cultural or customary complications for the implementation of the Project with Japanese experts?

4. For the latter half of the Project

- Do you have any points to focus on for the latter half of the Project?

5. Recommendations

- Do you have any recommendations or requests to the relevant organizations (MOH, NICVB, WHO, POLYVAC staff, Japanese experts, JICA Vietnam etc.)?

Questionnaire to the counterparts at POLYVAC
for the Mid-term Evaluation
of Measles Vaccine Production Project in Vietnam

To the managers of QA, QC, Final dept., Bulk dept., Medium dept, Technical dept.

Please accept this questionnaire for the mid-term evaluation of Measles Vaccine Production Project in Vietnam, which will be held during December 5th to 19th, 2007. This is prepared for the information collection by the counterparts at POLYVAC, because all of you are the key persons being responsible of measles vaccine production in the future. I would like to request to the Managers and your staffs to share some time for interview during my visit to POLYVAC during December 6th to 10th. I am grateful for your cooperation in advance.

Ms. Kido Chiaki, Evaluation Analysis

1. In general

- How do you evaluate the progress of the capacity building of you and the staff at your department since the beginning of the Project?
- What do you consider as the biggest factor of the steady progress at your department so far?

2. Current situation

Technology transfer

- Currently your department has sufficient number of staffs to manage the activities of the Project?
- Do you consider that staffs at your department are confident enough to perform the required tasks at this moment? What is the expectation at the end of the Project?
- Are you satisfied with the process and contents of technology transfer by Japanese experts so far?

3. Difficulties or problems

- Do (or Did) you feel/ any difficulties or problems for the implementation of this project? If so, what are (or were) the main problems?
- Do (or Did) you feel any cultural or customary complications for the implementation of the Project with Japanese experts?

4. For the latter half of the Project

- Do you have any points to focus on for the latter half of the Project?

5. Recommendations

- Do you have any recommendations or requests to the relevant organizations (MOH, NICVB, WHO, POLYVAC director/other departments/your staff, Japanese experts, JICA Vietnam etc.)?