NO.	NO JPRI	DESCRIPTION OF GOODS SPECIFICATION	MANUFACTURE	TOTAL NEEDED	T C ALREADY GET	T C ALREADY ORDER	G A I	G A II	G A III	STILL NEEDED	GET FROM	ROOM NO	PRICE ¥ (YEN)	REMARKS
0977	0966	Tube Sealer w/ Transformer 220/100 V		1	1					0		Q138	230,000	Mar 07,1991
0978	0967 (M)	Centifugator Large type		2 2	1 2	1				0 0		P210 P140	3,200,000 6,180,000	Mar 31,1992 Mar 17,1991
0979	0968	Rotor RR5 S2 (Consumable) 1.Inner cup 1 L set / 6 pcs 2.Inner cup adapter set/2pcs 3.1000 ml bottle set /6 pcs 4.Adapter 500 ml set / 6 pcs 5.200GS1000 Adapter set/2pcs 6.S302859A 2kg Balancer 7.Service Manual	HITACHI	2 sets	2 + 1 2sets 3sets 20sets 1 set 3sets 1 set					0		P 204	1,000,000 22,000 31,500 240,000 240,000 69,000 50,000	Mar 31,1992
	(M)	Rotor RR5 S2 (Consumable) 1.Inner cup 1 L set / 6 pcs 2.Inner cup adapter set/2pcs 3.1000 ml bottle set /6 pcs 4.Adapter 500 ml set / 6 pcs 5.200GS1000 Adapter set/2pcs 6.S302859A 2kg Balancer 7.Service Manual	HITACHI	2 sets	5 sets 4 sets 6 sets 40sets 2 sets 6 sets 3 sets 1 set					0			1,800,000 38,800 46,800 388,000 420,000 127,300 83,400	Mar 17,1991
0980	0969	Tube for RR5 S2		200	200					0				
0981	0970	Centrifugator Small type High speed Refrigerated Centrifuge Model RS-18-IV for 220V 50 Hz AC.	TOMMY	1	1					0		Q158		Mar 17,1991
0982	0971	Rotor Bucket 14N-2 17N TS-7		1 set 1 set 1 set	1 set 1 set 1 set					0		Q158		Mar 17,1991
0983	0972	Bucket 50ml x 8 Bucket 15ml x 32		1 set 1 set	1 set 1 set					0		Q158		Mar 17,1991
0984	0973	Stainless Steel Mesh No 83 180 / um -1m x 1m		2	2					0		P 230	28,000	Apr 02,1992
0985	0974	Pincette 170 mm (Dressing - forceps Natsume A 24) Long curved 80 mm.	NATSUME	10	10					0		Q 149	39,900	Apr 02,1992
0986	0975	Working Table (A) Stainless		2						2				
0987	0976	Working Table (B) Stainless		2						2				
0988	0977	Working Table (C) Stainless		8						8				

*) Note :(M)= Measles (C)= Common Use

NO.	NO JPRI	DESCRIPTION OF GOODS SPECIFICATION	MANUFACTURE	TOTAL NEEDED	T C ALREADY		G A			STILL NEEDED	GET FROM	ROOM NO	PRICE ¥ (YEN)	REMARKS
					GET	ORDER	I	II	III					
0989	0978	Working Table (D)-Stainless		1						1				
0990	0979	Working Table (E)-Stainless		1						1				
0991	0980	Working Table (E1)-Stainless		1						1				
0992	0981	Working Table (F)-Stainless		9						9				
0993	0982	Working Table(F1)-Stainless		34		23	11			0				
0994	0983	Working Table(F2)-Stainless		26		20	6			0				
0995	0984	Stainless Shelf (G) Type 4 shelf slated/NPR 12 - 50 A Dim:1200 x 500 x 1800 mm	NAYATI	24	24					0		P 230:17 AnimalH:7	Rp. 18.720.000	May , 1992
0996	0985	Stainless Shelf (H)		14						14				
0997	0986	Stainless Shelf (I)												
0998	0987	Stainless Shelf (J)												
0999	0988	Stainless Wagon (K)		4						4				
1000	0989	Stainless Wagon (K 1)		8						8				

NO.	NO JPRI	DESCRIPTION OF GOODS SPECIFICATION	MANUFACTURE	TOTAL NEEDED	T C ALREADY		G A			STILL NEEDED	GET FROM	ROOM NO	PRICE ¥ (YEN)	REMARKS
					GET	ORDER	I	II	III					
1001	0990	Stainless Hand Truck (L)		3						3				
1002	0991	Stainless Hand Truck (M)		3						3				
1003	0992	Stainless Hand Truck (N)		8						8				
1004	0993	Stainless Hand Truck (O)		3			3			0				
1005	0994	Tool Box Wagon (P)		1			1			0				
1006	0995	Tool Box Wagon (Q)		2			2			0				
1007	0996	Steel Locker (R)		30			30			0				
1008	0997	Shoe Locker (S)		3			3			0				
1009	0998	Chemical Storage Cabinet LT		5			5			0				
1010	0999	Chemical Storage Cabinet LU		5			5			0				
1011	1000	FileCabinet for Equipment V		3			3			0				
1012	1001	FileCabinet for EquipmentV1		11			5			6				

NO.	NO JPRI	DESCRIPTION OF GOODS SPECIFICATION	MANUFACTURE	TOTAL NEEDED	T C ALREADY		G A			STILL NEEDED	GET FROM	ROOM NO	PRICE ¥ (YEN)	REMARKS
					GET	ORDER	I	II	III					
1025	1014	Soal Clean (G)												
1026	1015	Frame Mat (H)												
1027	1016	Clean Room Door Mat IUCHI 7-110-01 (L)												
1028	1017	Clean Room Door Mat IUCHI 7-110-02 (S)												
1029	1018	Hand Truck for Clean Room Stainless steel chart Dim:450x350x400 (WxDxH) OKB ⌀ 3".2pcs free.2pcs free with brake	NAYATI	30	30					0		P 224:1 P 226:1 P 219:7 P 218:7 P 230:3 P 208:1 Q 155:10	Rp.11.250.000	Mar 09,1992
1030	1019	Working Table for Inspection RM 75 x 150		8						8				
1031	1020	Chair for Above		20						20				
1032	1021	Stool		12						12				
1033	1022	Stainless wagon(Hand Truck) Dim:740x480x850 mm(wxdxh) c/w non marking caster wheel OKB ⌀ 3".2pcs free.2 free w/ brake	NAYATI	30	10					20		AnimalH:8 P 230 :2	Rp. 4.710.000	Mar 10,1992
1034	1023	Gas Range		3						3				
1035	1024	Stand		20						20				
1036	1025	Uniform for Animal												

NO.	NO JPRI	DESCRIPTION OF GOODS SPECIFICATION	MANUFACTURE	TOTAL NEEDED	T C ALREADY		G A			STILL NEEDED	GET FROM	ROOM NO	PRICE ¥ (YEN)	REMARKS
					GET	ORDER	I	II	III					
1037	1026A	Rubber Stopper No.0	KOTOBUKI	1000	1000					0		P 203 (Storage)		Jun 09,1992
	1026B	Rubber Stopper No.1	BUCHIRU	1000	1000					0		P 204 (Storage)	22,000	Apr 02,1992
1038	1027	Rubber Stopper NO.6	BUCHIRU	400	200 + 200					0		P 204 P 203 (Storage)	14,000	Apr 02,1992 Jun 09,1992
1039	1028	Plastic Culture bottle Corning 26/60-225												
1040		L - R Bottle holder	CELCO	20	20					0		P 230	Rp.1.650.000	Mar 17,1992
1041		Nunc sellfactore 164327 (Multi tray)		5 boxes	5boxes					0		M.R II	239,500	Apr 24,1992
1042		Specific gravity bottle Gay-Lussac with thermometer		1 pcs	1 pcs					0		P 230	4,200	Apr 24,1992
1043		Silicone Rubber board Shin Etsu Silicone 1000 x 1000 x 2 mm		5 pcs	5 pcs					0		M.R II	109,250	Apr 24,1992
1044		Sineto Silicone		5 pcs	5 pcs					0		M.R II	7,750	Apr 24,1992
1045		Sterilized Tespers S		20 pcs	20 pcs					0		P 204 (storage)	176,000	Apr 24,1992
1046		Sterilized Tespers C		10 pcs	10 pcs					0		P 204 (storage)	88,000	Apr 24,1992
1047		Sarsted pipet aid		1 pcs	1 pcs					0		M.R II	63,250	Apr 24,1992
1048		Cover glass No 24 x 60 mm 1000 pcs / box		1 box	1 box					0		Q 149	21,000	Apr 24,1992

NO.	NO JPRI	DESCRIPTION OF GOODS SPECIFICATION	MANUFACTURE	TOTAL NEEDED	T C ALREADY		G A			STILL NEEDED	GET FROM	ROOM NO	PRICE ¥ (YEN)	REMARKS
					GET	ORDER	I	II	III					
1013	1002	File Cabinet for Equipment X		3						3				
1014	1003	Steel Shelf for Equipment X1		10						10				
1015	1004	Steel Shelf for Equipment X1		5			3			2				
1016	1005	Steel Shelf for Equipment X2		3						3				
1017	1006	Stainless Table (Y)		1						1				
1018	1007	Stainless Table (Z)		1						1				
1019	1008	Stool for Clean Room (A)		74						74				
1020	1009	Clean Room Uniform (B)		720						720				
1021	1010	Clean Room Uniform (C)		260						260				
1022	1011	Mask (D)												
1023	1012	Glove (E)		1200						1200				
1024	1013	Socks (F)		1700						1700				

NO.	NO JPRI	DESCRIPTION OF GOODS SPECIFICATION	MANUFACTURE	TOTAL NEEDED	T C ALREADY GET	T C ALREADY ORDER	G A I	G A II	G A III	STILL NEEDED	GET FROM	ROOM NO	PRICE ¥ (YEN)	REMARKS
1049		Sanyo Cooled Incubator Model Mir 552 (for 220V,AC 50 Hz) Exterior Dim:800x832x1810mm Interior Dim:640x550x1160mm Efective Cap:406 ls Temp.range :-10 - +50°C Accessories :Shelves x 5 Key 1 set		2 sets	2sets					0		P 138	1,638,000	May 04,1992
1050		Hibitine gluconate 500 ml Hibitine Sumitomo 18 L Hibitine Sumitomo 500ml 5%		10 pcs 5	4 pcs 10 pcs 5					0 0		Q 139 P 210 MRII	469,000 7,500	May 14,1990(1) Apr 02,1992 May 01,1992(K)
1051		Sodium Acetate 3 H20 WAKO 500 gr	WAKO	1 pcs	1 pcs					0		P 202	960	
1052		Bromo phenol blue WAKO S25g	WAKO	1 pcs	1 pcs					0		P 202	4,800	Mar 26,1992
1053		Strach (soluble) 1 ST WAKO 500 g	WAKO	1 pcs	1 pcs					0		P 202	1,200	Apr 02,1992
1054		Potassium Sodiumtartarate S 500 gr	WAKO	1 pcs	1 pcs					0		P 202	2,100	Apr 02,1992
1055		N/10 Sodium Thiosulfate	WAKO	500 ml	500 ml					0		P 136		Apr 03,1992
1056		Potassium Chromate S 25 G	WAKO	1 pcs	1 pcs					0		P 136	800	Apr 02,1992
1057														

4. 協 議 結 果

4－1　ポリオワクチン

4－2　麻疹ワクチン

4－1　ポリオワクチン

1．ポリオ関係人員

構成人員は、製造及び品質管理関係（動物管理は除く）者は、部長格のDr. Inaを含め26人で、順調に増員されている。今後養成期間を考慮し早めに増員を図るようDr. Inaに薦めた。

2．試験製造進捗状況

1992年4月27日より週2頭のペースでサル腎細胞培養、Ⅰ型ウイルス培養を開始し、7月29日現在24頭処理中、次の製造工程に進め得る品質を示したのは8頭（25.4ℓ）である。1992年中は更に2型、3型の試験製造を進め、サルの合格率、ウイルス収量などの基礎資料の蓄積期間と定め、その資料があって初めて今後の計画が立つことになることを強調した。

製造に使用するサルは、サルFoamyウイルス感染陰性または疑陽性のサルを用いているが、目的のサルが順調に得られず、今後の最も大きな課題となっている。

3．今後の製造計画

Bio Farma側は少量でも早期に完成品を出すことを希望しており、1992年度中に量にこだわらず、1，2，3各型ウイルス原液を製造し、1993年8月に1，2，3型混合ポリオワクチンの試験製造が出来るよう指導した。

また、この計画に合わせて日本ポリオ研究所より専門家が送れるよう立案した。

4．問題点

4－1　サルの供給

今回の調査でポリオ関係では最重要課題であることを両者が認識しており、多くの時間を費やして検討された。調査団側はポリオ製造及び関連試験には次の3種のサルに分けて考える必要性を説いた。

1）製造用サル：

体重1.8kg以下の若いサル。Foamyウイルスの持続感染が無い所以クリーンなサル。

2）サル神経毒力試験、in Vitro試験用サル：

1.5kg以上の健康なサルで、Foamyウイルス感染は関係ない。

3）ワクチン中の外来性ウイルス否定試験用のサル：

妊娠ザルか、生後数ヵ月の仔ザルなど、高率にクリーンなサル。

現時点ではFoamyウイルス感染を血清試験で確実にチェック出来る迄には至っておらず、データを積み重ねる必要がある。Bio Farma側は、目的のサルを得るために特別のチームを編成し、業者の開拓、サル捕獲現地調査など巾広く努力することを約束した。

4－2　ポリオワクチン用安定剤と分注量

これ迄、世界で使用されている安定剤や研究開発中の安定剤を示し、Bio Farma側で選択するよう促して来たが、未だ決定されておらず、今後の検討課題として残った。またBio Farma側は、予定ワクチン分注量を1瓶当り10人分として来たが、調査団は1瓶20人分とすると、製造能力が2倍になるばかりでなく、製品全体のコスト、保存スペースに大きく影響することを示し、Bio Farma側は当局と再検討するとした。

5．Bio Farma側からの要請

5－1　無菌試験用インキュベーター

ポリオ、はしかワクチン用無菌試験用インキュベーターのスペースが不足して、作業に支障を来しており、23℃、31℃用インキュベーターについて日本側からの援助が求められた。

5－2　サル免疫不全ウイルス（ＳＩＶ）抗原の供給

総裁よりポリオワクチンへのＳＩＶ迷入を危惧している旨の発言があった。調査団は、自然状態でＳＩＶによるカニクイザルへの感染は報告されていない（ミドリザルは25%あるいはそれ以上）ことを説明したが、今後ＳＩＶ診断用抗原の供給を続けるよう要請があった。

5－3　日本製ウイルス原液

総裁は、Bio Farmaで予定通り各型ウイルス原液が出来るのが予想より遅れることを懸念しており、ワクチンバルクをポリオ研究所より得ることを議事録に入れたいとの希望があった。しかしこの件は今後の検討課題として残した。

6．感　想

Bio Farma側は本年4月末からの試験製造で、サルＣＰＥ因子陰性のサルが得られる頻度が低く、クリーンなサルを得るため、従来の購入方法では困難で、特別な努力を要することを理解しはじめたようで、今回の調査指導の成果と言える。

Bio Farma側スタッフには熱意があり、Ｃ／Ｐの技術レベルも向上しており、全般的に好い印象を受けた。

ウイルスワクチン製造の中心的Ｃ／ＰであるDr. Inaが本年9月で定年となるが、Bio Farma幹部にDr. Inaの経験が生かせるよう善処を求め、諒解を得た。

4－2　麻疹ワクチン

1．麻疹ワクチン製造に関する進行状況

本プロジェクト開始の1989年より延13名のカウンターパートの受け入れと９名の長・短期専門家の派遣により、現在までに一通り技術移転が終了し、Bio Farma新施設でワクチンの試作に成功し、その試作ワクチンの臨床試験で期待通りの成績を得て、インドネシア国の麻疹生ワクチンの製造承認手続も完了している。

1－1　施　設

施設の整備は完了し試験製造を行ない、特に問題のないことが確認されている。

1－2　製造用種ウイルス

少なくとも10年以上使用可能な量の製造用種ウイルスが確保されている。

1－3　インドネシア国からの製造承認

Bio Farmaで製造された試作ワクチンの臨床試験が今年１月に実施され、その結果、国より製造承認を取得している。

1－4　原材料及び資材の調達

フルスケールの生産に必要な原材料及び資材の調達は可能であるが、輸入品にたよらず、さらに原価を下げるためには、さらにBio Farma側の努力が必要である。

1－4－1　ＳＰＦ－ニワトリ胎児

自家生産するためにＳＰＦ鶏群を確立し、良好な状態で維持されているが、今後の計画を継続することで、さらに、整ったものになると思われる。1992年８月より安藤専門家により、ＳＰＦニワトリ胎児の生産効率を上げることと、ワクチンの検定に使用するＣ／Ｏ遺伝型質を持つニワトリ胎児を得る為に、ホモローガスＣ／Ｏ系の確立を計画している。

1－4－2　牛血清

輸入牛血清を使用することでワクチン生産には支障はないが、安定供給と原価を下げるためには、国産牛血清の調達が有効であると考えられる。既に調達ルートは調査しルートは確認されているが、使用の可否についてさらにつめる必要がある。

1－4－3　最終製品に使用する資材

バイオル瓶、ゴム栓等使用可能な資材の確保は問題なし、但しさらに安価なゴム栓を使用可能にするための検討を行なっているが、岡田専門家（今年７月～９月）の滞在中に解決される見込み。

1－5　ワクチン原液の製造

今年１月から少量生産を開始して、現在では年間目標の750万人分の製造のための原液は、数ヵ月で製造が可能であることを示唆する成績が得られている。

1－6　最終製品（小分・凍結乾燥）の製造

現在岡田専門家により、少量の試験製造を行なうことで指導しているが、9月末にはコマーシャル・ベースでフルスケールの凍結乾燥製品が製造可能となる予定である。

1－7　品質管理

試作ワクチンの検定を通じて、一応技術移転は終了しているものと思われる。但し検定に使用する試薬類の調達で、市販品がなく自家生産するものについて、これからの協力が必要である。

2．麻疹ワクチン製造に関する現時点での問題点とその対策

ワクチン製造上障害になるような大きな問題点はないものと思われるが、更に向上を計る観点から次の点が上げられる。

2－1　原液製造工程中の収率向上

まれに工程中で環境細菌の迷入（混入）が見られ、廃棄される原液が見られるが、できるだけ廃棄率を0に近づけることが望ましい。

対策は、作業員の教育と、経験を積み重ねて、チーム全体の能力を向上させることで、Bio Farma側の努力により解決する。

2－2　品質管理精度の向上

品質管理のために必要な各試験は、レベルがまちまちで、一部に更にレベルを向上させる必要がある。特に市販品がなく、自家生産により供給される試薬（抗原、抗体）の調整について、カウンターパートの研修が必要である。本プロジェクトの残り2年間で解決する。

2－3　原材料、資材、消耗品、の安定供給

原液製造に使用する牛血清、製品用ゴム栓は現在輸入しているが、安定供給と原価を考えると、国産品を使用できるようにすることが望ましい。現在、既に着手している牛血清、ゴム栓については、まもなく国産品が使用可能となる予定。

3．総　括

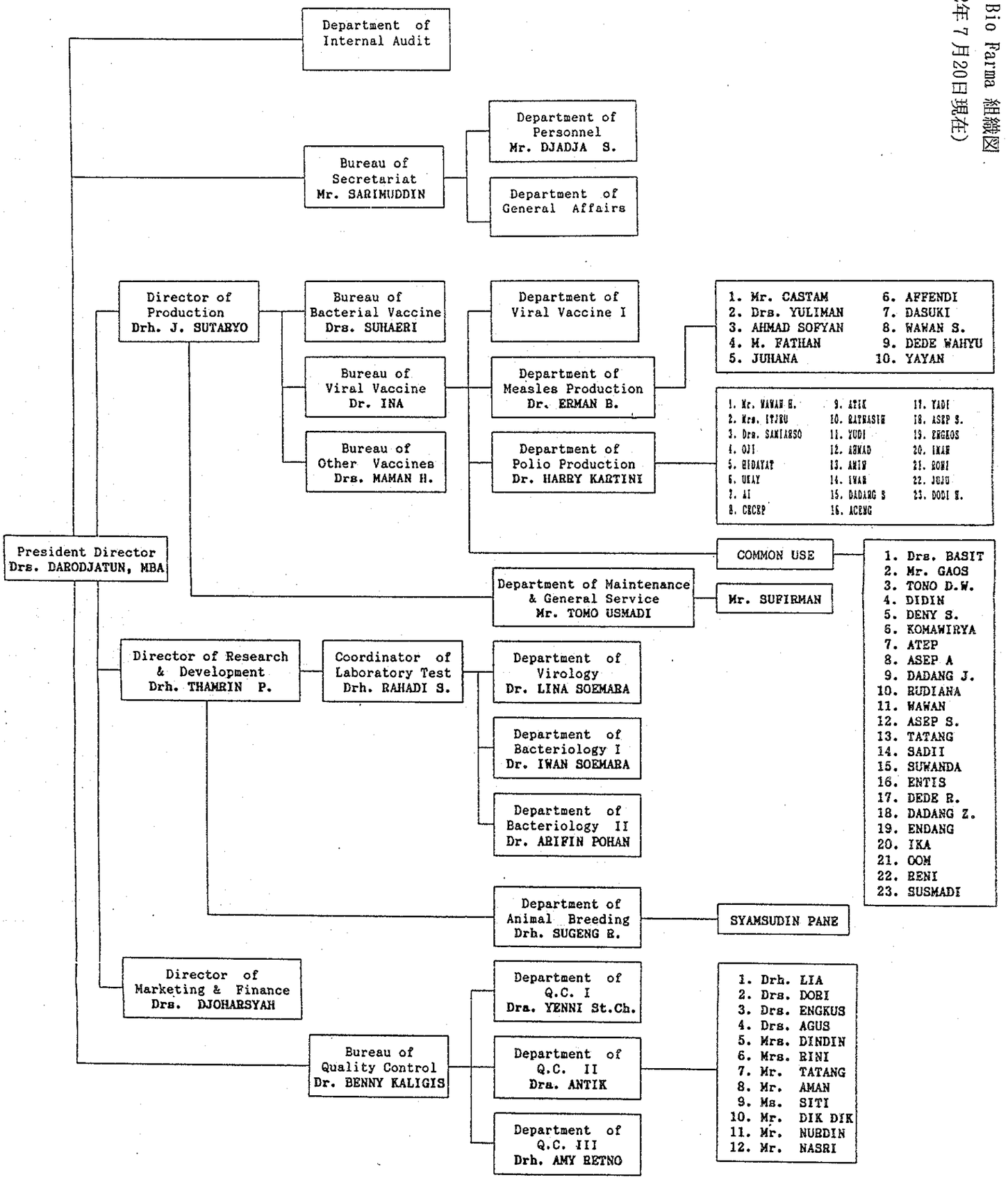
麻疹ワクチンの製造に関しては、予想よりも早く進展し、原液製造は、既にコマーシャル・ベースに入っており、最終製品のための小分凍結乾燥については移転の最終段階にきている。大きな問題もなく、今年秋にはBio Farma 製ワクチンを市場に出すことが可能と思われる。本プロジェクトの残り2年間は、インドネシア側に自立の精神で進めて行き、年2回短期専門家の派遣でチェックを行ないつつ、完成するものと思われる。

附 属 資 料

1) Bio Farma組織図
2) Department of Polio Productionからの資料
3) Department of Measles Productionからの資料
4) Bureau of Quality Controlからの資料
5) Department of Animal Breedingからの資料
6) ミニッツ
7) Bio Farmaの本件プロジェクトに対する予算実績

1. Bio Farma 組織図
(92年7月20日現在)

The Organization of BIO FARMA



Bio Farma 組織図（本プロジェクトC／P）

SCHEMA OF JOB DISCRIPTION
POLIO AND MEASLES VACCINE PRODUCTION

PRODUCTION DIRECTOR
(Vet) J. Sutaryo,58.

VIRAL VACCINE PRODUCTION BUREAU
(MD) Ina Madiadipura,56.

QUALITY CONTROL BUREAU
(MD.Benny Kaligis)

QUALITY CONTROL DEPARTMENT

POLIO PRODUCTION DEPARTMENT
(MD) Harry Kartini,39.

MEASLES PRODUCTION DEPARTMENT
(MD)Erman Boedisetianto,40.

COMMON USE

BULK PREPARATION	- MONOVALENT BULK PREPARATION - BLENDING - FILLING	TISSUE CULTURE SAFETY TEST	VIRAL TESTING	NEURO VIRULENCE TEST	BULK PREPARATION	-POOLING -FILLING -FREEZE DRYING
(T)Wawan H,27.	*(Vet)Samiarso L,28.*	(T)Ai Hasanah,21.	(T)Itjeu,51.	*(Vet)Agus W,32.*	(T)Castam F,46.	(Ph)*Yuliman,30.*
(T)Oji R,23.	(T)Cecep D,28.	(T)Atik S,27.	(Ph)Dori U,27.	(T)Asep S,24.	(T)Juhana,25.	(T)Achmad S,25.
(T)Hidayat S,23.	(T)*Ahmad A,28.*	(T)Iwan S,24.	*(T) UkaY S,24.*		(T)Wawan S,25.	(M)*Affendi,26.*
(T)Yudi K,21.	(T)Amin , 24.	(T)Aceng S,25	(T) Ratnasih,25.		*(T)M.Fathan,24.*	(M)Dede W,26.
(M) Dadang S,21	(Ps) Iman	(Ps) Dodi H,				(M)Yayan,20.
(Ps) Asep S,	(Ps) Ronny					
(Ps) Engkos K,	(Ps) Juju					
	(Ps) Yadi					

ANIMAL HOUSE	GENERAL SERVICE	MEDIUM PREPARATION & WASHING	LABELLING & PACKAGING
(Vet) Sugeng R,	(M+)Tono D.W,28.	*(B)Basit S,40.*	(SH)Dede R ,26.
(T) *Syamsudin Pane*	(M)Didin,22.	(T)Gaos S,49.	*(SH)Da*dang Z.A.28.
	(M)(Deny S,24.	*(PS)Sadii,40.*	(SH)Endang R,22.
	(M)Komawirya,22.	(M+)Dadang J,26.	(SH)Ika,21.
	[redacted]	(SH)Suwanda,28.	(SH)Reni,23.
	(M)*Atep K,20.*	(M)Rudiana,28.	*(SH)Oom ,24.*
	(M)Asep A,21.	(M)Wawan R,28.	(M)Susmadi,20.
	(M)*Tatang K ,23.*	*(SH)Entis* S,21	
		(M)Asep S,23.	

Keterangan:

PS = Primary School
PH = Primary High School
SH = Secondary High School
M = Mechanic
T = Technician
B = Biologist
Ph = Pharmacist
V = Veterinarian
MD = Medical Doctor

2. Department of Polio Productionからの資料

July 28 1992

Review and Tentative Schedule for the OPV Production in Bio Farma

On the 27th and 28th of July 1992, polio staffs of Bio Farma, experts from JPRI and Japanese mission reviewed briefly about past technological development in Bio Farma and planned for interchange of personnel and production schedule in near future and discussed about problems.

1. Progress of technical transfer from JPRI up to July 1992

1-1 Indonesian c/p visited JPRI

Name	Period*	Disciplines
Dr.Ina A.Madiadipura	Apr.26 - Dec.15, 1989	Production(Prod) Quality control (QC)
Dr.Harry Kartini S. .Iskandar	Nov.27,1989 - Nov.15, 1990	Administration (Admi) Prod QC
Mrs.Itjeu I. Salim	Jan.19 - Jul. 6, 1990	Prod QC
Dr.Agus W. Widayanto	Oct.12,1990 - May 17, 1991	NVT QC
Mr.Wawan Hermawan	Jun.17 - Dec.12, 1991	Prod QC
Dr.Benyamin Kaligis	Jan. 7 - Feb.29, 1992	Admi QC
Dr.Samiarso Laksono	Apr. 6 - Aug.28, 1992	QC NVT
Mr. Oji Rojikin	Jun.15 - Oct.14, 1992	Prod QC

* Period stayed only JPRI, not include period of orientation and language training in TIC and staying other laboratory

1-2 JPRI expert visited Bio Farma

Name	Period	Disciplines
Dr.Yutaka Doi	Jan.11 - Feb. 3, 1990	Admi
Mr.Yoshio Tano	May 10 - Aug. 9, 1990	QC
Mr.Hiroshi Yarimizu	Sep.27 - Dec.26, 1990	Prod QC
Mr.Hitoshi Horie	Jan.28 - May 10, 1991	QC
Dr.Toshio Karasawa	Apr.25 - Sep.30, 1991	Prod QC

Dr.Shinobu Abe	Sep.24 - Dec.23, 1991	QC	NVT
Mr.Hiroshi Yamamoto	Jan. 6 - Jun. 4, 1992	Prod	QC
Dr.Yutaka Doi	Apr. 1 - Apr.29, 1992	Admi	
Mr.Isamu Takekuchi	Apr. 1 - Jun.30, 1992	Kitchen	
Mr.Hideo Ohyama	Apr. 1 - Jul.31, 1992	Media	
Mr.Hiroshi Yarimizu	May 27 - Dec.26, 1992	QC	Prod
Dr.Shinobu Abe	Aug.23 - Oct.24, 1992	QC	NVT
Mr.Keishi Sato	Sep.9,1992 - Jan.30,1993	Prod	
Mr.Hitoshi Horie	Jan.21 - Apr.20,1993	QC	

1-3 Progress of production and QC

Trial production has started since Apr. 29, 1992 sacrificing 2 cynomolgus monkeys per week for Sabin type 1 virus culture

1-4 Establishment of NVT laboratory and accumulation of average lesion score for WHO NVT reference viruses

Sabin type 1 virus (SO+2) 2 times

Sabin type 2 virus (SO+2) 2 times

Sabin type 3 virus (SO+2) 1 times

2. Share of procurement on the indispensable materials in future

2-1 By JICA

a. Frozen clean green monkey kidney cells

b. Adult geen monkeys for breeding

c. Polio seed viruses

d. Poliovirus AS and diagnostic reagents until Bio Farma can prepare themselves

2-2 By Bio Farma

a. Animals (cynomolgus monkeys, rabbits ect.)

b. Media

c. Chemical reagents (including proteolytic enzymes and vaccine stabilizer)

d. Calf sera

e. Glasswares and plastic containers

f. Filters (for media filtration and laminarflow systems)

g. UV lamps etc.

3. Sending of Indonesian trainee to JPRI in FY1992

Dr.Samiarso Laksono	Feb.18 - Sep. 1, 1992
Mr.Oji Rojikin	Jun. 8 - Oct.17, 1992
Mr.Dori Ugijadi	Aug.24 - Dec.22, 1992
Mr.Hidayat Supriat	Jan. - Apr. 1993

4. Visiting of experts from JPRI in FY1992 and 1993

See attached sheet

5. Plan in FY1992

5-1 Production

Sacrificing 2 - 3 cynomolgus monkeys per week, single virus harvests and fundamental data will be accumulalted.

5-1-1 Establishment of screening technology for the selection of clean cynomolgus monkeys

5-1-2 Estimation of average virus yield (virus titer and volume) from a clean monkey

5-1-3 Estimation of monkey number shall be sacrificed to produce expected TOPV production

5-1-4 Accumulation of single virus harvests for each type to make monovalent bulks

5-1-5 Training of monovalent pool production using type 1 and type 2 Japanese OK'ed virus pool donated through JICA

5-1-6 Producltion of Bio Farma's monovalent bulks for each type virus

5-2 In process QC

5-2-1 Preparation of materials to be used for QC

1) Preparation of viruses other than polioviruses such as,SV40, SV5, Measles, Herpes simplex, simian immunodeficiency

2) Banking of adventitious agent free cynomolgus monkey kidney cells

3) Banking of continuous cell lines such as, Vero, HEp-2C, GMK-2 and HeLa

4) Preparation of concentrated and purified poliovirus immune antigens

5) Preparation and standardization of enough volume of anti-poliovirus rabbit sera

5-2-2 Start of green monkey breeding in captivity

5-2-3 Establishment of in process QC technique

1) Observation of 25% control cell cultures and grading of single harvest

2) Detection of CPE agents in the TCF and VCF using cynomolgus monkey kidney, green monkey kidney, rabbit kidney and Vero cells

3) rct and d marker tests

4) Neurovirulence tests in cynomolgus monkeys

a. For WHO NVT reference type 1, 2 and 3 viruses

Data shall be accumulated not less than 4 times for each type

b. For Indonesian NVT reference type 1, 2 and 3 viruses

6 Plan in FY1993

Reviewing the data from FY1992, monkey to be sacrificed shall be incleased

6-1 Production of monovalent bulks

Two monovalent bulks for type 1 and a monovalent bulk for type 3

The volume shall be scaled up than the bulks prepared in 1992

6-2 Production 2 lots of TOPV

1) TOPV Lot 1(2 - 3 filling batches) Aug. 1993

40L/batch x 2 or 3 batches 10 doses/vial

800,000 - 1,200,000 doses

2) TOPV Lot 2(3 - 4 filling batches) Mar. 1994

40L/batch x 3 or 4 batches 10 doses/vial

1,200,000 - 1,600,000 doses

7. Problems

7-1 Constant supply of young and clean cynomolgus monkeys for production and pregnant or baby monkeys for cell culture test

7-2 Constant procurement of mycoplasma and bovine virus free and poliovirus inhibitor less calf sera

7-3 Procurement of large glassware and Roux bottles for cell culture

7-4 Selection and decision of TOPV stabilizer

7-5 Decision of materials for filling works(vial, rubber stopper, alluminum cap)

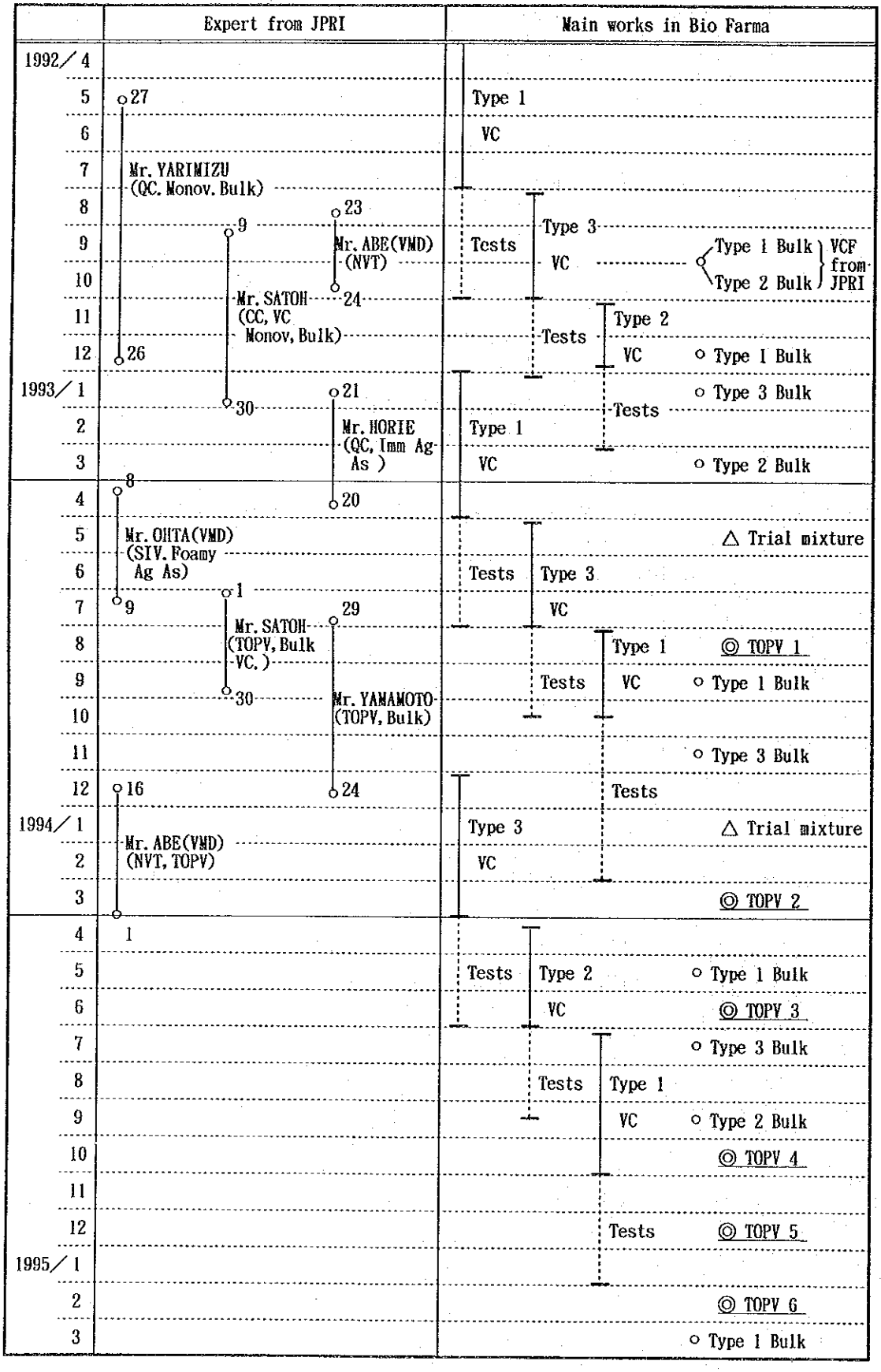
7-6 Amount of vaccine doses to be filled in a vial and volume of one dose

This conditions should be refrected considerably to the capacity of production, cost of final prcduct and the space of storage and transportation

7-7 Discussions between Bio Farma and FDA of Indonesia about national control system on the domestic measles and polio vaccines

Jul. 28, 1992

A tentative schedule for the production and dispatch of expert from JPRI

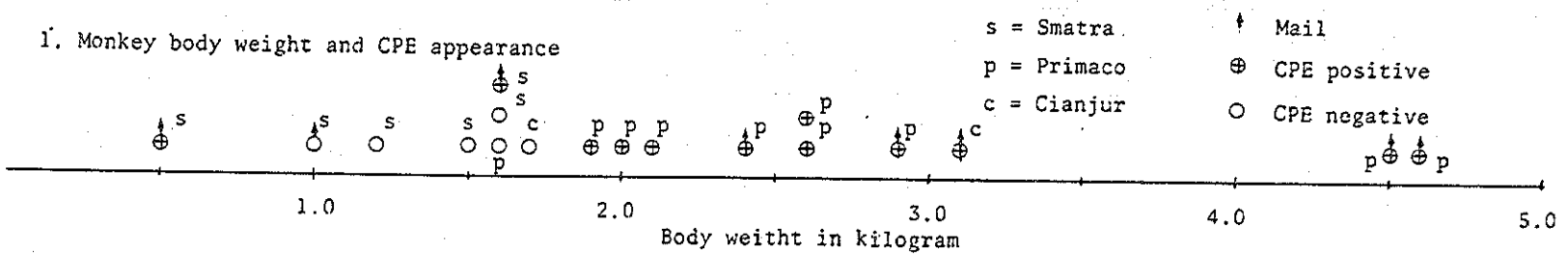


July 15. 1992

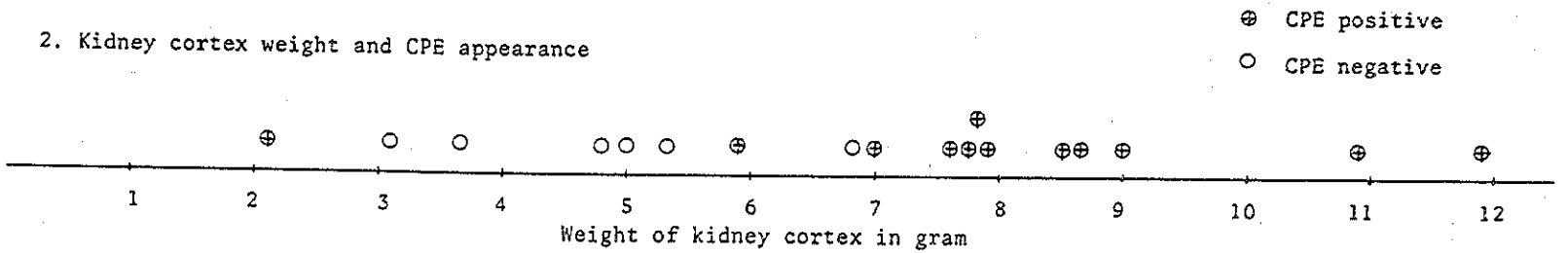
Relationship between Cynomolgus Monkey Conditions and CPE Appearance in 25% Control Cell Culture

(from the Bio Farma's Polio Progress Records)

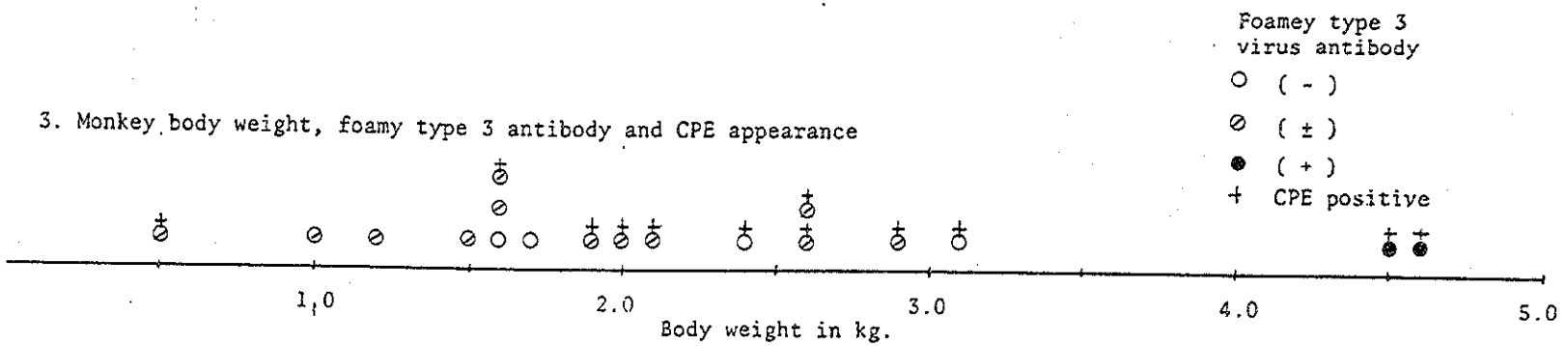
1. Monkey body weight and CPE appearance



2. Kidney cortex weight and CPE appearance



3. Monkey body weight, foamy type 3 antibody and CPE appearance



EVALUATION OF MONKEY USED FOR PRODUCTION

FAT	No.	Code of Neph Monkey	Origin	O K	Not O K		Body Weight			% of O K Monkey
					Appearance of CPE		CPE	CPE	O K	
					<D7	>D7	< D7	> D7		
A(-)	1	C C6	Cianjur	-	D3		2,4			
	2	C 25	Primaco	1	-		-		1,6	
	3	OCS3	Cianjur	1					1,7	→50%
	4	CCS4	Cianjur			D10		3,1		
B(+)	1	E 10	Primaco	-	D6		2,6			
	2	E 18	Primaco	-		D10		2,0		→43.75
	3	E 22	Primaco	-		D11		2,1		
	4	E 44	Primaco	-	D4		2,6			
	5	E 47	Primaco	-	D4		1,9			→41,6%
	6	E 50	Primaco	-		D13		2,9		
	7	F 4	Sumatera	1					1,2	
	8	F 11	Sumatera	1					1,6	
	9	F 12	Sumatera	-		D12		0,5		
	10	G 18	Sumatera	1					1,0	
	11	H 2	Sumatera	1					1,6	
	12	H 7	Sumatera	1					1,5	

No.	MONKEY Group	DATE OF ARRIVAL	MONKEY ORIGIN	SUPPLIER	No.OF MONKEY	No.OF SAMPLE TESTED	NEGATIVE FAT AGAINST FOAMY AG(%)	PRICE (/MONK) RUPIAH	TOTAL PRICE	NEG.FAT MONKEY DIED	REMARKS
1	E	4-27-92	Palembang	Primaco	50	49	6(12.2)	50.000	2.500.000	1	1 SAMPLE NO GOOD
2	F	4-28-92	Palembang	Salim	22	14	5(35.7)	27.500	605.000	2	7 MONKEY DIED
3	G	6-6-92	Palembang	Salim	27	26	2(07.6)	27.500	742.500	1	1 MONKEY DIED
4	H	5-15-92	Palembang	Salim	59	156	15(9.6)	27.500	1.622.500	1	7 MONKEY NO GOOD CONDITION 3 MONKEY DIED 4 MONKEYS PREGN
		5-19-92	Lampung	CV.Kemala sari	76 (175)			40.000	3.400.000		
		5-22-92	Palembang	Salim	40			50.000	1.600.000		
									6.622.500		
						245	28(11.43%)	±Rp.38.750	10.469.500	6	

PRODUCTION :
No of explantation : 20 kera
No of D14 CPE negative monkeys : 7 (43.75%) --------→ 7 from 16

FAT	No.	Origin	D14 CPE Neg	Origin	Body Weight
(-)	4	Primaco (1) Cianjur (3)	2 (50%)	Primaco (1) Cianjur (1)	1.6 kg 1.7 kg
(±)	12	Primaco (6) Sumatera(6)	5 (41.6%)	Sumatera (5)	1.2 kg 1.6 kg 1.0 kg 1.5 kg 1.5 kg
Total	16		7(43,75%)		

Bandung July 21,1992

OPV PRODUCTION

1. Screening of monkeys

Code no of monkey	No. of monkeys	No. of Sample Tested	No. of FAT -/±	Precentage of Neg monkey
A	45	45	10	22.2%
B	41	41	15	36.6%
J	-	20	4	20.0%
C	40	40	6	15.0%
CC	6	6	1	16.7%
CCU	3	3	0	0
DCS	6	6	2	33.3%
E	50	49	6	12.2%
F	22	14	5	35.7%
G	27	26	2	7.6%
H	175	156	15	9.6%
I	-	60	2	3.3%
Total		466	68	14.5 %

2. Production of 22 batches :

Vol of Cell Suspension / m = 6.0 lt

Vol of Virus suspension / m = 4.2 lt

FAT (-) Monk = 3.27lt

3. Production Control :

- Observation of 25 % Control bottles
- Virus testing
- RCT Marker test
- Results attached

4. NVT :

Training : 2x (Type 1, Type 2)

Qualifying Test : 1x Type 3 (Not yet finished)

PROGRESS RECORD OF POLIVIRUS TYPE ..I.. SINGLE HARVESTS

	Monkey No	Sex	Body Weight (kg)	Date of Arrival	Monkey Origin	Antibodies vs			Production Code	Date of Nephrect	Cortex Weight	Cells Suspension Vol(l) (...) x 10^5	25 % Cell Control			VCF Vol (lt)
						FV 3	SV 40						HAd		CPE (14D)	
													D 4	D 14		
1	C32	M	4.6	11-5 91	Primaco	+			19201A	4-29 92	7.6	5.4 (0.99)	-	ND	+	3.6
2	C23	F	4.5	11-5 91	Primaco	+			19201B	4-29 92	8.5	6.0 (0.99)	-	ND	+	4.0
3	CC6	F	2.4	11-25 91	Cianjur	-			19202A	5-7 92	11.9	8.8 (0.94)	-	ND	+	6.3
4	C25	M	1.6	11-5 91	Primaco	-			19202B	5-7 92	4.8	4.2 (0.79)	-	-	-	2.8
5	DCS3	M	1.7	3-17 92	Cianjur	-			19203A	5-13 92	6.8	5.5 (0.86)	-	-	-	3.8
6	DCS4	F	3.1	3-17 92	Cianjur	-			19203B	5-13 92	10.9	8.5 (0.89)	-	-	+	6.3
7	E10	F	2.6	4-27 92	Primaco	+ -			19204A	5-20 92	7.7	7.7 (0.70)	-	ND	+	5.0
8	E18	F	2.0	4-27 92	Primaco	+ -			19204B	5-20 92	7.9	7.9 (0.70)	-	ND	+	5.4
9	E22	F	2.1	4-27 92	Primaco	+ -			19205A	5-27 92	7.0	8.2 (0.60)	-	ND	+	5.7
10	E44	F	2.6	4-27 92	Primaco	+ -			19205B	5-27 92	9.0	10.5 (0.60)	-	ND	+	7.0
11	E47	F	1.9	4-27 92	Primaco	+ -			19206A	6-3 92	7.8	6.3 (0.99)	-	ND	+	4.2
12	E50	M	2.9	4-27 92	Primaco	+ -			19206B	6-3 92	8.6	6.7 (1.03)	-	-	+	4.4
13	F4	M	1.2	4-28 92	Sumatera	+ -			19207A	6-10 92	3.7	3.5 (0.85)	-	-	-	2.2
14	F11	M	1.6	4-28 92	Sumatera	+ -			19207B	6-10 92	5.3	6.1 (0.70)	-	-	-	4.3
15	F12	F	0.5	4-28 92	Sumatera	+ -			19208A	6-17 92	2.1	1.4 (1.20)	-	ND	+	0.6
16	G18	M	1.0	5-6 92	Sumatera	+ -			19208B	6-17 92	3.1	2.1 (1.18)	-	-	-	1.2
17	H2	M	1.6	5-20 92	Sumatera	+ -			19209A	6-24 92	5.9	5.6 (0.84)	-	-	-	3.9
18	H7	M	1.5	5-20 92	Sumatera	+ -			19209B	6-24 92	5.0	7.0 (0.57)	-	-	-	4.7
19	H44	F	0.8	5-20 92	Sumatera	-			19210A	7-1 92	3.0	4.0 (0.60)				
20	H12	M	1.7	5-20 92	Sumatera	+ -			19210B	7-1 92	8.4	12.3 (0.55)				
21	H42	M	1.6	5-20 92	Sumatera	+ -			19211A	7-8 92	6.8	5.0 (1.22)				
22	H67	F	1.0	5-20 92	Sumatera	+ -			19211B	7-8 92	3.7	3.0 (1.10)				

PROGRESS RECORD OF POLIVIRUS TYPE ..I.. SINGLE HARVESTS

Monkey No	Sex	Body Weight	Date of Arrival	Monkey Origin	Antibodies vs			Production Code	Date of Nephrect	Cortex Weight	Cells Suspension Vol(l) (....) x 10^5	25 % Cell Control			VCF Vol (lt)
					FV 3	SV 40						HAd D 4	HAd D 14	CPE (140)	
H45	F	0.6	5-20 92	Sumatera	±			19212A	7-16 92	3.8	3.2 (1.08)				
H48	M	1.5	5-20 92	Sumatera	+			19212B	7-16 92	6.2	4.8 (1.16)				

A S S I G N M E N T O F M A N P O W E R

Department/ section		Before 1990			1990			1991			1992			Total
		S	T	A	S	T	A	S	T	A	S	T	A	
A.	Measles Production	1	1	2	-	4	2	1	(+2)	4	-	-	-	17
B.	Q C Measles	1	2	1 *	-	2	2	2	2	1	-	2	2	17
C.	Common Use													
	a.Medium Preparation and washing	-	1	2	-	-	-	1	-	5	-	-	-	9
	b.General service	-	-	-	-	-	-	-	(+3)	-	-	(+1)	-	(+4)
	c.Animal house	-	-	-	-	-	-	-	1	-	-	1	-	2
D.	Polio Production and QC	1	1	-	3	4	-	-	3(+3)	-	-	7	7	26(+3)
Total		3	5	5	3	10	4	4	6(+8)	10	-	10(+1)	9	69(+9)
Grand Total		13			17			28			20			78

Note : S = Scientist
T = Technician
A = Attendant
( ) = Mechanic
* = Retired

3. Department of Measles Productionからの資料

PROGRESS REPORT FOR MEASLES VACCINE PRODUCTION

I. RESUME OF PRODUCTION RESULT OF MEASLES BULK AND VACCINE.

1.July 1991 to Dec.1991:

- Single harvest :	7 batches from	13 batches	(=53%)	(Avrg.=58%)
- Clarif.of Bulk :	5 batches from	7 batches	(=71%)	
- Final Product (=Vaccine) :	3 batches from	6 batches	(=50%)	

2.Jan.1992 to July 1992:

- Single harvest :	14 batches from	18 batches	(=77.7%)	(Avrg.=67.5%)
- Clarif.of Bulk :	5 batches from	10 batches	(=50%)	
- Final Product (=Vaccine) :	3 batches from	4 batches	(=75%)	

II.PROBLEMS.

1. Technical : - contamination.
   - not enaugh equipment/material, for example :
     - small pooling tank (40 L , 60 L) ,
     - siphon ,
     - uniform III.
2. Trouble of Equipment : - Factory fault.
   - Not enaugh spare part.

III.SOLVE THE PROBLEMS :

1. Technical:- Still need short term expert to assist during start the commercial production.
   - Counterpart training in Biken.
2. Trouble of Equipment :
   - Need calibration/Validation equipment.
   - Counterpart training in Factory of equipment.
   - Enaugh spare part.

IV.TENTATIVE ANNUAL ROUTINE PRODUCTION OF MEASLES VACCINE & BULK.

VACCINE : 1,000,000 VIAL/YEAR ⟶ 30 BATCHES @ 33,000 VIALS
↓ x 3 ml
↓ 30x FREEZE DRYING (30 WEEKS)

FINAL BULK : 3,000,000 ml
↓ : 10 (dilution rate)

BULK : 300,000 ml (=300 L) ⟶ + 50% ⟶ 450 L
↓ 15 L / BATCH
↓ 30 BATCHES
↓ 30 x (= 30 WEEKS)

EXPLANTATION OF EGGS : ..... 30 x 100 EGGS (=3,000 EGGS)

SPF EGGS NEEDED :

TENTATIVE ANNUAL WORK PLAN OF SHORT-TERM EXPERTS FOR MEASLES VACCINE PRODUCTION REQUESTED BY BIO FARMA

ITEM	1st Year												2nd Year												3rd Year												4th Year												5th Year									
	1989		1990										1991												1992												1993												1994									
	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9									
Japanese Expert																																																										
1. Routine Measles Bulk Production (large scale)																																																										
2. Routine Measles Vaccine Production (freeze drying; large scale)																																																										
3. Basic Technology of GMP Control																																																										

RESUME OF PRODUCTION RESULTS OF MEASLES VACCINE.
(July 1991 to July 1992)

MEASLES BULK PRODUCTION IN 1991.	No.of Cell Culture (MC)	No. of Single Harvest (MH):	No.of Clarified Bulk (MB):	Volume : (ml)	Remark:
No.of Passed test		7 batches (53%)	5 batches (71%)	44,310 ml	Rejected bulk:MB-9101,MB-9102 is low titer and MB-9103 Contaminated by bacterial. Bulk used: MB-9104,MB-9105 used for Freeze drying as Experiment and "Field Trial Vaccine". MB-9111,MB-9112,MB-9113 used for Working Seed.
No.of Rejected		6 batches	2 batches		
Total	13 batches	13 batches	7 batches	44,310 ml	

VACCINE PRODUCTION IN 1991	FREEZE DRYING	AMOUNT (VIAL)	REMARK :
No. of Passed test	3 batches (50%)	3,254 vials	Rejected vaccine: MFP-9101 Stability dropped; MFP-9102,MFP-9104 Contaminated by bacterial. Vaccine used:MFP-9105 used for Field Clinical Trials MFP-9106 used for reference. MFP-9103 " " "
No. of Rejected	3 batches	2,102 vials	
Total	6 batches	5,356 vials	

MEASLES BULK PRODUCTION IN 1992.	No.of Cell Culture (MC):	No. of Single Harvest (MH):	No.of Clarified Bulk (MB):	Volume : (ml)	Remark :
No.of Passed test		14 batches (77.7%)	5 batches (50%)	42,700 ml	Rejected: MB-9205,MB-9207,MB-9208 Bulk used: MB-9201 has already finished for using experiment and validation. MB-9202,MB-9203,MB-9204,MB-9206 will be used for training and commercial production.
No.of Rejected		2 batches	3 batches	-	
Not Yet Finished		2 batches	2 batches	32,000 ml	
Total	20 batches	18 batches	10 batches	74,700 ml	

VACCINE PRODUCTION IN 1992	FREEZE DRYING	AMOUNT (VIAL)	REMARK :
No. of Passed test	3 batches (75%)	7,693 vials	
No. of Rejected	-	-	
Not Yet Finished test	1 batch	5,476 vials	
Total	4 batches	13,169 vials	

CONCLUSION OF DISCUSSION FOR MEASLES (BULK & VACCINE) PRODUCTION ON JULY 27,1992 .

I.PROBLEM & SOLVE THE PROBLEM.

1.Contamination ; the cause is technical work.

Still need training ; - in Japan : counterpart training.

- in Indonesia : short term expert.
(2 expert/year)

2.Request for schedule of short-term expert : for Measles Production

Item:	1993												1994								
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9
1.Routine Measles Bulk Prod (large scale)	«——»							«——»							«——»						
2.Routine Measles Vaccine Prod.(F.D.)				«——»						«——»								«——»			

Note: 1. Mr.Koyama/Mr.Otsuka.

2. Mr.Okada/Mr.Hara.

3. Need some equipment/materials :

- small pooling tank (40 L , 60 L) : request for 1993.
- siphon & rubber closer : will come in ~~September~~/October'92./Nov'92
- uniform-III : request for 1993.

MINUTES OF DISCUSSION (MEASLES VACCINE)
JULY 27 - 28, 1992

Present : 1. Dr. T. Konobe
2. Mr. K. Miyatake
3. Mr. H. Okada

4. Drs. J. Sutaryo
5. Dr. Benny Kaligis
6. Drs. Maman Hidayat
7. Dr. Erman Boedisetianto
8. Dra. Antik Tjantika
9. Drh. Lia St. Halimah
10. Drs. Basit Sadikin
11. Drh. Sugeng Raharso
12. Drs. Juliman
13. Drs. Engkus Kuswala
14. Mr. Tomo Usmadi
15. Mr. Tono Dwi Rusanto

I. Statements :

1. Disinfectant : Bio Farma will try to find in Indonesia (Pacoma & Environt)

2. Japanese Expert (Mr. Ando) will help Bio Farma to find c/o type of chicken.

3. SPF chicken eggs from vaksindo can be used for production if pass of all monitoring item and for introduction in geneticallу system.

4. Rubber stopper for using Freeze Drying vaccine :

Rubber stopper	The stability test of vaccine	The weighing test of rubber stopper
1. Daikyo V10-75-2	good	good
2. West S87M/4833/45	good	not good
3. West S87M/9310/50	not yet	good

5. Test of Calf Serum :

Calf Serum	Growth of		Titer
	Cell culture	Virus Culture	
a. from Biken	good	good	good
b. from Gibco	good	less	lower than (a)
c. local serum	good	good	good

6. Pooling tank 150 litre : the bearing should be replaced by harder one.

II. Expert dispatch :

Two short term expert annualy for Bulk Production, Final Product and Quality Control Respectively.

III. Counterpart Training :

1. Counterpart training :
   a. for preparation of antigen and antibody, reagents for SPF monitoring.
   b. for preparation of mycoplasma, mycobacteria, fungi and bacteria; growth test, vialibility test, sensitivity test.
   c. for Group Training Course for Biological Product Technology with emphasis on Measles QC and Basic Technology of GMP Control.

2. For validation and calibration of equipment.

IV. Request for Equipment / Material :

1. small pooling tank (40 L, 60 L : @ 2 pcs) request for 1993

2. uniform III (1 pc uniform : 75 set) request for 1993

3. a. small incubator chamber for stability test.
   b. Egg incubator (300 eggs capacity).

4. a. Pacoma solution : 10 Can (@ 18 litre)
   b. Vitamin "Tannarich" : 4 can (@ 18 litre)

4. Bureau of Quality Control からの資料

MANPOWER ASSIGNMENT IN QC (July 1992)

Quality control manager	: Dr. Benny Kaligis
Head of viral vaccine control	: Dra. Antik T.
Extraneous virus & potency test (in vitro)	: Drh. Lia S.H. Ms. Siti Aminah Mr. Nurdin Wijaya
Extraneous virus & safety test (in vivo)	: Mr. Tatang Ridwan Mr. Nasru Taman
Tissue culture maintenance	: Ms. Rini Karyani
Sterility test	: Ms. Dindin Nuryamah Mr. Dikdik Sodikin
Chemical test	: Drs. Engkus Kuswala
SPF monitoring/immunological test	: Drh. Lia S.H. Mr. Aman Priyatna
Neurovirulence test	: Drh. Agus W.W.
Polio QC	: Drs. Dori Ugiyadi
Attendant	: Mr. M. Jafar Mr. M. Sobirin Mr. Rasman Mr. Suwanda Mr. Dody Mr. Hada Mr. Mamat

Total manpower : 21

TRAINING IN JAPAN

Name	Duration	Time	Subject
1. Dra. Antik T.	3 months	Oct-Dec 1988	Group training Basic technology
	6 months	Oct'90-March'91	Counterpart training Microbiological test
2. Drh. Lia S.H.	3 months	Oct-Dec 1988	Group training Basic technology
	6 months	Oct'90-March'91	Counterpart training SPF monitoring
3. Ny. Dindin N.	3 months	Sept-Dec 1989	Counterpart training Basic technology
4. Tatang Ridwan	3 months	Sept-Dec 1989	Group training Basic technology
5. Aman Priyatna	10 months	May'91-March'92	Group training QC measles vaccine
6. Rini Karyani	3 months	Sept-Dec 1991	Counterpart training Cells maintenance & Test in cell culture
7. Drh. Agus W.W.	12 months	Oct'90-Oct'91	Counterpart training Neurovirulence test & small animal test

Japanese Expert

N a m e	Subject	Duration
	Pathological test of QC; preparation antigen dan antibody	Sept - Dec.1993
	Preparation of local reference, stability test, and GMP	April - July 1993
	- Growth test, viability test, sensitivity test for preparation of sterility test	April - July 1993
	- Maintenance of Bacterial, fungi, mycoplasma & mycobacteria for positive control of sterility test	

Problems of Quality Control ;

1. Propagation of positive control : RAV-1
   RAV-2
   REV
   BVD
   IBRV
   PI 3 ; etc.

2. Purification of Antigen : - Ultraconcentrator
   - Ultracentrifuge

3. Preparation of Antigen and Antibody

SUMMARY OF MEETING ON JULY 27, 1992

QUALITY CONTROL

I. ACHIEVEMENT

Quality Control Test for :

1. Production of test vaccine lot.
2. Production of working seed lot.
3. Production of bulk materials.
4. Production of final product.

2. PROBLEMS

a. Preparation and supplying of reagents for monitoring of SPF - chicken flock.

b. Preparation of antigen and antibody for testing of routine production of bulk and final product (measles Ag & Ab).

c. Purification of antigen by Ultraconcentrator and Ultracentrifugation and other methods.

d. Propagation of viruses for positive control test such as : RAV-1, RAV-2, REV, BVD, IBRV, PI3 viruses, etc.

3. DESPATCH OF JAPANESE EXPERTS

I T E M	1993												1994												1995				
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5
A. Preparation of local reference, stability test and basic technology of GMP Control. (April - July 1993)				⟷																									
B. Virological test of QC; preparation of antigen and antibody. (Aug - Dec 1993)									⟷																				
C. Growth test, viability test, sensitivity test for preparation of sterility test; Maintenance and Propagation of Mycoplasma, Mycobacteria, Fungi & Bacteria for positive control of sterility test. (Jan - March) 1994													⟷																

4. COUNTERPART TRAINING

I T E M	1993												1994												1995				
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5
A. Preparation of antigen and antibody; preparation of reagents for SPF monitoring.(Apr - Sept 93).				⟷					⟷																				
B. -- idem ---- (Apr - Sept 94).																⟷					⟷								
C. Preparation of Mycoplasma, Mycobacteria, Fungi & Bacteria; Growth test, viability test, sensitivity test. (Sept - Dec 93).									⟷			⟷																	
D. Group Training Course for Biological Product Technology with emphasis on Measles Quality Control and Basic Technology of GMP Control. (Mei 1993 - Feb 1994).					⟷								⟷																

5. EQUIPMENT

a. Small Incubator Chamber for Stability test.

b. Egg Incubator (200 eggs capacity).

5) Department of Animal Breedingからの資料

CONCLUSION MEETING 27－7－1992

- Procentage of SPB chicken eggs embryonated almost same with in Biken.
- Disinfectant (Pacoma and Bnvironf) should be tried to find in Indonesia (import or change to another disinfectant that usually used in breeder farm in Indonesia.
- SPF eggs C/O homozygotes type that Bio Farma request are not available because embryonated eggs very low caused by inbreeding.
- Mr. Ando will help us to find C/O type chicken in Bio Farma.
- SPF chicken eggs that seed from Vaksindo can be used for production if pass all of monitoring items; and for introduction in genetically system.
- Autoclave, in new facility.

Material request :

- Pacoma solution 10 Can @ 18 liter
- Vitamin "Tannarich" 4 Can @ 18 liter

6. ミニッツ

THE MINUTES OF DISCUSSION BETWEEN THE JAPANESE ADVISORY SURVEY TEAM AND THE AUTHORITIES CONCERNED OF THE GOVERNMENT OF THE REPUBLIC OF INDONESIA ON THE FUNDAMENTAL TECHNOLOGY TRANSFER PROJECT FOR PRODUCTION OF LIVE ATTENUATED MEASLES AND POLIOMYELITIS VACCINES

The Japanese Advisory Survey Team (hereinafter referred to as "the Team") organized by Japan International Cooperation Agency (hereinafter referred to as "JICA") and headed by Dr. Takeo Konobe, Director, Kanonji Institute, the Research Foundation for Microbial Diseases of Osaka University, visited the Republic of Indonesia from July 22 to July 30, 1992 for the purpose of reviewing the activities concerning the Fundamental Technology Transfer Project for Production of Live Attenuated Measles and Poliomyelitis Vaccines (hereinafter referred to as "the Project") and discussing the future implementation plan of the Project.

During its stay, the Team exchanged views and had a series of discussions with Perum Bio Farma about the activities and implementation of the Project.

As a result of the discussions, both sides agreed upon the matters referred to in the document attached hereto.

Bandung, July 29, 1992

Takeo Konobe

Dr. Takeo Konobe
Leader,
Advisory Survey Team
Japan International
Cooperation Agency

Drs. Darodjatun, MBA
President Director
Perum Bio Farma

I. GENERAL REVIEW

The Project has been started from first of September 1989 for five-years for the purpose of Fundamental Technology Transfer for production and quality control of live attenuated measles and poliomyelitis vaccines in Perum Bio Farma, the Republic of Indonesia.

In accordance with the Record of Discussions signed on 9 of June, 1989 by both sides, JICA has dispatched 3 long-term experts and 30 short-term experts to Indonesia and has accepted 21 counterparts for training in Japan, and supply necessary equipment also has taken important steps, for smooth implementation of the Project.

Both sides reviewed the activities of the achievement made so far with regard to the implementation of the Project. Thus, based on the common recognition of the present state of the art of the Project, both sides confirmed the continuous cooperation between the Japanese and Indonesian Governments for the further progress of the Project.

II. ACHIEVEMENT OF TENTATIVE SCHEDULE OF IMPLEMENTATION

The technical cooperation activities under the Project which have been carried out in Fiscal Year 1989, Fiscal Year 1990 and Fiscal Year 1991 are presented in ANNEX I, II and III.

III. SPECIFIC DISCUSSIONS

A. MEASLES VACCINE

1. Disinfectant (Pacoma & Environt) : Bio Farma will try to find in Indonesia. Biken will advise the technical data of disinfectant and alternatives if available.

2. Japanese Expert (Mr. Ando) will help Bio Farma to find C/O type of chicken.

3. SPF chicken eggs from Vaksindo can be used for production if pass of all monitoring item and for introduction in genetically system.

4. Rubber stopper for using Freeze Drying vaccine :

Rubber stopper	The stability test of vaccine	The weighing test of rubber stopper
1. Daikyo V10-75-2	good	good
2. West S87M/4833/45	good	fair
3. West S87M/9310/50	not yet (waiting result)	good

* All the rubber stopper are meeting the requirement with certain grade of quality.

5. Test of Calf Serum :

Calf Serum	Growth of		Titer
	Cell culture	Virus Culture	
a. from Biken	good	good	good
b. from Gibco	good	fair	lower than(a)*
c. local serum	good	good	good **)

Note : *) In general all calf serum are passed the test.
**) Local serum need more investigation for virus contamination.

6. Expert dispatch :

Two times short term experts will be dispatched annually for routine Bulk Production, Final Product and Quality Control.

7. Counterpart Training :

7.1. for preparation of antigen and antibody, reagents for SPF monitoring.

7.2. for preparation of mycoplasma, mycobacteria, fungi and bacteria; growth test, vialibility test, sensitivity test.

7.3. for Group Training Course for Biological Product Technology with emphasis on Measles QC and Basic Technology of GMP Control.

8. Request for Equipment/Materials for 1993 :

8.1. Small Pooling Tank 40 L and 60 L : @ 2 pcs.

8.2. Uniform III (1 pc uniform) : 75 set.

8.3. Small Incubator Chamber (climatic chamber) for stability test (4°C and 37°C).

8.4. Egg Incubator (300 eggs capacity).

8.5. Pacoma solution : 10 Can (@ 18 litre)

8.6. Vitamin "Tannarich" : 4 can (@ 18 litre)

B. ORAL POLIO VACCINE

1. Progress of technical transfer from JPRI up to July 1992

1.1. Indonesian c/p visited JPRI (See Annex II)

1.2. JPRI expert visited Bio Farma (See Annex I)

1.3. Progress of production and quality control

Trial production has been started since April 29, 1992 sacrificing 2 cynomolgus monkeys per week for Sabin type 1 virus culture.

1.4. Establishment of NVT laboratory and accumulation of average lesion score for WHO NVT reference viruses.

Sabin type 1 virus (SO + 2)	2 times
Sabin type 2 virus (SO + 2)	2 times
Sabin type 3 virus (SO + 2)	1 time

2. Share of procurement on the indispensable materials in future.

2.1. By JICA

a. Frozen clean green monkey kidney cells

b. Adult green monkeys for breeding

c. Polio seed viruses

d. Poliovirus AS and diagnostic reagents among others SIV antigens until Bio Farma can prepare themselves.

2.2. By Bio Farma

a. Animals (cynomolgus monkeys, rabbits, etc.)

b. Media

c. Chemical reagents (including proteolytic enzymes and vaccine stabilizer)

d. Calf sera

e. Glasswares and plastic containers

f. Filters (for media filtration and laminar flow systems).

g. UV lamps, etc.

3. Sending of counterpart

3.1. Fiscal Year 1992 :

Mr. Oji Rojikin	June 8 - October 17, 1992
Mr. Dori Ugiyadi	August 24 - December 22,1992
Mr. Hidayat Supriatna	January - April 1993

3.2. Fiscal Year 1993 :

Bio Farma requests to send 3 to 4 persons.

4. Visiting of experts from JPRI in Fiscal Year 1992 and 1993 (See attached sheet).

5. Plan in Fiscal Year 1992

5.1. Production

Sacrificing 2-3 cynomolgus monkeys per week, single virus harvests and fundamental data will be accumulated.

5.1.1. Establishment of screening technology for the selection of clean cynomolgus monkeys.

5.1.2. Estimation of average virus yield (virus titer and volume) from a clean monkey.

5.1.3. Estimation of monkey number shall be sacrificed to produce expected TOPV production.

5.1.4. Accumulation of single virus harvests for each type to make monovalent bulks.

5.1.5. Training of monovalent pool production using type 1 and type 2 Japanese OK'ed virus pool donated through JICA.

5.1.6. Production of Bio Farma's monovalent bulks for each type virus.

5.2. In process quality control

5.2.1. Preparation of materials to be used for quality control.

1). Preparation of viruses other than polioviruses such as SV40, SV5, Measles, Herpes simplex, simian immunodeficiency.

2). Banking of adventitious agent free cynomolgus monkey kidney cells.

3). Banking of continuous cell lines such as Vero, HEP-2C, GMK-2 and HeLa.

4). Preparation of concentrated and purified poliovirus immune antigens.

5). Preparation and standardization of enough volume of antipoliovirus rabbit sera.

5.2.2. Start of green monkey breeding in captivity.

5.2.3. Establishment of in process quality control technique.

1). Observation of 25 % control cell cultures and grading of single harvest.

2). Detection of CPE agents in the TCF and VCF using cynomolgus monkey kidney, green

monkey kidney, rabbit kidney and Vero cells.

3). rct and d marker tests

4). Neurovirulence tests in cynomolgus monkeys

a. For WHO NVT reference type 1, 2 and 3 viruses.

Data shall be accumulated not less than 4 times for each type.

b. For Indonesian NVT reference type 1, 2 and 3 viruses.

6. Plan in Fiscal Year 1993

Reviewing the data from Fiscal Year 1992, monkey to be sacrificed shall be increased.

6.1. Production of monovalent bulks :

One monovalent bulk for type 1 and one monovalent bulk for type 3. The volume shall be scaled up than the bulks prepared in 1992.

6.2. Production 2 lots of TOPV :

1). TOPV Lot 1 (2-3 filling batches) August 1993
40L/batch x 2 or 3 batches 10 doses/vial
800,000 - 1,200,000 doses

2). TOPV Lot 2 (3-4 filling batches) March 1994
40L/batch x 3 or 4 batches 10 doses/vial
1,200,000 - 1,600,000 doses.

7. Problems

7.1. Constant supply of sufficient quantity of young and clean cynomolgus monkeys for production and pregnant or baby monkeys for cell culture test.

7.1.1. As Bio Farma has no experience in getting required monkeys it is necessary to collect data during 6 months. This will give more information about availability of monkeys needed for production.

7.1.2. The effort for the establishment of getting clean monkeys for production among others :
i.e. : - getting the blood samples of monkey
- taking care of the wild caught monkey.
Bio Farma should form a team, which will continuously deal with the supplier by arranging more binding agreement.
The deployment of more suppliers is considered necessary to maximize the effort.

7.1.3. If due to some reason the target of production could not be fulfilled both parties should discuss to find out another alternatives.

7.2. Constant procurement for routine use of mycoplasma and bovine virus free and poliovirus inhibitor less calf sera.

7.3. Procurement of large size glassware and Roux bottles for cell culture.

7.4. Selection and decision of TOPV stabilizer

Bio Farma and JPRI will jointly investigate to choose a suitable stabilizer to be used in routine production.

7.5. Decision of materials for filling works (vial, rubber stopper, alumunium cap)

7.6. Amount of vaccine doses to be filled in a vial and volume of one dose.

The decision will considerably influence to the capacity of production, cost of final product and the space of storage and transportation.

7.7. Pooling tank 150 litre (Polio equipment;SAKURA-TEKKO: "SAKUMA") : the bearing should be replaced by harder one. Based on current experience ceramic bearing would be the best alternative.

C. Others

1. For fiscal year 1992 Bio Farma send Mr. Tono Dwi Rusanto and Mr. Didin Nurdin for training in maintenance and services of the equipment.
2. Both parties agree that it is important for the project to have the equipment for validation and calibration.

ANNEX I

LIST OF JAPANESE EXPERTS DISPATCHED BY JICA

Team Leader

1. Dr. Hideo Ohata	: May 27, 1992 - August 31, 1994	(long term)

Coordinator

2. Ms. Terumi Shimamoto	: March 15, 1990 - March 14, 1993	(long term)

Production and Quality Control for Measles Vaccine :

3. Mr.Katsumasa Miyatake	: September 5,1989 - September 4,1992	(long term)
4. Mr.Shigeyoshi Takahashi	: December 5, 1990 - December 25,1990	(short term)
5. Mr. Kuniaki Koyama	: January 22, 1991 - February 19,1991	(short term)
6. Mr. Shinichi Miyake	: June 4, 1991 - September 3,1991	(short term)
7. Mr. Hisashi Okada	: August 20, 1991 - September 17,1991	(short term)
8. Mr. Shinichi Miyake	: November 6, 1991- February 5, 1992	(short term)
9. Mr. Kuniaki Koyama	: March 10, 1992 - April 9, 1992	(short term)
10. Mr. Shinichi Miyake	: April 28, 1992 - July 27, 1992	(short term)
11. Mr. Hisashi Okada	: July 14, 1992 - September 13,1992	(short term)

Production and Quality Control for Poliomyelitis Vaccine :

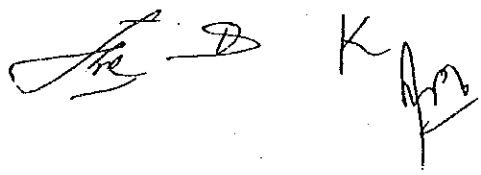
12. Dr. Yutaka Doi	: January 11,1990 - February 3,1990	(short term)
13. Mr. Yoshio Tano	: May 10, 1990 - August 9, 1990	(short term)
14. Mr.Hiroshi Yarimizu	: September 27,1990- December 26, 1990	(short term)
15. Mr. Hitoshi Horie	: January 28,1991 - May 19, 1991	(short term)
16. Mr. Toshio Karasawa	: April 25, 1991 - September 30,1991	(short term)
17. Mr. Shinobu Abe	: September 24,1991- December 23, 1991	(short term)
18. Mr. Hiroshi Yamamoto	: November 18,1991 - November 30,1991	(short term)
19. Mr. Hiroshi Yamamoto	: January 6, 1992 - June 5, 1992	(short term)
20. Mr. Yutaka Doi	: April 1, 1992 - April 29, 1992	(short term)
21. Mr. Isamu Takeuchi	: April 1, 1992 - June 30, 1992	(short term)
22. Mr. Hideoki Ohyama	: April 1, 1992 - July 31, 1992	(short term)
23. Mr. Hiroshi Yarimizu	: May 27, 1992 - December 26,1992	(short term)

Breeding for Monkey :

24. Dr. Humiaki Cho	: April 25,1991- May 15, 1991	(short term)

Medical Engineering :

25. Mr. Toshiaki Mashiko	: May 28, 1991 - June 8, 1991	(short term)



Survey for equipment :

26. Mr. Koichi Noguchi	: January 24,1990- February 4,1990	(short term)
27. Mr. Koichi Noguchi	: April 25, 1991 - May 10, 1991	(short term)

Technical Cooperation

28. Mr. Yoshiyuki Takahashi	: January 24,1990- February 4,1991	(short term)
29. Dr. Toshihiko Hasegawa	: April 26, 1991- May 2, 1991	(short term)
30. Mr. Toshimichi Aoki	: April 26, 1991 - May 2, 1991	(short term)

ANNEX II

LIST OF INDONESIAN COUNTERPART PERSONNEL SENT TO JAPAN

Production and Quality Control for Measles Vaccine :

1.	Ms. Lia Siti Halimah Gunawan	: September 29, 1988 - December 19, 1988
2.	Ms. Antik Tjantika Teguh	: September 29, 1988 - December 19, 1988
3.	Mr. Erman Boedisetianto	: March 23, 1989 - March 3, 1990
4.	Ms. Dindin Nuryamah	: September 1, 1989- December 18, 1989
5.	Mr. Sugeng Raharso	: November 20, 1989- November 19, 1990
6.	Mr. Suhaeri Suramihardja	: March 29, 1990 - September 28, 1990
7.	Mr. Mohamad Sufirman	: March 29, 1990 - December 20, 1990
8.	Mr. Castam Fahtadinata	: October 8, 1990 - March 30, 1991
9.	Mr. Gaos Setjapradja	: October 8, 1990 - January 20, 1991
10.	Ms. Lia Siti Halimah Gunawan	: October 8, 1990 - March 30, 1991
11.	Ms. Antik Tjantika Teguh	: October 8, 1990 - March 30, 1991
12.	Mr. Maman Hidayat	: July 9, 1991 - December 4, 1991
13.	Ms. Rini Karyani	: September 13, 1991 - December 27, 1991

Production and Quality Control for Poliomyelitis Vaccine :

14. Dr. Ina Abdulkadir Madiadipura	: March 23, 1989 - March 20, 1990
15. Ms. Harry Kartini S. Iskandar	: November 20, 1989 - November 19, 1990
16. Ms. Itjeu Iim Salim	: January 12, 1990 - July 11, 1990
17. Mr. Agus Wahyu Widayanto	: October 4, 1990 - October 2, 1991
18. Mr. Wawan Hermawan	: May 7, 1991 - December 15, 1991
19. Mr. Samiarso Laksono	: February 18, 1992 - September 1, 1992
20. Dr. Benny Kaligis	: January 7, 1992 - March 29, 1992
21. Mr. Oji Rojikin	: June 8, 1992 - October 17, 1992

ANNEX III

PROVISION OF MACHINERY AND EQUIPMENT

Machinery, equipment and other materials (hereinafter referred to as "the Equipment") necessary for the implementation of the Project have been provided Fiscal in Year 1990 and Fiscal Year 1991.

The total amount of equipment is 427 million yens approximately on CIF basis.

The following is the list of main Equipment provided to the Bio Farma.

Fiscal Year 1990 :

1. Production area for measles vaccine
   1. Deep freezer (-80°C)
   2. Filtration device
   3. Pooling tank
   4. Centrifuge
   5. Equipment for tissue culture (Roux bottle, etc.)
   6. CAM-70 master seed virus

2. Quality Control area
   7. Deep freezer (-80°C)
   8. Microscope
   9. Technical balance
   10. Filtration device
   11. Microtome

12. Auto tissue processor

13. Paraffin oven

14. Incubator

15. Waterbath

16. Moisture content apparatus

17. Electric cleaner

3. Production area for poliomyelitis vaccine :

18. Deep freezer (-80°C)

19. Ultra centrifuge

20. Microscope

21. Centrifuge

22. Electric dispenser

23. Equipment for tissue culture (Roux bottle, etc.)

Fiscal Year 1991 :

1. Production area for measles vaccine :

1). Spare parts for SPF vinylisolator

2). Equipment for tissue culture (Roux bottle, etc.)

2. Quality Control area :

3). Tissue Tek III

4). Technical balance

3. Production area for poliomyelitis vaccine :

5). Deep freezer (-80°C)

6). Microscope

7). Technical balance

8). Filtration device

9). Centrifuge

10). Electric dispenser

11). Equipment for tissue culture (Roux bottle, etc.)

12). Freezer (-20°C)

13). Incubator

14). Waterbath

15). Pooling tank

16). Electric cleaner

17). Electric dispenser

18). Seed virus (type I, II, III)

4. Animal House facilities :

19). Monkey cage

20). Rack for cage

ANNEX IV

Participant of discussions :

JICA side :

1. Dr. T. Konobe
2. Dr. Y. Doi
3. Mr. H. Yoshida
4. Mr. H. Ohata
5. Ms. T. Shimamoto
6. Mr. K. Miyatake
7. Mr. H. Okada
8. Mr. H. Yarimizu

Indonesian side :

1. Drs. Darodjatun, MBA
2. Drs. J. Sutaryo
3. Drs. Djoharsjah
4. Drh. Thamrin Poeloengan
5. Dr. Benny Kaligis
6. Dr. Ina Madiadipura
7. Drs. Maman Hidayat
8. Dr. Erman Boedisetianto
9. Dra. Antik Tjantika
10. Dr. Harry Kartini
11. Drh. Lia St. Halimah
12. Drs. Basit Sadikin
13. Drh. Sugeng Raharso
14. Drs. Juliman
15. Drs. Engkus Kuswala
16. Drh. Agus Wahyu W.
17. Mr. Tomo Usmadi
18. Mr. Tono Dwi Rusanto
19. Ms. Itjeu Iim Salim

（7） Bio Farma の本件プロジェクトに対する予算実績

EXPENSES FOR FMD : MODELS PRACTICE PROJECT

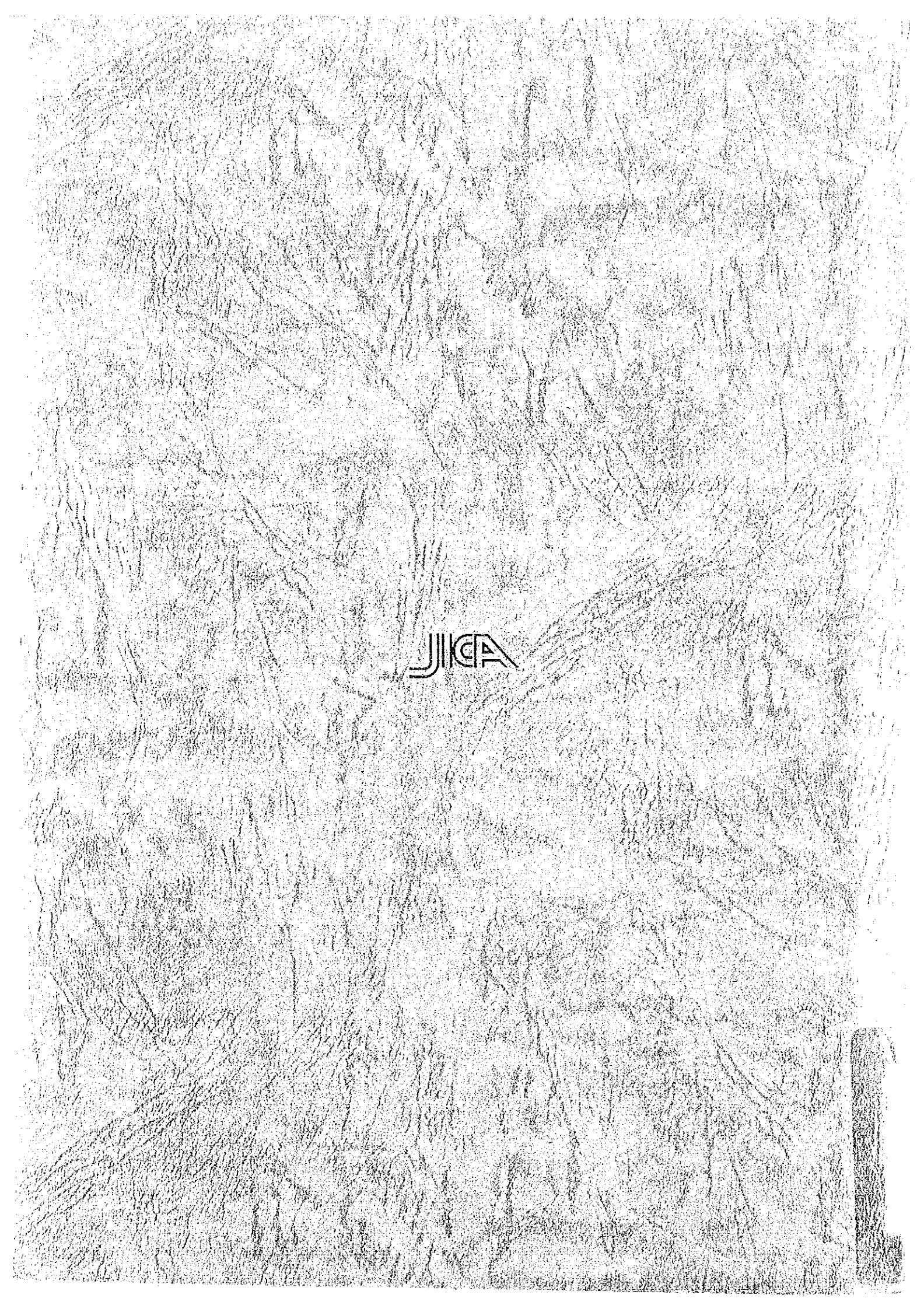
NO	DESCRIPTION	1989 (Rp)	1990 (Rp)	1991 (Rp)	UP TO JUNE 1992 (Rp)	T O T A L (Rp)
1	Soil Investigation and Building Permission	13,007,500.00	23,890,400.00	-	-	36,897,900.00
2	Artesis Well (Recervoir and Accessories)	14,531,000.00	69,754,992.00	22,375,000.00	-	106,660,992.00
3	Steam Piping	-	70,861,954.99	-	-	70,861,954.99
4	Power House	-	47,606,000.00	-	-	47,606,000.00
5	Animal House and Storage	-	20,998,000.00	4,796,500.00	-	25,794,500.00
6	Fuel Tank	-	20,684,000.00	3,199,900.00	-	23,883,900.00
7	Bank & Labour Insurance, Clearing	-	20,943,155.00	14,775,461.00	-	35,718,616.00
8	Telephone Installation	-	7,582,500.00	-	-	7,582,500.00
9	Machinery Installation, Maitenance, Technical Equipments (Fluorescent Lamp, Circuit Breaker Etc.)	-	9,257,614.00	41,742,134.00	2,800,000.00	53,799,748.00
10	Power Panel installation	-	-	17,190,000.00	14,459,270.00	31,649,270.00
11	Consultant Fee	-	-	74,804,887.00	-	74,804,887.00
12	Glasses and Laboratories Equipment	-	-	44,893,170.00	-	44,893,170.00
13	Office Inventories (Chairs, Tables, Cupboards, File Cabinet)	-	-	31,307,300.00	1,795,190.00	33,102,990.00
14	Direct Expenses for Chemical, Medicine, Packing, Experimental Animal Etc.	-	-	102,207,592.27	81,134,121.00	183,341,713.27
15	Building Maintenance Expenses	-	-	-	17,085,484.00	17,085,484.00
16	Office Expenses	-	-	14,656,620.00	4,701,175.00	19,357,795.00
17	Fuel Expenses	-	-	-	165,702,000.00	165,702,000.00
18	Labour Expenses	-	-	-	111,461,599.00	111,461,599.00
19	General Expenses	-	-	-	69,441,162.00	69,441,162.00
	T O T A L	27,538,500.00	291,578,615.99	371,949,064.27	468,580,001.00	1,159,646,181.26

Bandung, 28 J u l y 1992

Perusahaan Umum Bio Farma

Finance Manager

Achmad Soleh.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