MINUTES OF THE MEETING

**PRE BID MEETING OF TENDER FOR
SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION
OF PRODUCTION SCALE FERMENTOR
AT PASTEUR INSTITUTE OF INDIA, COONOOR**

Document No. : **NPI/110831/EQP/TD/02**

Venue : **HLL, Ticel Biopark, Chennai**

Date : **31.07.2013**

Project : **Revival of DPT Vaccine Manufacturing Facility, PII,Coonoor**

Attendees :

HLL Lifecare Ltd.,	**NNE Pharmaplan**	**PII, Coonoor**	**Vendors:**
Mr. Renjith M C Mr. Anto Felix Mr. Vigneshwaran Mr. Sudeep Mr. Shibulal Mr. Kiruba Sankar Mr. Suresh S Mr. Nagarajan	Dr. Naveen Nagaraj	Dr. B Sekar Mr. B Sundran Mr. Kamaludeen Mr. R Mohan Mr. B Annamalai Ms. Lalitha Ms. Shanthi Mani Dr. K C Shivanandappa	Sartorius • Mr. Sudhir Puri • Mr. Sanat Kumar • Mr. Prashant • Mr. Shivraj BioEngineering • Mr. S Ramgopal • Mr. P K Shankar Biozeen • Mr. A C Subhash • Mr. Sankhajeet Kole Scigenics India • Mr. Charles • Mr. P Shankar

Issued by **:** Dr. Naveen Nagaraj
Issued on **:** 1st August 2013
Issued from **:** NNE Pharmaplan India Limited, Bangalore

Agenda	
1.	• Pre-bid Meeting for Production Scale Fermentors for PIIC

S. No.	Clarifications on queries	
	Tender for Supply , Installation, commissioning and Validation of Production scale Fermentor at PII, Coonoor : NPI/110831/EQP/TD/02	
A	**Discussion on Tender Enquiry Document: NPI/110831/EQP/ TD/02**	
	General Discussion Points	
1.	Payment terms have been explained to vendor and there will be no changes in payment terms. Tender conditions with regards to the payment terms will hold good.	
2.	Earnest Money Deposit (EMD) to be payable at "Chennai" instead of "Trivandrum"	
3.	In the Tender at the following places, it has been changed as "**Chennai**" instead of "**Trivandrum**". a) Pg No:- 20 0f 86 Point no.:- 18.2 *b)* Pg No.:- 20 of 86 Point no.:- 18.4 *c)* Pg No:- 86 of 86 Section - XXIII ; schedule of fiscal aspects - Point No. :- 11	
S. No.	**Clarifications on URSs**	
	General Points: • Individual SCADA with PC is required for Diphtheria, Pertussis , Tetanus and Formulation areas. • *Diphtheria , Pertussis & Tetanus Fermentors*:- Independent Sterilization for vent, overlay, sparger included • *Diphtheria , Pertussis & Tetanus Fermentors* :In the HMI recipe Full transfer & partial level transfer of the harvest • *Pertussis & Formulation Blending vessel* :In the HMI recipe Full transfer & partial level transfer of the harvest • *Diphtheria , Pertussis & Tetanus Fermentors, Pertussis & Formulation Blending vessel*:- All valves shall be of forged type • *Diphtheria , Pertussis & Tetanus Fermentors, Pertussis & Formulation Blending vessel*:- Thermal mapping shall be performed during FAT with minimum of 8 probes. • *Diphtheria , Pertussis & Tetanus Fermentors, Pertussis & Formulation Blending vessel*:- CIP trolley & Diphtheria media filtration system is not be a part of the supply • *Diphtheria , Pertussis & Tetanus Fermentors, Pertussis & Formulation Blending vessel*:- Mechanical lid lifting device – Manual type is finalized. • *Diphtheria , Pertussis & Tetanus Fermentors, Pertussis & Formulation Blending vessel*:- Sterility run [Media hold] shall be 72 Hrs. • *Diphtheria , Pertussis fermentors*:- Top mounted agitator is finalized.	
B	**URS: D-FER 01**	
4.	**Specific revision in the URS**	
	URS Point number and excerpt* / description of the specification *	**Comment / Point modified as below**
a)	Point 2.03 Temperature control during cultivation 35-37^{0}C (tolerance limit: ±0.1 ºC) & during sterilization (tolerance limit: ±0.1 ºC)	Point 2.03 (i) Temperature control during cultivation 35 ^{0}C (tolerance limit: ±0.1 ºC) & during sterilization (tolerance limit: ± 1.0 ºC) ***[Common for URS: P-FER 01, 02 & T-FER 01,02]***
b)	Point 2.03 **Vent Line/Exhaust Line** Fermentor vent line includes: • a sterile hydrophobic vent filter.	Point 2.03 **Vent Line/Exhaust Line** Fermentor vent line includes: • a sterile hydrophobic vent filter.[Code 7]

S. No.	Clarifications on queries	
	• Back pressure control valve in vent/exhaust line (Also mentioned Under pressure control) • A Rupture disc is mounted on Fermentor vessel to relieve excess pressure during operations.	• Back pressure control valve in vent/exhaust line (Also mentioned Under pressure control) • A Rupture disc is mounted on Fermentor vessel to relieve excess pressure during operations. Upon rupture of the disc the broth from the fermentor will be emptied into the drain. • pipe in pipe heat exchanger should be present in exhaust line. ***[Common for URS: P-FER 01,02 & T-FER 01,02]***
c)	Point 2.03 **Agitator Shaft seal:** Double mechanical dry running seal with Thermo syphon, pressurization shall be by means of sterile air during operation, during seal SIP by means of pure steam.	Point 2.03 **Agitator Shaft seal:** Double mechanical running seal with Thermo syphon, pressurization shall be by means of sterile air during operation, during seal SIP by means of pure steam. ***[Common for URS: P-FER 01,02]***
d)	**Flush Bottom Valve:** It should be zero dead leg type valve attached directly to the at the bottom of the vessel, with a provision for sterilization. The diaphragm shall be of PTFE type.	**Flush Bottom Valve:** It should be zero dead leg type valve attached directly to the at the bottom of the vessel, with a provision for sterilization. The diaphragm shall be of EPDM having PTFE coating. ***[Common for URS: D-FER 01 , P-FER 01,02 & T-FER 01,02, P BLV 01 , F1 BLV 01]***
e)	Point 2.04 25 mm Spare port-1 No Automatic back pressure control valve. -1 No	Point 2.04 25 mm Spare port with TC -1 No Automatic back pressure control valve. -1 No – *Deleted* ***[Common for URS: D-FER 01 , P-FER 01,02 & T-FER 01,02]***
f)	Point 2.04 (2) 25 mm Spare port-1 No	Point 2.04 (2) 25 mm Spare port-1 No - *Deleted* ***[Common for URS: D-FER 01 , P-FER 01,02 & T-FER 01,02]***
g)	**6.4 Level of instrumentation** <table><tr><td>Pump</td><td>To dose inoculum, media, antifoam, acid, base, etc</td><td>Peristaltic pump(4 Nos)</td></tr></table>	**6.4 Level of instrumentation** <table><tr><td>Pump</td><td>To dose inoculum, antifoam, acid, base, etc</td><td>Peristaltic pump(4 Nos)</td></tr></table> ***[Common for URS: D-FER 01 , P-FER 01,02 & T-FER 01,02]***
h)	**6.7 Specific Requirements:** 6.7.10 .2 Nos of fixed speed Peristaltic pumps are required for Media, Inoculum addition with pump head compatible with the tube size:12x17 mm .	**6.7 Specific Requirements:** 6.7.10. 2 Nos of fixed speed Peristaltic pumps are required for Inoculum addition with pump head compatible with the tube size:12x17 mm .

<table>
<tr><th>S. No.</th><th colspan="2">Clarifications on queries</th></tr>
<tr><td>i)</td><td>URS Annexure 3: List of Preferred Make of components
<table><tr><td>11</td><td>DC source</td><td>Shavision/ Yokogawa/ Emerson</td></tr><tr><td>24</td><td>Flow switch</td><td>Orion/ Wika/Emerson</td></tr><tr><td>31</td><td>Heater</td><td>Common wealth</td></tr></table></td><td>URS Annexure 3: List of Preferred Make of components
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<tr><td>C</td><td colspan="2">URS: P-FERM 01</td></tr>
<tr><td>5.</td><td colspan="2">Specific revision in the URS</td></tr>
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<tr><td>a)</td><td>2.0.1. Table -1
<table><tr><th>Description</th><th>Purpose</th><th>MOC</th></tr><tr><td>Top closure</td><td>Torispherical dish</td><td>SS316L</td></tr></table></td><td>2.0.1. Table -1
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<tr><td>6.</td><td colspan="2">Specific revision in the URS</td></tr>
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Point modified as below</td></tr>
<tr><td>a)</td><td>Point No:- 2.0.3.
f. Process air and Nitrogen Supply System: system consists of Overlay Line with Process air and Nitrogen gas with the flow rate of 2-50 LPM</td><td>Point No:- 2.0.3.
f. Process air and Nitrogen Supply System: system consists of Overlay and Sparger Line with Process air and Nitrogen gas with the flow rate of 2-50 LPM.</td></tr>
<tr><td>D</td><td colspan="2">URS: P-BLV 01</td></tr>
<tr><td>7.</td><td colspan="2">Specific revision in the URS</td></tr>
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<tr><td>a)</td><td>Point 2.03
h) Temperature Control: The temperature during blending shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, etc) in the jacket with electric heater and steam and a circulation pump. Temperature control during blending should be 30 ºC (tolerance limit: ±0.1 ºC) & during sterilization (tolerance limit: ±0.1 ºC)

The system consists of closed loop pressurized thermostat system with recirculation pump, 2 heat exchangers for heating and cooling alternatively which provides a high flow through the hollow vessel jacket and ensures fast temperature control at high accuracy with PT 100 probe (sterilizable).
• Electrical heater ,Heat exchanger and steam for</td><td>Point 2.03
h) Temperature Control: Temperature control during during sterilization (tolerance limit: ±1 ºC)

The system consists of hollow vessel jacket and ensures fast temperature control at high accuracy with PT 100 probe (sterilizable).
• Safety relief valve
• Bourdon type pressure gauge for jacket utility
• Pneumatically operated valves for steam and cooling water/ chilled water</td></tr>
</table>

S. No.	Clarifications on queries	
	cooling water & chilled water for operation temperature • Safety relief valve • Bourdon type pressure gauge for jacket utility • Pneumatically operated valves for steam and cooling water/ chilled water	
b)	**3.3 Output & Discharging method** The blended bacterial mass is collected in sterile bottles (under LAF) and stored in cold room.	**3.3 Output & Discharging method** The blended bacterial mass is collected in sterile bottles and stored in cold room. ***Note:- Vendor to provide the suitable sterile connection for harvesting the bacterial mass in multiple numbers of Nalgene bottles and provision to be made for independent SIP for the harvest line.***
c)	Point 6.7.11 1 No of fixed speed Peristaltic pump is required for the recirculation of blending solution into the blending vessel @ rate of 280 L/hr with the pump head compatible with the tube size :9.6/14.4 mm	Point 6.7.11 **Point deleted**
D	**URS: F1-BLV 01**	
8.	**Specific revision in the URS**	
	URS Point number and excerpt* / description of the specification *	**Comment / Point modified as below**
a)	**Point 2.03 (d)** **Dosing Unit for saline:** The Saline will be added to the Blending vessel through sterile valve assembly by pressure transfer. 0.45 µ on line sterile filter unit should be provided in the inlet line for the clarification of the saline.	**Point 2.03 (d)** **Dosing Unit for saline:** The Saline will be added to the Blending vessel through sterile valve assembly by pressure transfer. 0.45 µ on line sterile filter unit should be provided in the inlet line for the clarification of the saline. (SS housing [suitable for SIP] with reusable liquid filter 0.45 micron code 7.)
b)	**Point 2.03** **h) Temperature Control:** The temperature during ***blending*** shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, etc) in the jacket with electric heater and steam and a circulation pump. Temperature control during blending should be 30 ºC (tolerance limit: ±0.1 ºC) & during sterilization (tolerance limit: ±0.1 ºC) The system consists of closed loop pressurized thermostat system with recirculation pump, 2 heat exchangers for heating and cooling alternatively which provides a high flow through the hollow vessel jacket and ensures fast temperature control at high accuracy with PT 100 probe (sterilizable). • Electrical heater ,Heat exchanger and steam for cooling water & chilled water for operation	**Point 2.03** **h) Temperature Control:** Temperature control during during sterilization (tolerance limit: ±1 ºC) The system consists of hollow vessel jacket and ensures fast temperature control at high accuracy with PT 100 probe (sterilizable). • Safety relief valve • Bourdon type pressure gauge for jacket utility • Pneumatically operated valves for steam and cooling water/ chilled water

S. No.	Clarifications on queries	
	temperature • Safety relief valve • Bourdon type pressure gauge for jacket utility • Pneumatically operated valves for steam and cooling water/ chilled water	

For HLL Lifecare Limited

Vice President (Projects)

LIST OF ATTENDEES

PROJECT : REVIVAL OF DPT VACINE MANUFATURING FACILITY PII, COONOOR

DATE : 31ST JULY '13

CLIENT : M/S PASTEUR INSTITUTE OF INDIA, COONOOR

VENUE : M/S HLL LIFECARE LIMITED, CHENNAI

SUBJECT : PREBID MEETING – PRODUCTION SCALE FERMENTOR PACKAGE

SL NO	NAME	COMPANY	SIGNATURE
1.	VIGNESHKUMARAN T	HLL LIFECARE LTD	
2	R. MOHAN	P.I.I. COONOOR	31/07/13
3	B. ANNAMALAI	P.I.I. COONOOR	
4.	Dr. B. SEKAR	P.I.I. COONOOR	31/7/13
5.	B. SUNDARAN	P.I.I. COONOOR	31/7
6.	Sudhir Rini	Sartorius	31/7
7	Sanat Kumar	Sartorius	
8	Prashant	Sartorius	
9	Shivraj	Sartorius	
10	S. RAMGOPAL	BIOENGINEERING AG	
11	P.K. Shankar	Bio Engineering AG	
12	SHANTHI MANI	PII, COONOOR	31/7/13
13	KAMALUDEEN	PII - COONOOR	31/7/13
14	MRS. T. LALITHA	PII, COONOOR	31/7/13
15	Dr. K.C. Shivanandappa	PII, COONOOR	31/7/13
16	P. Shankar	Scigenics India Pvt Ltd	31/7/13

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SL NO	NAME	COMPANY	SIGNATURE
17	M. Charles	Scigenics India	M.
18	Sudeep.B	HLL Lifecare Ltd	31/7/13
19.	Shibulal.	HLL Lifecare Ltd	31/7/13.
20.	Sankhajeet Kole	BIOZEEN	31/7/2013
21.	A.C. SUBHASH	Biozeen.	31/7/13.
22.	S. SURESH.	HBL, Chennai	31/7/13.
23.	R. KIRUBA SANKAR	HBL, Chennai	31/7/13
24	DR. NAVEEN NAGARAJ	NNE PHARMAPLAN	
25.	A. ANTO FELIX	HLL Life Care	
26.	Renjith MC	HLL	