



MINUTES OF THE MEETING

PRE BID MEETING FOR FABRICATION EQUIPMENT TENDER – BCGVL PROJECT

Document No.NPI/110729/EQP/TD/07

Venue: HLL, Tichel Biopark, Chennai

Project : BCG Vaccine Manufacturing Facility, Chennai

Date of the meeting : 30th April 2013

Attendees :

Company/vendor	Name of the Participant
Katalyst Bioengineering	Mr. R Ganesh Mr. Biplabendu Dandapat
Scigenics (India) Pvt. Ltd.,	Mr. S Muthuswamy Mr. R Srinivasan
Neela Systems	Mr. Sushant Malviya
Biozeen	Mr. Sankhajeet Kole Mr. Thejhu Avinash
Jo-Pra Tech	Mr. J V S Prasad
Client/Consultant Team	
BCGVL	Mr. C Robinson Dr. T F Hassan
HLL Lifecare	Mr. A Antofelix Mr. Vigneshwaran Ms. Polima Sreenath Mr. Jithin James Mr. S Suresh Mr. Bhaskar C
NEE Pharmaplan	Mr. Vikas Katial Dr. Naveen Nagaraj

Issued by : Vice President (Projects)
HLL Lifecare Limited

Issued on : 2nd May 2013

Agenda : Prebid Meeting – Tender for Supply , Installation & commissioning of Fabrication equipment



S. No.	Clarifications on queries																	
	<p>purchase order copies or bill of entry copy to be attached).</p> <p>2. Their Client's list must include at-least two facilities approved from national regulatory body (NRA)(Schedule M) or international regulatory bodies (viz., US-FDA / UK-MHRA / WHO / EU).</p>	<p>client or purchase order copies or bill of entry copy to be attached).</p> <p>2. Their Client's list must include at-least two facilities approved from national regulatory body (NRA)(Schedule M) or international regulatory bodies (viz., US-FDA / UK-MHRA / WHO / EU).</p>																
	General point applicable for all the URS																	
	Comment																	
7.	6.3 Level sensor shall be capacitance type for collection tank & kill tank	For info to all concerned																
8.	6.2.3 Pressure switch shall be provided in plant steam line	For info to all concerned																
S. No.	Clarifications on URSs																	
B	Biowaste inactivation system URS/ K1 – KIL 01																	
	Specific revision in the URS																	
	URS Point number and excerpt* / description of the specification *	Comment																
9.	<p>2.1 General Requirements</p> <p>The general design must be hygienic, with no dead legs and no air pockets. The bio-waste inactivationsystem must be fully drainable with flush bottom valve at the outlet.</p>	<p>2.1 General Requirements</p> <p>The general design must be hygienic, with no dead legs and no air pockets. The bio-waste inactivation system must be fully drainable with Automatic diaphragm valve at the outlet (Dead leg from the vessel bottom to the valve not more than 1.5 D).</p>																
10.	<p>2.2.2 General vessel specifications for 250L (Kill Tank) are as under:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Rise in temperature per minute (heating capacity)</td> <td style="width: 30%;"><i>Vendor to specify (heating from ambient to 121°C)</i></td> <td style="width: 30%;">Rise in temperature per minute (heating capacity)</td> <td style="width: 10%;">30 minutes (heating from ambient to 121°C)</td> </tr> <tr> <td>Fall in temperature (cooling capacity)</td> <td><i>Vendor to specify (before discharging to ETP,</i></td> <td>Fall in temperature (cooling capacity)</td> <td>45 minutes (before discharging to ETP,</td> </tr> </table>	Rise in temperature per minute (heating capacity)	<i>Vendor to specify (heating from ambient to 121°C)</i>	Rise in temperature per minute (heating capacity)	30 minutes (heating from ambient to 121°C)	Fall in temperature (cooling capacity)	<i>Vendor to specify (before discharging to ETP,</i>	Fall in temperature (cooling capacity)	45 minutes (before discharging to ETP,	<p>2.2.2 General vessel specifications for 250L (Kill Tank) are as under:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Rise in temperature per minute (heating capacity)</td> <td style="width: 30%;"><i>Vendor to specify (heating from ambient to 121°C)</i></td> <td style="width: 30%;">Rise in temperature per minute (heating capacity)</td> <td style="width: 10%;">30 minutes (heating from ambient to 121°C)</td> </tr> <tr> <td>Fall in temperature (cooling capacity)</td> <td><i>Vendor to specify (before discharging to ETP,</i></td> <td>Fall in temperature (cooling capacity)</td> <td>45 minutes (before discharging to ETP,</td> </tr> </table>	Rise in temperature per minute (heating capacity)	<i>Vendor to specify (heating from ambient to 121°C)</i>	Rise in temperature per minute (heating capacity)	30 minutes (heating from ambient to 121°C)	Fall in temperature (cooling capacity)	<i>Vendor to specify (before discharging to ETP,</i>	Fall in temperature (cooling capacity)	45 minutes (before discharging to ETP,
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Fall in temperature (cooling capacity)	<i>Vendor to specify (before discharging to ETP,</i>	Fall in temperature (cooling capacity)	45 minutes (before discharging to ETP,															
11.	<p>3.2 Brief Process Steps</p> <p>d) Inactivation: After achieving high level in kill tank pump stops and inactivation process start, plant steam valve opens and get the desired temperature for inactivation. Inactivation temperature till 90 °C-95°C is achieved by using Plant steam in jacket and later by both the addition of steam directly to tank and by jacket. Allow the biowaste to hold it for sometime (procedures will be defined during PQ or internal validation SOP) at 121°C. The temperature shall be controlled by ON/OFF Valves.</p>	<p>3.2 Brief Process Steps</p> <p>d) Inactivation: After achieving high level in kill tank pump stops and inactivation process start, plant steam valve opens and get the desired temperature for inactivation. Allow the biowaste to hold it for some time (procedures will be defined during PQ or internal validation SOP) at 121°C. The temperature shall be controlled by vessel temperature sensor.</p>																
12.	<p>6.5.9 Centrifugal pumps shall be provided to transfer effluent from collection tank to kill tank and from kill tank to ETP area. These pumps shall be connected to the control panel. The same pump shall be used for the recirculation of the cleaning fluid during cleaning. The pump shall be of non-sanitary type, leak proof and spill proof.</p> <p>Pump Specification:</p> <p>I. Flow rate: 2m³/ hr II. Operating Temperature: 50°C - 60°C III. MOC: SS 304 IV. Flooded type</p>	<p>6.5.9 Centrifugal pumps shall be provided to transfer effluent from collection tank to kill tank . These pumps shall be connected to the control panel. The same pump shall be used for the recirculation of the cleaning fluid during cleaning.</p> <p>Pump Specification:</p> <p>I. Flow rate: 5.5 m³/ hr II. Operating Temperature: 50°C - 60°C III. MOC: SS 304 IV. Flooded type</p> <p>and from kill tank to ETP area.</p> <p>Pump Specification:</p> <p>I. Flow rate: 5.0 m³/ hr II. Operating Temperature: 50°C - 60°C III. MOC: SS 304</p>																



S. No.	Clarifications on queries	
		IV. Flooded type These pumps shall be of non-sanitary type, leak proof and spill proof.
13.	6.6.2 The vessel shall be provided with the following on the Top lid : Spray ball port – 2 no	6.6.2 The vessel shall be provided with the following on the Top lid : Spray ball port – 1 no
14.	6.6.9 Design Parameters (Common for Collection and Kill Tank): <ul style="list-style-type: none"> Shell working Pressure- Atmospheric pressure Shell working Temperature- 20-134°C Shell sterilization Temperature- 121-134°C Shell design Pressure- Full Vacuum to 3.5 bar(g) Shell design Temperature- 0-150 °C Jacket working Pressure- 3.5 bar(g) Jacket working Temperature- 150°C Jacket design Pressure- Full vacuum to 4.5 bar(g) Jacket design Temperature- Vendor to specify 	6.6.9 Design Parameters (Common for Collection and Kill Tank): <ul style="list-style-type: none"> Shell working pressure for kill tank - 2.5 bar (g) Shell sterilization Temperature- 121-134°C Shell design Pressure- Full Vacuum to 3.5 bar(g) Shell design Temperature- 0-150 °C Jacket working Pressure- 3.5 bar(g) Jacket working Temperature- 150°C Jacket design Pressure- Full vacuum to 4.5 bar(g) Jacket design Temperature- Vendor to specify
15.	6.6.17 Basic PLC Based Controller with control panel (Displaying synoptic view of running parameters like temperature, level sensor, valve position etc). Vendor to perform a criticality assessment to assess the applicability of the system to Part 11 regulation. Software, if used to generate, process, store the quality critical data must be validated and must comply 21 CFR Part 11 requirements	6.6.17 System shall be equipped with serial printing which shall be triggered by the process parameters and the settable interval to be selected by the user.
16.	URS Annexure 3: List of preferred make of components 3.Pneumatic valve(in harvest line) -Alfalaval/Saunders(Crane) 15. Electrical Tracing for Vent Filter - PALL 16. Filter Integrity Connector- Sartorius/ pall/ millipore	URS Annexure 3: List of preferred make of components 3. Pneumatic valve(in harvest line) -Alfalaval/Saunders(Crane)/ Burkert 15. Electrical Tracing for Vent Filter – PALL / MKS (deleted) 16. Filter Integrity Connector- Sartorius/ pall/ millipore/Staubli
C	Buffer preparation URS/BF-BPT 01	
	Specific revision in the URS	
	URS Point number and excerpt* / description of the specification *	Comment
17.	2.1 General Requirements d. Sampling Valve: It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It shall be provided with a separate line for pure steam sterilization e. Flush Bottom Valve: It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It shall be provided with a separate line for pure steam sterilization	2.1 General Requirements d. Flush Bottom Valve with sampling valve: It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm with sample valve. [Preferred make:- GEMU / NOVASEPTIC]
18.	2.2 Purpose of use Surface Finish Internally Electro polished up to <0.4 Ra Externally Mechanically polished up to <1.2 Ra, matt finish.	2.2 Purpose of use Surface Finish Internally Electro polished up to <0.6 Ra Externally Mechanically polished up to <1.2 Ra, matt finish
19.	6.3 In –Process control Sampling shall be done with sampling port, with the separate line for sterilization with Pure steam	6.3 In –Process control Point deleted
20.	6.7.2 Exhaust port with sterile vent air filter-1 no Code 7 sterile hydrophobic vent filter and cartridge 0.22/0.2 µm hydrophobic	6.7.2 Exhaust port with sterile vent air filter-1 no Code 7 sterile hydrophobic vent filter and cartridge 0.22/0.2 µm hydrophobic of suitable size in



S. No.		Clarifications on queries	
		of suitable size in S316L construction.	S316L construction. Vendor shall provide the valve for air inlet to the housing and isolation valve b/w vessel to housing.
21.		6.7.3 On the lower wall side: Sampling port shall be provided at the level of 8L (W.V) – 1 no. (side wall)	Point deleted
22.		6.7.4 The vessel shall be provided with the following on the Bottom dish: <ul style="list-style-type: none"> Vessel bottom to be Torispherically dished with a transfer line Port with fixed type of Magnetic GMP mixer-1 no Flush bottom valve -1 no (with separate steam line for steam sterilization) 	6.7.4 The vessel shall be provided with the following on the Bottom dish: <ul style="list-style-type: none"> Vessel bottom to be Torispherically dished with a transfer line Port with fixed type of Magnetic GMP mixer-1 no Flush bottom valve with sampling valve -1
D Media preparation URS/BF - MPT 01			
Specific revision in the URS			
		URS Point number and excerpt* / description of the specification *	Comment
23.		2.1 General Requirements d. Sampling Valve: It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It shall be provided with a separate line for pure steam sterilization e. Flush Bottom Valve: It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It shall be provided with a separate line for pure steam sterilization	2.1 General Requirements d. Flush Bottom Valve with sampling valve: It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm with sample valve. [Preferred make:- GEMU / NOVASEPTIC]
24.		2.2 Purpose of use Surface Finish Internally Electro polished up to <0.4 Ra Externally Mechanically polished up to <1.2 Ra, matt finish	2.2 Purpose of use Surface Finish Internally Electro polished up to <0.6 Ra Externally Mechanically polished up to <1.2 Ra, matt finish
25.		6.3 In –Process control Sampling shall be done with sampling port, with the separate line for sterilization with Pure steam	6.3 In –Process control Point deleted
26.		6.7.2 Exhaust port with sterile vent air filter-1 no Code 7 sterile hydrophobic vent filter and cartridge 0.22/0.2 µm hydrophobic of suitable size in S316L construction.	6.7.2 Exhaust port with sterile vent air filter-1 no Code 7 sterile hydrophobic vent filter and cartridge 0.22/0.2 µm hydrophobic of suitable size in S316L construction. Vendor shall provide the valve for air inlet to the housing and isolation valve b/w vessel to housing.
27.		6.7.3 On the lower wall side: Sampling port shall be provided at the level of 8L (W.V)- 1 no. (side wall)	Point deleted
28.		6.7.4 The vessel shall be provided with the following on the Bottom dish: <ul style="list-style-type: none"> Vessel bottom to be Torispherically dished with a transfer line Port with fixed type of Magnetic GMP mixer-1 no Flush bottom valve -1 no (with separate steam line for steam sterilization) 	6.7.4 The vessel shall be provided with the following on the Bottom dish: <ul style="list-style-type: none"> Vessel bottom to be Torispherically dished with a transfer line Port with fixed type of Magnetic GMP mixer-1 no Flush bottom valve with sampling valve -1 no
E Mobile CIP Trolley: URS/ BF-CIT 01			
Specific revision in the URS			



Clarifications on queries		
S. No.	URS Point number and excerpt* / description of the specification *	Comment
29.	6.1 Process control The equipment must operate and control the following process cycle: 6.1.1 Duration of each cycle. 6.1.2 Pressure 6.1.3 Conductivity (0 to 200 S/cm) 6.1.4 Quantities of wash liquid in each cycle. 6.1.5 No flow - cut –off of pump	6.1 Process control The equipment must operate and control the following process cycle: 6.1.1 Duration of each cycle. 6.1.2 Conductivity (0 to 200 S/cm) 6.1.3 No flow - cut –off of pump 6.1.4 Pressure gauge
30.	6.7.8 The Vendor shall ensure maintenance parts availability for a minimum of 15 months from delivery.	Point deleted
31.	6.7.10 Vendor to perform a criticality assessment to assess the applicability of the system to Part 11 regulation. Software, if used to generate, process, store the quality critical data must be validated and must comply 21 CFR Part 11 requirements	System shall be equipped with serial printing which shall be triggered by the process parameter and the settable interval to be selected by the user.
32.	6.7 Specific requirements 6.7.5 The supply and suction pumps should have capacity for minimum 2 volume changes per hour of the highest volume vessel.	6.7 Specific requirements 6.7.5 The supply and suction pumps should have capacity for minimum 2 volume changes per hour of the highest volume vessel and vendor shall provide the flexible hose for CIP:- i) 2 meter x 3 no.s ii) 3 meter x 1 no
33.	URS Annexure 2: List of Preferred Make of components	URS Annexure 2: List of Preferred Make of components 10. deleted 11. Deleted 12. Deleted 13. Deleted 14. Deleted 15. deleted
Revised P&ID for Mobile CIP attached in Annexure - 1		
F	Bulk Vessel _ FG-BLV-01	
Revised Bulk Vessel datasheet along with Indicative drawing attached in Annexure 2.		

For HLL Lifecare Limited

Vice President (Projects)



List of Attendees

Date: 30 April 2013
 Client: M/s. HLL Lifecare Limited, Chennai
 Venue: HLL Lifecare Limited, Chennai
 Project: REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

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