



MINUTES OF THE MEETING

PRE BID MEETING FOR STERILIZATION EQUIPMENT TENDER – BCGVL PROJECT

Document No.NPI/110729/EQP/TD/05

Venue: HLL, Tichel Biopark, Chennai

Project : **BCG Vaccine Manufacturing Facility, Chennai**

Date of the meeting : **20th March 2013**

Attendees : See attached list of attendees

Distribution to : **HLL Lifecare Limited**

- All Concerned Persons

NNE Pharmaplan India Limited

- All Concerned Persons

Sterilization equipment Vendors

- M/s Pharmalab
Mr. Anant Ravi
- M/s Machin Fabrik
Mr. TSS Narayanan
- M/s Saksham
Mr. Karthik
Mr.Srinivas
- M/s Metal Chem
Mr.Amrolia
Mr. Rathod

Issued by : Vice President (Projects)
HLL Lifecare Limited

Issued on : 20th March 2013

Agenda : Prebid Meeting – Tender for Supply , Installation, commissioning and Validation of Sterilization equipment



S. No.	Clarifications on queries		
	Tender for Supply , Installation, commissioning and Validation of Sterilization equipment		
A	Discussion on Tender Enquiry Document: NPI/110729/EQP/ TD/05		
	General Discussion Points		
1	The last date for the tender submission has been extended till 10th April 2013; 15:00 hrs and the tender opening will be on 10th April 2013 ; 15:30 hrs.		
2	Warranty period will start after the validation and hand over.		
3	There is no change in payment terms. Same is as per tender conditions.		
	Specific revision in the Tender Enquiry Document		
	Tender Point number and description	Comment	
4	SECTION XI C: PRICE BID FORMAT – COMPREHENSIVE MAINTENANCE CHARGES Total Annual Comprehensive Maintenance Contract Cost for 5 Years [5 x (4a+4b+4c+4d+4e)]	Errata :- Column No.-5 Shall be corrected as [3 x (4a+4b+4c+4d+4e)]	
5	General point applicable for all the URS	Comment	
5.1	Temperature trend chart recording and printing software to be provided.	Batch report should not be in strip chart recording i.e. online printing is desired with minimum storage of 10 cycles. After the cycle completion the batch report and as well as trend print out should be in different colours. Printers (colour) should be placed inside the control cabinet.	
5.2	Equipment drains connection	Drain point: - Suppler to connect the equipment drain point to the nearest floor drain located in the equipment technical area (within 3 m).	
5.3	Lyophilizer frame size	Lyophiliser frame GA drawing was requested by vendors and the same will be shared during DQ stage with the successful bidder.	
S. No.	Clarifications on URSs		
B	Autoclave - cum Bung Processor URS/ FG-ABP 01		
6	Specific revision in the URS		
	URS Point number and excerpt* / description of the specification *	Comment	
6.1	6.4 Level of Instrumentation -	" SCR " refers to "HMI screen"	
	Type of control		Purpose/ Observatio
	Pressure transmitter-2 No		To give pressure input to PLC and SCR
6.2	6.7.6 The Vendor shall ensure maintenance parts availability for a minimum of 15 months from delivery.	Point is deleted.	



S. No.	Clarifications on queries	
6.3	6.7.7 Cables, air tubes, etc required from the point (single utility point) to equipment is in scope of vendor	6.7.7 All utility points will be provided nearer to the equipment. Hooking up of the equipments to the nearest utility points will be in the vendors scope.
6.4	<p>6.7.13 Door Safety The following door safety features shall be provided for operator safety: Door interlocking to prevent simultaneous opening of both the doors. Door Process Lock to prevent opening of doors when the process is on</p>	6.7.13: Door obstructive sensor to be included in door safety.
C	Sterilization Autoclave URS/ BF-SAT 01-2	
7	Specific revision in the URS	
	URS Point number and excerpt* / description of the specification *	Comment
7.1	6.4 Level of Instrumentation -	
	Type of control	Purpose/ Observation
	Pressure transmitter-2 No	To give pressure input to PLC and SCR
7.2	<p>6.7.6 Door Safety The following door safety features shall be provided for operator safety: Door interlocking to prevent simultaneous opening of both the doors. Door Process Lock to prevent opening of doors when the process is on</p>	6.7.6 Door obstructive sensor to be included in door safety.
7.3	6.7.13 The Vendor shall ensure maintenance parts availability for a minimum of 15 months from delivery.	Point is deleted.
7.4	6.7.14 Cables, air tubes, etc required from the point (single utility point) to equipment is in scope of vendor	6.7.14 All utility points will be provided nearer to the equipment. Hooking up of the equipments to the nearest utility points will be in the vendors scope.
D	Decontamination Autoclave URS/BF-DAT01 & FG- DAT 01	
8	Specific revision in the URS	
	URS Point number and excerpt* / description of the specification *	Comment
8.1	6.7.6 The Vendor shall ensure maintenance parts availability for a minimum of 15 months from delivery.	Point is deleted.
8.2	6.7.7 Cables, air tubes, etc required from the point (single utility point) to equipment is in scope of vendor	6.7.7 All utility points will be provided nearer to the equipment. Hooking up of the equipments to the nearest utility points will be in the vendors scope.



S. No.	Clarifications on queries	
8.3	<p>6.7.14 Door Safety The following door safety features shall be provided for operator safety: Door interlocking to prevent simultaneous opening of both the doors. Door Process Lock to prevent opening of doors when the process is on</p>	6.7.14 Door obstructive sensor to be included in door safety.
E	Dry Heat Sterilizer URS/ FG-DHS-01 & BF-DHS-02	
9	Specific revision in the URS	
	URS Point number and excerpt* / description of the specification *	Comment
9.1	3.2.4 Holding up for a set period at sterilization/Depyrogenation temperature(250 - 350° C)	<i>This point has to be read as</i> 3.2.4 Holding up for a set period at sterilization/Depyrogenation temperature (250-300 ° C)
9.2	6.1.1 Chamber temperature 0 to 300 deg C	<i>Additional point added:</i> 6.1.1 Point to be added: multipoint temperature probe (minimum 5 nos.) for measuring chamber temperature, the range should be 0°C to +300 °C
9.3	6.1.5 Depyrogenation hold time (45 min to 60 min)	<i>The control of hold temperature should be as per the following concept.</i> 6.1.5 Thyristor based temperature control required for depyrogenation hold time. While designing the heater bank the voltage bank to be considered as 415 ± 20 V.
9.4	6.1.6 Sterilization Overshoot temperature more than 275 ° C	<i>This point is corrected as:</i> 6.1.6 sterilization overshoot temperature not more that 275 ° C
9.5	6.1.10 Cooling time (not more than 90 min)	<i>This point has to be read as:</i> 6.1.10 Cooling temp time is mentioned as 90 mins but the time may extend in case of glasswares by another 30 mins.
9.6	6.2.3.7 The door shall not open with a chamber temperature inside. (Not more than 45 °C approx)	This point is deleted.
9.7	6.6.7 When the preventative maintenance requirements recommended by Vendor are followed, the machine shall have no more than one unscheduled repair per year	This point is deleted.
9.8	6.7.3 The downstream connections of the supply and exhaust air HEPA filters with the duct should be easily removable (preferably without nuts/ bolts) for periodic HEPA filter replacement.	<i>This point has been further clarified as follows:</i> 6.7.3 Exhaust blower capacity should be designed to blow out an exhaust air up to 15m distance from the equipment exhaust point of DHS. Ducting for exhaust air from the exhaust blower outlet to the outside atmosphere will not be in the vendor scope.
9.9	6.7.6 Automatic FH value calculation for each temperature monitoring port. (Optional)	6.7.6 " Optional " word to be deleted



S. No. Clarifications on queries		
9.10	6.7.7 Forced cooling system such as cooling coil (to be quoted as optional).	6.7.7 This point is deleted.
S. No. Clarifications on IRSs		
F	IRS Document No: NPI/110729/IRS/BCG-01	
10	Specific revision in the IRS	
	IRS Point number and excerpt* / description of the specification *	Comment
10.1	5.3.2 Vendor shall support and provide all necessary documents and test procedures to client for proper execution of all the qualification phases. Note: Vendor to provide the actual man days required for the above qualification along with the cost bid.	Point 5.3.2. "Note" is deleted
10.2	7.5 Necessary transport and lifting equipment will be made available on site.	<i>The point has been revised:</i> 7.5 to include the " vendor scope"

For HLL Lifecare Limited

Vice President (Projects)



LIST OF ATTENDEES

Date : Wednesday , 20th March, 2013
 Venue : HBL, Tidel Biopark, Taramani, Chennai.
 Project : Revival of BCG Manufacturing Facility for BCGVL, Guindy.
 Subject : Pre-Bid Meeting - Tender for Supply, Installation, Commissioning and Validation of Sterilization Equipment.

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