

MINUTES OF THE MEETING

**PRE BID MEETING OF TENDER FOR
SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION
OF FILTRATION SYSTEM – II AND ULTRACENTRIFUGE AT IVC, CHENGALPATTU**

Document No. : NPI-120310-EQP-S1-TD-17

Venue : HLL Biotech Limited, Chennai

Date : 03.06.2016

Project : Integrated Vaccines Complex, Chengalpattu

Attendees : See attached list of attendees

Issued by : HBL

Issued on : 10th June 2016

Agenda	
1.	Pre-bid Meeting for Filtration system - II and Ultracentrifuge at IVC, Chengalpattu

S. No.	Clarifications on queries
	Tender for Supply , Installation, commissioning and Validation of Filtration equipment package at HLL Biotech limited, Chengalpattu : NPI-120310-EQP-S1-TD-17
A	Discussion on Tender Enquiry Document: NPI-120310-EQP-S1-TD-17
1.	The last date for the tender submission has been extended till 6th July 2016; 03:00 PM and the tender opening will be on 6th July 2016; 03:30 PM
2.	<p>Tender document Page no: 38 of 91, Point no.21 The Revised payment terms is as follows, Payment Terms Payment shall be made subject to recoveries, if any, by way of liquidated damages or any other charges as per terms & conditions of contract in the following manner. A) Payment for Domestic Goods Or Foreign Origin Located Within India. Payment shall be made in Indian Rupees as specified in the contract in the following manner: a) Advance An advance of 10% of the contract value shall be released against Bank guarantee equivalent to 110% of the advance amount and submission of 5 % of the contract value as Security Deposit/ Performance Security in the form of Bank Guarantee from any scheduled commercial bank. The advance bank guarantee shall be valid for a period upto the completion of the contract. When the vendor has supplied the Equipment in complete to the site and fulfilled all his supply obligations as per the contract and any delay on the part of the purchaser resulting in deferment in the services/Execution of the contract, then the purchaser may decide on returning the ABG on its expiry. b) DQ Approval: 10% of the contract value shall be released against approval of DQ and submission of Proforma Invoice. c) The 80% of payment shall be made within 15 days from the date submission of all the required documents and invoice as per the schedule given below.</p> <p>I. On delivery at site: 60 % of the contract price shall be paid on receipt of goods in good condition and upon the submission of the following documents: (i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount; (ii) Consignee Receipt Certificate as per Section XVII in original issued by the authorized representative of the consignee; (iii) Two copies of packing list identifying contents of each package; (iv) Dispatch Clearance from Purchaser or authorized agent (v) Inspection certificate issued by the nominated Inspection agency, if any. (vi) Certificate of Country of origin.</p> <p>II. On Installation Qualification (IQ) & Submission of IQ report by client/ purchaser 5% of the contract Value</p> <p>III. On Operational Qualification (OQ) & submission of OQ report by client/ purchaser 5% of the Contract Value</p> <p>IV. On validation and Final Acceptance Certificate by Purchaser: Balance 10 % payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.</p>
3.	<p>B) Payment for Imported Goods: Payment against Imported goods shall be made as specified in the contract in the following manner: a) Advance 10% of the net DAP price after submission of Bank guarantee equivalent to 110% of the advance</p>

S. No.	Clarifications on queries
	<p>amount in the same currency along with submission of Security Deposit / Performance security equal to 5% of the contract value in the form of a bank guarantee from or in the case of a foreign tenderer, the same shall be endorsed by /routed through any Scheduled Commercial Bank. When the vendor has supplied the Equipment in complete to the site and fulfilled all his supply obligations as per the contract and any delay on the part of the purchaser resulting in deferment in the services/Execution of the contract, then the purchaser may decide on returning the ABG on its expiry.</p> <p>b) DQ Approval: 10% of the contract value shall be released against approval of DQ and submission of Proforma Invoice.</p> <p>80% of Payment against Imported goods shall be made in the currency through irrevocable, non-transferable Letter of Credit (LC) opened in favour of the supplier in a bank in his country as specified in the contract in the following manner:</p> <p>c) On Despatch of Goods:</p> <p>60% of the net DAP price (DAP price less Indian Agency commission) of the goods despatched shall be paid and upon submission of documents specified hereunder:</p> <p>(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;</p> <p>(ii) Original and four copies of the negotiable clean, on-board Bill of Lading/ Airway bill, marked freight pre-paid and four copies of non-negotiable Bill of Lading/Airway bill;</p> <p>(iii) Four Copies of packing list identifying contents of each package;</p> <p>(iv) Documents also to be submitted for payment of LC confirming that dispatch documents has already been sent to all concerned as per the contract within 24 hours;</p> <p>(v) Manufacturer's/Supplier's warranty certificate;</p> <p>(vi) Manufacturer's own factory inspection report and</p> <p>(vii) Certificate of origin by the chamber of commerce of the concerned country;</p> <p>d) On Installation Qualification (IQ) & Submission of IQ report by client/ purchaser 5% of the contract Value</p> <p>e) On Operational Qualification (OQ) & submission of OQ report by client/ purchaser 5% of the Contract Value</p> <p>f) On validation and Final Acceptance Certificate by Purchaser: Balance 10 % of the net DAP price payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.</p>
4.	<p>Tender document Page no: 53 of 91, Point no.5 Financial years (2013-14, 2014-15 and 2015-16) are revised as (2012-13, 2013-14 and 2014-15)</p>
5.	<p>SECTION – XI B PRICE SCHEDULE is attached as Annexure – I Note: The price should be quoted in DAP Basis. The customs clearance is in the scope of vendor. The Customs duty shall be paid by HBL at the time of Customs clearance, However the customs clearance agent should be appointed by the vendor.</p>
6.	<p>Revised delivery time for all schedules: 06 (Six) months from date of issue of PO Installation, Commissioning and Validation within 02 (Two) month from the delivery of the equipment at site.</p>

S. No.	Clarifications on URSS													
B	URS: SS Filtration Housing Unit (URS-SFU 02) & (URS-SFU 03)													
	Specific revision in the URS													
	URS Point number and excerpt* / description of the specification *	Point modified as / Comment												
1	Point no: 2.0 Suitable provision to be provided for filter integrity testing.	Point no: 2.0 Suitable integrity connectors to be provided for filter integrity testing.												
2	Point no: 6.6.1 Overall size of the filtration housing train (including all the vents and supporting frame) should be compatible/suitable for sterilization/decontamination in the smallest autoclave with the height of 750mm.	Point no: 6.6.1 Overall size of the filtration housing train (including all the vents, pressure gauges, valves and supporting frame) should be compatible/suitable for sterilization/decontamination in the smallest autoclave of size (900 x 900 x 1200)mm (Width x Height x Depth)												
3	<u>Annexure I. List of Preferred Make of components</u> <table border="1" data-bbox="199 1064 769 1189"> <tr> <td>1</td> <td>Pressure gauges</td> <td>WIKA / Denver / Negele</td> </tr> <tr> <td>3</td> <td>Diaphragm valve(Manual)</td> <td>GEMU / Saunders</td> </tr> </table>	1	Pressure gauges	WIKA / Denver / Negele	3	Diaphragm valve(Manual)	GEMU / Saunders	<u>Annexure I. List of Preferred Make of components</u> <table border="1" data-bbox="802 1095 1410 1220"> <tr> <td>1</td> <td>Pressure gauges</td> <td>WIKA</td> </tr> <tr> <td>3</td> <td>Diaphragm valve(Manual) Autoclavable</td> <td>GEMU</td> </tr> </table>	1	Pressure gauges	WIKA	3	Diaphragm valve(Manual) Autoclavable	GEMU
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1	Pressure gauges	WIKA												
3	Diaphragm valve(Manual) Autoclavable	GEMU												
4	For URS/SFU 02: R1-SFU 05-14: 1 x 6"; SS filter housing to suit Code 7 type filter cartridge Quantity: 10	For URS/SFU 02: R1-SFU 05-14: 1 x 6" or 1 x 5"; SS filter housing to suit Code 7 type filter cartridge Quantity: 10												
	URS: Filter Integrity Testing Machine (URS/FIT 01)													
5	Point no: 2.0, Point no: 4 Multipoint diffusion test	Deleted												
6	Point no: 4.0, g, iv NRV should be fitted on air inlet and outlet.	Point no: 4.0, g, iv NRV should be fitted on air inlet.												
7	Point no: 4.0, k, ii HMI: shall be 10" colour display touch screen.	Point no: 4.0, k, ii HMI: shall not be less than 7" colour display touch screen.												
8	Point no: 4.0, p Vendor shall provide all the necessary fittings, valves wherever required for easy operation.	Point no: 4.0, p Vendor shall provide all the necessary fittings, valves wherever required for easy operation.												

		(Vendor to provide the 3 nos. of each type of 1 inch, ½ inch & ¼ inch TC connectors with one side nipple connection with each equipment)
9	Point no: 5.0, e Pressure drop: 0.001 bar to 2 bar	Deleted
10	Point no: 6.0, e (Addition) Vendor to bring the necessary accessories / requirements during SAT to carry out the testing	
URS: Ultra Filtration System (URS/UFS 02)		
11	Point no: 2.1: General specifications, Table-1	Deleted
12	Point no: 2.5 Vessel design specification, Table-5 SS Vessel Capacity (L) B1-UFS 01: 30 B1-UFS 02: 30 B1-UFS 03: 10 B1-UFS 04: 20 B1-UFS 05: 60 B1-UFS 06: 10	Point no: 2.5 Vessel design specification, Table-5 Revised SS Vessel Capacity (L) B1-UFS 01: 60 B1-UFS 02: 60 B1-UFS 03: 10 B1-UFS 04: 60 B1-UFS 05: 60 B1-UFS 06: 10
13	Point no: 2.5 Vessel design specification, Table-5 Vessel minimum working volume B1-UFS 01: 9L B1-UFS 02: 9L B1-UFS 03: 3L B1-UFS 04: 6L B1-UFS 05: 18L B1-UFS 06: 3L	Point no: 2.5 Vessel design specification, Table-5 Revised SS Vessel Capacity (L) B1-UFS 01: 4L B1-UFS 02: 4L B1-UFS 03: 500L B1-UFS 04: 4L B1-UFS 05: 4L B1-UFS 06: 500mL Note: Mixers are required for all the systems
14	Point no: 2.6, B Vent Line/Exhaust Line: The feed Vessel should include a vent filter with SS housing. The hydrophobic vent filter shall be of sterilizing grade code 7 type. It shall be equipped with necessary drain arrangement. Integrity connector for in-situ integrity testing of filters shall be provided.	Point no: 2.6, B Vent Line/Exhaust Line: The feed Vessel should include a vent filter with SS housing. The hydrophobic vent filter shall be of sterilizing grade code 7 type. It shall be equipped with necessary drain arrangement. Integrity connector for in-situ integrity testing of filters shall be provided. Vendor to provide the suitable filters for the feed

		vessels of capacity \leq 10L. SS housing shall be capable of performing integrity test & 4 nos. of spare filters to be provided					
15	Point no: 2.2 Operating conditions, Table-2						
	Revised table is as follows						
		HiB				Hep B	
	Parameters	B1-UFS-01	B1-UFS-02	B1-UFS-03	B1-UFS-04	B1-UFS-05	B1-UFS-06
	Working Temperature range	2-8°C	2-8°C	2-8°C	2-8°C	2-8°C	2-8°C
	Effective filtration area of the membrane (m ²)	1 to 5 m ²	1 to 5 m ²	0.1 to 0.5 m ²	1 to 5 m ²	1 to 5 m ²	0.1 to 0.5 m ²
	Type of pump to be used	Rotary lobe pump, SIPable	Rotary lobe pump, SIPable	Diaphragm pump, SIPable	Rotary lobe pump, SIPable	Rotary lobe pump, SIPable	Diaphragm pump, SIPable
	Maximum number of cassettes to be hold	10	10	5	10	10	5
	Min. permeate Flow rate (L/Min)	2	2	1	2	2	2
	Initial Volume (L)	500	7-25	2-8	20	800	150
	Concentration Volume (L)	7-25	No concentration	0.2-2	4	15-30	0.5
	No Of Diafiltration cycle	10-20	10-20	5	10	10-20	10-20
MWCO (KDa)	100	300	10	10	100	100	
Level measurement	Level sensor (radar type)	Level sensor (radar type)	Load cell	Level sensor (radar type)	Level sensor (radar type)	Load cell	
Peristaltic pump	Each system has to be provided with Individual Peristaltic pump (integrated type to flow control) 0 to 10LPM						

16	<p>Point no: 2.6, F Retentate Line: The following components/instruments to be provided,</p> <ul style="list-style-type: none"> • Control valve - Pneumatically actuated diaphragm valve for ΔP and TMP control • Pneumatically actuated diaphragm valve, steam trap • Manual diaphragm valves for fluid flow path sample and drain. • Diaphragm type pressure gauge, Temperature sensor, Conductivity sensor and pressure transmitter 	<p>Point no: 2.6, F Retentate Line: The following components/instruments to be provided,</p> <ul style="list-style-type: none"> • Control valve - Pneumatically actuated diaphragm valve for ΔP and TMP control • Pneumatically actuated diaphragm valve, steam trap • Temperature sensor and pressure transmitter • electromagnetic flow meter • Manual sampling valve
17	<p>Point no: 2.6, G Permeate Line: The following components/instruments to be provided,</p> <ul style="list-style-type: none"> • Mass Flow meter and transmitter[in l/min or l/hr and total volume] • Manual diaphragm sampling valve • Manual control of product flow in permeate must be possible • Diaphragm type pressure gauge, Conductivity sensor ,Temperature sensor, pH sensor and pressure sensor with transmitter • Pneumatically actuated diaphragm valve 	<p>Point no: 2.6, G Permeate Line: The following components/instruments to be provided,</p> <ul style="list-style-type: none"> • Mass Flow meter and transmitter[in l/min or l/hr and total volume] • Manual diaphragm sampling valve • Automatic pneumatic control of product flow in permeate must be possible • Conductivity sensor ,Temperature sensor, sensor and pressure sensor with transmitter • Pneumatically actuated diaphragm valve
18	<p>Point no: 2.6, K, IV</p> <ul style="list-style-type: none"> • Pneumatic angle seat valve for steam inlet • Pneumatic angle seat valve for condensate outlet with steam trap • Jacket vent 	Deleted
19	<p>Point no: 6.1.2 Manual control of product flow in permeate and retentate line</p>	Deleted
20	<p>Point no: 6.4 pH: To monitor, indicate and record the pH: pH Sensor</p>	Deleted
21	<p>Point no: 6.4 Flow rate: Monitor the rate of permeate flow: Mass Flow meter with transmitter</p>	<p>Point no: 6.4 Flow rate: Monitor the rate of permeate flow: Mass Flow meter with transmitter in retentate line</p>
22	<p>Point no: 6.5.8 (Addition) Batch data shall be in non-editable format and should have provision to take colour trend print</p>	

23	Point no: 6.7.6 Auto Torque hardware for uniform cassette sealing should be provided	Point no: 6.7.6 Settable Torque hardware for uniform cassette sealing should be provided (2 nos)																																										
24	Point no: 6.7.15 Pump rate: 2m ³ /hr @ 4 bar(g)	Point no: 6.7.15 Pump rate: 3 m ³ /hr @ 4 bar(g)																																										
25	Point no: 6.7.21.1 Sterility of the complete system during SAT	Deleted																																										
26	Point no: 6.7.21.2 Flux- to be demonstrated with dummy cassettes during SAT	Point no: 6.7.21.2 Flux- to be demonstrated with demo cassettes during SAT																																										
27	Point no: 6.7.21.4 Temperature Control along with the level accuracy to be demonstrated.	Deleted																																										
28	Point no: 6.7.22 (Addition) <u>Pump specification: Sterile Sanitary design</u> Type: Diaphragm pump CIP able : Yes SIP able: Yes Surface finish: Ra <0.5 µm [EP] MOC: SS316L Pump rate: Not less than 600 LPH Speed: Vendor to specify Elastomers: EPDM – FDA/ USP																																											
29	Point no: 6.7.23 (Addition) Vendor to provide the 21 CFR part 11 Compliant HMI of size minimum 10 inch Vendor to Isolate the vessel and to provide separate Assembly For buffer exchange																																											
30	Annexure-1: <u>List of Preferred Make of components</u> <table border="1"> <tr> <td>9</td> <td>Level sensor</td> <td>E&H / Mettler Toledo</td> </tr> <tr> <td>11</td> <td>Rupture disc</td> <td>Fike</td> </tr> <tr> <td>18</td> <td>Ball valve(Manual)</td> <td>Modentic/Alfa laval</td> </tr> <tr> <td>21</td> <td>Diaphragm valve(Automatic)</td> <td>GEMU /Burkert/Saunders</td> </tr> <tr> <td>22</td> <td>Angle Seat valve</td> <td>GEMU/Burkert/Saunders</td> </tr> </table>	9	Level sensor	E&H / Mettler Toledo	11	Rupture disc	Fike	18	Ball valve(Manual)	Modentic/Alfa laval	21	Diaphragm valve(Automatic)	GEMU /Burkert/Saunders	22	Angle Seat valve	GEMU/Burkert/Saunders	Annexure-1: <u>List of Preferred Make of components</u> <table border="1"> <tr> <td>9</td> <td>Level sensor</td> <td>E&H / Mettler Toledo / Vega</td> </tr> <tr> <td>11</td> <td>Rupture disc</td> <td>Fike / Zook</td> </tr> <tr> <td>18</td> <td>Ball valve(Manual)</td> <td>Gemu</td> </tr> <tr> <td>10A</td> <td>Magnetic Mixer</td> <td>Roplan / novaseptic for More than 10L</td> </tr> <tr> <td>10B</td> <td>Load cell</td> <td>Mettler toledo / Sartorius</td> </tr> <tr> <td>10C</td> <td>Diaphragm Pumps</td> <td>Sartojet / Quattrow flow</td> </tr> <tr> <td>21</td> <td>Diaphragm valve(Automatic)</td> <td>GEMU</td> </tr> <tr> <td>22</td> <td>Angle Seat valve</td> <td>GEMU</td> </tr> <tr> <td>23</td> <td>Rotary lobe pump</td> <td>Wright flow/ jhonson</td> </tr> </table>	9	Level sensor	E&H / Mettler Toledo / Vega	11	Rupture disc	Fike / Zook	18	Ball valve(Manual)	Gemu	10A	Magnetic Mixer	Roplan / novaseptic for More than 10L	10B	Load cell	Mettler toledo / Sartorius	10C	Diaphragm Pumps	Sartojet / Quattrow flow	21	Diaphragm valve(Automatic)	GEMU	22	Angle Seat valve	GEMU	23	Rotary lobe pump	Wright flow/ jhonson
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URS: Depth filtration unit (URS/DFT 01)		
31	Point no: 6.4 Level of instrumentation	Table deleted
32	Point no: 6.7.8 Alarm should be provided for Flow, Temperature and Pressure if it deviates beyond the set point and tolerance limit	Deleted
33	Point no: 6.7.10 Suitable accessory to be provided to spray the CIP solution within the filter housing.	Point no: 6.7.10 Suitable accessory to be provided to CIP solution within the filter housing.
URS: Ultracentrifuge (URS/UCF 01)		
34	<ul style="list-style-type: none"> a. Vendor has requested for the change in Technical Specification (2.0 equipment Description) capacity and G-Force. But HBL clarified that the mentioned values in the URS is final and the same was required for the process. b. Laser colour jet -1 No. to be provided and integrated with all the 4 nos. of centrifuge by the vendor .Preferred Makes: Canon/HP/Epson c. Vendor to supply min 250 Nos. of sealable tubes per centrifuge d. Vendor to Provide Servo stabilizer with stand for each centrifuge e. Vendor to provide 2 Nos. of sealing tool for the entire 4 centrifuge. 	

For HLL Biotech Limited



10/6/16

S.Suresh,
Senior Manager (Procurement)

ANNEXURE – I
SECTION – XI B PRICE SCHEDULE
PRICE SCHEDULE FOR GOODS TO BE IMPORTED FROM ABROAD

1	2	3	4	5									6
				Price per unit (Currency)									
Schedule	Brief Description of Goods	Country of Origin	Quantity (Nos.)	Gross FOB price at sea / air port of Lading (inclusive of Agency Commission)	Amount and percentage of Agency Commission **	Net FOB (excluding Agency Commission) (a-b)	Freight	Net CFR Port of destination by Air/sea (c+d)	Customs Clearance & Handling Charges **	Loading / unloading / inland transportation & incidental cost till consignee's site **	Installation, commissioning, supervision, Demonstration, training Documentaion and Qualification at the consignee's site **	Unit price on DAP basis at consignee's site (a+d+f+g+h)	Total price on DAP basis at consignee's site 4X 5 (i)
				(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)

** To be paid in Indian Currency (Rs.) or to the principal in their currency
 Customs Duty :% approx & HS Code :

Total DAP at Consignee site price in figures:

And in words: _____

Note: -

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.
2. The charges for Annual Maintenance Contract (AMC) after warranty shall be quoted separately as per Section – XI – Price Schedule C
3. The Tenderer will be fully responsible for the safe arrival of the goods at Consignee Site.
4. The bidders break up of prices under various columns are for comparison of prises up to delivery of goods at consignee's site for tender evaluation and will be allowed on actual basis subject to bidders quoted prices as ceiling under various heads which will be adjusted later against balance payment.
5. The quoted price should be bidder's best lowest rate supported with original proforma invoice from the foreign manufacturers Indian Agent to be paid in Indian Currency.

Signature of Tenderer : _____

Name : _____

Business Address : _____

Seal of the Tender : _____

Date : _____

Place : _____