

**MINUTES OF THE MEETING**

**PRE BID MEETING OF TENDER FOR  
 SUPPLY, INSTALLATION, COMMISSIONING & VALIDATION OF FERMENTOR PACKAGE AT HLL  
 BIOTECH LIMITED, CHENGALPATTU, CHENNAI**

**Document No. :** NPI-120310-EQP-S1-TD-10

**Venue :** HLL Biotech Limited, Chennai

**Date :** 27.04.2015

**Project :** Integrated Vaccines Complex, Chengalpattu

**Attendees :** See attached list of attendees

**Issued on :** 30<sup>th</sup> April 2015

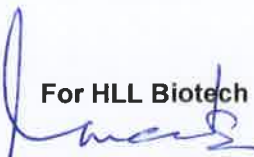
Agenda	
1.	Pre-bid Meeting for Fermentor package s for IVC, Chengalpattu

S. No.	Clarifications on queries	
	Tender for Supply , Installation, commissioning and Validation of Fermentor package at HLL Biotech limited, Chengalpattu : NPI-120310-EQP-S1-TD-10	
<b>A</b>	<b>Discussion on Tender Enquiry Document: NPI-120310-EQP-S1-TD-10</b>	
	<b>General Discussion Points</b>	
1.	There are no changes in bid submission, tender terms and conditions, Fiscal aspects[For info]-Tender terms and conditions holds good.	
2.	<b><u>Vendor Query on Tender terms and conditions</u></b>	<b><u>Clarification on vendors Queries:-</u></b>
3.	Vendor asked whether customs duty exemption certificate will be provided for this particular tender.	It is clarified that Customs Duty Exemption Certificate will not be provided.
4.	Vendor asked that Service tax for Incidental Services has to be quoted separately in the price schedule, separate column to be provided.	It is clarified that the bidder has to quote as per Section XI (Price Schedule) of the tender document. Incidental services has to be quoted inclusive of service tax, with the service tax percentage mentioned separately.
5.	Vendor asked that whether any variation in the taxes during the currency of the tender will be absorbed by HBL.	The “ <b>Statutory Variation</b> ” clause in Special Condition of Contract in the Tender document <b>holds good</b> .
6.	Vendor asked for a change in the payment schedule to facilitate 20% advance instead of 10% advance as mentioned in the tender enquiry document.	There shall be <b>no change</b> in the “ <b>Payment Schedule</b> ”. Clause 21 of the GCC of the Tender Enquiry Document remains the same.
7.	Vendor raised a query in case of agent quoting on behalf of the manufacturer whether the previous supply details of the agent or manufacturer will be considered.	Only the <b>past supply experience of the tenderer</b> , whether it be the agent or the manufacturer will be considered. In case the agent is participating in the tender, the supply experience of the manufacturer will not be taken into account.
8.	Vendor raised a query as to whether online Bank Guarantee can be submitted as EMD.	It is clarified that bidder has to submit <b>hardcopy of the EMD Bank Guarantee</b> duly sealed and signed by the bank as per the format provided in the Tender enquiry document.
9.	Vendor raised a query whether advance will be provided without submission of the Advance Bank Guarantee or whether Advance Bank Guarantee for the exact amount of the advance.	There shall be <b>no change in the “Payment Schedule</b> ”. Clause 21 of the GCC of the Tender Enquiry Document remains the same. Point No: 5 of the schedule of Fiscal Aspects in Tender enquiry documents <b>holds good</b> .

S. No.	Clarifications on URSS	
B	URS: NPI-120310-EQP-URS-FER-01	
5	Specific revision in the URS	
	URS Point number and excerpt* / description of the specification *	Point modified as / Comment
	2.0 Equipment Description: Table 2: Specific Requirements : Point no. 3 Max working volume : seed fermentor Hep B Fermentor – 35L	Max working volume : seed fermentor Hep B [ B1-FER-03] Fermentor – 28 L
5.4	2.0 Equipment Description: Table 2: Specific Requirements : Point no. 4 Geometric volume : Vendor to specify (head volume should be 30% of the total height)	Vendor to specify ( W.V must be 70% of G.V)
5.5	2.0 Equipment Description: Table 2: Specific Requirements : Point no. 5 Minimum operating volume, L – seed fermentor Hep-B 6L	Minimum operating volume, L – seed fermentor Hep-B : 7L
5.6	2.0 Equipment Description: Table 2: Specific Requirements : Point no. 5 Minimum operating volume, L – seed fermentor HIB section : Vendor to specify	Minimum operating volume, L – seed fermentor HIB section : 9L
5.7	2.0 Equipment Description: Table 2: Specific Requirements : Point no. 7 H/D Ratio - 500L fermentor Hep-B and HIB section 3:1	H/D ratio for 500L fermentor B1-FER-01,02,04,05 revised to 2.5:1 for both Hep-B and HIB section. H/D ratio for seed fermentor B1-FER-03,06 to remain same as 3:1.
5.8	2.0 Equipment Description: Table 2: Specific Requirements : Point no.8 Addition port (TC type)	B1-FER-01,02 – 8 addition ports – Inoculum,media,feed1,feed2,acid,base,antifoam, spare B1-FER-03 – 6 addition ports – media, inoculum, acid, base, antifoam, spare1 B1-FER-04,05 – 6 addition ports - Inoculum, media, acid, base, antifoam, spare1 B1-FER-06 – 6 addition ports – media, inoculum, acid, base, antifoam, spare B1-FV-01,02,03,04 - 2 addition ports each vessel
5.9	2.0 Equipment Description: Table 2: Specific Requirements : Point no.10- PRV for pure steam line – Yes for all fermentors	PRV for pure steam line – One PRV required for each fermentation skid. PRV to be provided with condensate drain arrangement.
5.10	2.0 Equipment Description: Table 2: Specific Requirements : Point no.16 – Aeration O <sub>2</sub> sparger	Aeration O <sub>2</sub> sparger revised to ' Ring Sparger'.

5.11	<p><b>2.0 Equipment Description: Table 2: Specific Requirements :</b></p> <p><b>Point no.20:</b> CIP 'Each line of Hep-B (1no production Fermentor, 1no seed Fermentor, 2nos feed vessel) should have a centrifugal pump'</p>	<p><b>For Hep-B</b> - 2 nos. FERMENTOR, 1No. SEED FERMENTOR, 4Nos. Feed vessels should have a centrifugal pump, and sensors for necessary valves.</p>
5.12	<p><b>2.1 General Design of the fermentor:</b></p> <p><b>Point No:- 2.1.1 Dosing Unit –</b></p>	<p><b>Point No:- 2.1.1 Dosing Unit – point Included as below</b></p> <p><b>B1-FER-01,02</b> - 4 fixed connections (Inoculum, media, feed-1, feed-2) 3 bottle assembly connections (acid, base, antifoam)</p> <p><b>B1-FER-03</b> - 5 addition ports all Bottle assembly connections.</p> <p><b>B1-FER-04,05</b> - 2 fixed connections (Inoculum, media) 3 bottle assembly connections (acid, base, antifoam).</p> <p><b>B1-FER-06</b> - 5 addition ports, all Bottle assembly connections.</p>
5.13	<p><b>2.1 General Design of the fermentor:</b></p> <p><b>Point No:- 2.1.2 Gas supply system</b></p>	<p><b>Point No:- 2.1.2 Gas supply system - Point Included as below</b></p> <p>For all fermentors [ Main fermentor &amp; Seed fermentor] Gas Mixing Station to be provided for supply of process Air and O<sub>2</sub> supply</p> <p><b>Note:- All fermentors must be designed for a gas flowrate of 2VMM.</b></p> <p>i. Process air MFC range for Main fermentor is 1-500 SLPM</p> <p>ii.O<sub>2</sub> MFC range for Main fermentor is 1-200 SLPM</p> <p>iii.Process air MFC range for Seed Fermentor is 1-200 SLPM</p> <p>iv.O<sub>2</sub> MFC range for Seed fermentor is 1-100 SLPM</p>
	<p><b>2.2 General Design of the Feed Vessel</b></p>	<p>Serial nos. Typographical error to be read as 2.2.1 to 2.2.11 instead to 2.1.1 to 2.1.11</p>
	<p><b>2.2 General Design of the Feed Vessel –</b></p> <p><b>Point No. 2.1.6 Mixer – speed range to change from 50-400 rpm</b></p>	<p><b>Point No. 2.2.6 Mixer</b> -VFD to adjust speed from 50-370 rpm</p>
	<p><b>2.2 General Design of the Feed Vessel –</b></p> <p><b>Note</b></p>	<p><b>Point Included as below</b></p> <p>1. Fermentor B1-FER-04,05 HIB section to design with a common work platform with two ladders for each fermentor. Work platform must be designed for atleast two people working space. Seed Fermentor B1-FER-06 to be located in front or behind the work platform to ensuring cGMP compliance.</p> <p>2. Fermentor B1-FER-01,02 Hep-B section to design with a common work platform with ladder for each fermentor. Work platform must be designed for atleast two people working space. Seed Fermentor B1-FER-03 to be located in front or behind the work platform to ensuring cGMP compliance.</p> <p>3. Point no. 3 - deleted</p>
	<p><b>2.3 General Requirements for fermentor – 2.3.1 Nozzle schedule for fermentor of Hep-B 500L capacity – 2.3.1.2 Upper side wall</b></p>	<p>All addition ports shall be 0.5" TC except for the media addition port which will be 1" TC.</p>

	<b>2.3 General Requirements for fermentor – 2.3.2 Nozzle schedule for fermentor of HIB 500L capacity – 2.3.2.2 Upper side wall</b>	All addition ports shall be 0.5” TC except for the media addition port which will be 1” TC.
	<b>2.3 General Requirements for fermentor – 2.3.2 Nozzle schedule for seed fermentor – 2.3.2.2 Upper side wall</b>	All addition ports shall be 0.5” TC
	<b>6.0 GMP Requirements : point 6.1.6</b> "rate of flow of process air, Overlay and Sparger"	To be revised to "Rate of air flow"
	<b>6.7 Specific Requirements –</b>	<i>New points added</i> 6.7.10 All hot and cold lines must be provided with proper insulation. 6.7.11 All process piping must be electro polished interior as well as exterior.
	<b>URS Annexure 3: List of preferred make of components:</b>	<i>As per suggestions following makes to be included/Modified as addition in the list</i> pH sensor : Mettler Toledo/E+H/Hamilton pressure transmitter : Wika/Dwyer/Sensocon/Afriso Agitator-Seed Fermentor : PRG/pfaudler DP sensor : E&H, Rosemount Potentiometric sensor : E&H, Alfa laval

  
 For HLL Biotech Limited  
 Chief Executive Officer



**List of Attendees**

**Date:** 27- April-2015  
**Venue:** HBL, TICEL Biopark, Chennai  
**Project:** Integrated Vaccine Complex [HBL]  
**Subject:** Pre-Bid meeting for Fermentor at IVC,Chengalpattu

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