MINUTES OF THE MEETING

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

Document No.	:	**NPI-120310-EQP-S1-TD-19**
Venue	:	**HLL Biotech Limited, Chennai**
Date	:	**19.01.2016**
Project	:	**Integrated Vaccines Complex, Chengalpattu**
Attendees	:	**See attached list of attendees**
Issued by	:	Mr. Raman K Ramachandran (CEO)
Issued on	:	29.01.2016
Issued from	:	HLL Biotech Limited, Chennai, NNE Pharmaplan India Limited, Bangalore.

Agenda	
1.	Pre-bid Meeting of Continuous Centrifuge for IVC, Chengalpattu

A	Clarification on Commercial Queries	
	Clause in Tender Document	Point modified as/ Comment
1.	**Clause 21 & Section XXIII: Terms and Mode of Payment**	**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 up to the completion of the contract. **b) Design Qualification Approval:** 10% of the contract value shall be released against approval of DQ and submission of Proforma invoice. **c) On delivery at site:** 70 % 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. **d) On validation and Final Acceptance Certificate by Purchaser:** Balance 10 % payment would be made

against **IQ, OQ documents approved by the purchaser** along with '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. **In the event of delayed Validation and FAT for the reasons attributable by the purchaser, the final 10% payment (subject to recoveries if any) shall be released within 6 months from the date of delivery of materials at site.**

All milestones payments shall be made within 30 days from the date of submission of necessary documents.

B) Payment for Imported Goods:

100% of the Payment 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:

a) Advance

10% of the net DAP price after submission of Bank guarantee equivalent to 110% of the advance 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 a Nationalized Indian Bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.

b) Design Qualification Approval:

10% of the contract value shall be released against approval of DQ and submission of Proforma invoice.

c) On Receipt of Goods at site:
70% of the net DAP price (DAP price less Indian Agency commission) of the goods delivered shall be paid and upon submission of documents specified hereunder:

(i) Four copies of supplier's invoice

showing contract number, goods description, quantity, unit price and total amount;

(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;

(iii) Four Copies of packing list identifying contents of each package;

(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;

(v) Manufacturer's/Supplier's warranty certificate;

(vi) Manufacturer's own factory inspection report and

(vii) Certificate of origin by the chamber of commerce of the concerned country;

(viii) Goods receipt certificate by the ultimate consignee on receipt of goods at this site/warehouse as per section XVII of this tender document.

d) On validation and Final Acceptance Certificate by Purchaser:

Balance 10 % payment would be made against **IQ, OQ documents approved by the purchaser** along with '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. **In the event of delayed Validation and FAT for the reasons attributable by the purchaser, the final 10% payment (subject to recoveries if any) shall be released within 6 months from the date of delivery of materials at site.**

All milestones payments shall be made 30 days from the date of submission of necessary documents.

2.	**Section I & XXIII:** Closing date & time for receipt of Tender: 02-02-2016, 10:30 Hrs	Closing date & time for receipt of Tender: **16-02-2016**, 15:00 Hrs
3.	**Section I & XXIII:** Time and date of opening of Techno-Commercial Bids: 02-02-2016, 11:00 Hrs	Time and date of opening of Techno-Commercial Bids: **16-02-2016**, 15:30 Hrs
4.	**Section XXIII:** 3. Delivery: 10(Ten) months from the date of issue of Letter of Intent (LOI). 8. Warranty Period: 12(Twelve) months from the date of Completion.	3. Delivery: **8(Eight) months** from the date of issue of **Purchase Order (PO).** 8. Warranty Period: 12(Twelve) months from the date of Completion of the project (IQ, OQ, FAT) or **18(Eighteen) months from the date of delivery of materials at site whichever is earlier.**
5.	**Section IV** **Clause 8.6, Page 30/97** The purchaser's/consignee's contractual right to inspect, test and, **if necessary**, reject the goods after the goods' arrival at the final destination shall have no bearing of the fact that the goods have previously been inspected and cleared by purchaser's inspector during pre-despatch inspection mentioned above.	The purchaser's/consignee's contractual right to inspect, test and, **if found that the equipment differs from the original inspected and approved equipment**, reject the goods after the goods' arrival at the final destination shall have no bearing of the fact that the goods have previously been inspected and cleared by purchaser's inspector during pre-despatch inspection mentioned above.
6.	**Clause 11, Page 31/97** If the equipment is not commissioned and handed over to the consignee within 3 months, the insurance will be extended by the supplier at their own cost till the successful installation, testing, commissioning and handing over of the goods to the consignee.	If the equipment is not commissioned and handed over to the consignee within 3 months, the insurance will be extended by the supplier at their own cost till the successful installation, testing, commissioning and handing over of the goods to the consignee. **In case the delay in the installation and commissioning is due to delay in handing over of the site to the supplier by the consignee, such extensions of the insurance will still be done by the supplier, but the insurance extension charges at actuals will be reimbursed for extended period.**
7.	**Clause 12, Page 31/97** b) In case the production of the spare parts is discontinued: i. Sufficient advance notice to the Purchaser/Consignee before such discontinuation to provide adequate time to the purchaser to purchase the required spare parts etc., and ii. Immediately following such discontinuation, providing the Purchaser/Consignee, free of cost, the designs, drawings, layouts and	b) In case the production of the spare parts is discontinued: i. Sufficient advance notice to the Purchaser/Consignee before such discontinuation to provide adequate time to the purchaser to purchase the required spare parts etc., and **ii.** Immediately following such discontinuation, **alternate**

	specifications of the spare parts, as and if requested by the Purchaser/Consignee.	**specification/make/model/preferred vendor, which is compatible to the supplied equipment must be provided.**
8.	**Clause 13, Page 31/97 & 32/97** **13. Incidental services** 13.1 Subject to the stipulation, if any, in the SCC (Section – V), List of Requirements (Section – VI) and the Technical Specification (Section – VII), the supplier shall be required to perform the following services. i. Installation & commissioning, Supervision and Demonstration of the goods ii. Providing required jigs and tools for assembly, **minor civil works** required for the Completion of the installation.	**13. Incidental services** 13.1 Subject to the stipulation, if any, in the SCC (Section – V), List of Requirements (Section – VI) and the Technical Specification (Section – VII), the supplier shall be required to perform the following services. i. Installation & commissioning, Supervision and Demonstration of the goods ii. Providing required jigs and tools and **any other necessary requirements** for assembly for the Completion of the installation.
9.	Page 4/97 Vendor requested clarification on **PQ** Quote for the unit against the URS, along with all options. The price to include all spare parts; documentation; packing; freight charges; start-up & commissioning; complete qualification package **(FAT, SAT, DQ, IQ, OQ, PQ)** and training and charges whatsoever required to complete the task in all respects to ensure the equipment operation is in accordance with the requirements of design documents.	Performance Qualification (PQ) support required for the purchaser to be provided by the Vendor.
10	Page 4/97 Vendor requested clarification on **Risk Analysis** Involve with the purchaser and the consultants to establish documented evidence that the proposed design of the system is in compliance with the GMP requirements mentioned in the User Requirement Specification, Installation requirement specification and Risk Analysis.	Risk Analysis document shall be done by the purchaser/consultant along with the support of the vendor. This analysis will be done during the DQ / functional specification of the equipment.
11	Page 14/97 **<u>Techno-Commercial Bid (Un priced Bid)</u>** Certificate of country of origin by the bidder from abroad. (Chamber of commerce)	"Country of Origin" declaration from the vendor in Letter head is sufficient.

12.	Page 21/97 IRS and URS given in Annexure-I, II & **III,** not duly filled, signed and stamped.	IRS and URS given in Annexure-I, & II not duly filled, signed and stamped.
13.	Page : 43/97 ACCESS TO SITE All necessary access to working area will have to be made and maintained by the Supplier. Such temporary constructions shall have to be removed after completion of the work or if so advised by Purchaser at any point of time at no extra cost. LABOUR AT SITE Purchaser will not allow any temporary or permanent hutments or colonies at the Work Site. The Supplier will have to make his own arrangement for such labour camp(s) away from site at his own cost. WATER AND ELECTRICITY FOR CONSTRUCTIONS The electricity, if available at site will be provided to the Supplier at a single point on a chargeable basis. The Supplier shall pay the Purchaser at the prices stated. The quantities consumed shall be determined by the Purchaser, who shall include the amounts due as deductions in Interim and final payment certificates. The Supplier shall, at his risk and cost, provide any apparatus necessary for such determination and for his use of these services. The Supplier should make his own arrangements for providing back up power supply (like D.G sets of required capacity) during the work.	Installation Requirement Specification (IRS) Clause 7.0 Page 27/31 &28/31 shall be applicable for these points.
14.	Page 45/97 The Supplier shall be responsible, in all respects, for the co-ordination of all the services work including electrical, piping and modular works or works of other Purchaser appointed agencies. Supplier shall ensure proper co-ordination for the inter-dependent / related activities between himself, services sub-Suppliers and other nominated, Specialist Suppliers etc.	The Supplier shall be responsible, in all respects, for the co-ordination of all the services work including electrical, piping and modular works or works of other Purchaser appointed agencies. Supplier shall ensure proper co-ordination for the inter-dependent / related activities between himself, services sub-Suppliers and other nominated, Specialist Suppliers etc.**(if required for the completion of this Project)**

	The Supplier shall arrange the water, electricity and scaffoldings required on their own. Page 46/97 The Supplier shall be responsible to work out a co-ordinated work schedule with the HVAC, Civil, Electrical, Mechanical &Piping and other nominated Suppliers.	The Supplier shall arrange the water, electricity and scaffoldings required on their own **(if required for the completion of the project).** Deleted
15	Page 47/97 Point's related to civil works.	Deleted
16	**General Points :** i. Opening of LC. ii. Request of Letter of Credit for Domestic Supplies iii. Vendors requested foreign currency fluctuation clause for items to be imported from foreign country.	i. Letter of Credit shall be opened within 10 days from the date of receipt LC draft confirmation from Vendor. ii. No Letter of Credit for Domestic supplies. iii. HBL reply: Quote the INR & Foreign currency portion separately and arrive at the total INR contract value with the exchange rate prevailing at the time of Bid Submission. However, HBL shall pay the foreign currency portion to the vendor at the time of supply at the prevailing exchange rate.

S. No.	Clarifications on URSs / Data sheets	
B	DS: NPI-120310-EQP-URS-CCF 01 – Continuous Centrifuge	
	Specific revision in the URS	
	URS Point number and excerpt* / description of the specification *	Point modified as / Comment
1.	**Table no. 1** **Point no. 2.0, 3** Gapless discs | For high sanitary requirements	**Table no. 1** **Point no. 2.0, 3** Gap free of spacers weld on disks | For high sanitary requirements
Table no. 2		
2.	**Point no. 2.0, 1** S No. | Description | Specification | Remarks from vendor	**Point no. 2.0, 1** S No. | Description | Specification | Remarks from vendor

S. No.	Clarifications on URSs / Data sheets							
	1	Through--put	50-500 LPH					
	2	PCV value of product at inlet	10% - 15%		1	Through--put	For HepB, Cell washing- 300 to 500 LPH Clarification - 50 to 150LPH For Hib, Clarification - 100 to 150 LPH	
	4	Disk Diameter	Vendor to specify					
	5	No. of disks	01					
	6	Speed (rpm)	7000-12000 rpm		2	PCV value of product at inlet	15% to 25% for Hep B 1% to 2% for Hib	
	7	Sludge Tank	Sludge tank required for collection of pellet. Minimum capacity1.4L Solid Discharge shall be collected in the sludge tank.		4		deleted	
					5		deleted	
	11	SIP – steam in place	Automatic SIP of the bowl / inlet and outlet lines / Solid Discharge i.e. the entire system shall be possible by injecting pure steam through upstream piping of the centrifuge lead through the filters and outlet from the downstream lines.	Steaming temperature ≥ 100°C	6	Speed (rpm)	7000-12000 RPM for Hep B 7000-12000 RPM for Hib	
					7	Solid Holding space	Minimum 4L (Partial ejection shall be available)	
	13	Gapless discs	The disk design as gapless welded space for highest sanitary requirements	Disk design: gapless welded spacers for highest sanitary vibration control should be provided.	11	Manual Steaming in place [SIP}	Manual Steaming in place for all product contact lines along with filter lines. The temp.recording during the steaming process must be provided). PRV, Needle value, Steam trap, Recorder, Temperature sensor, e.t.c are required for sterilisation and it will be in the scope of the vendor	
					13		**Deleted**	
	14	Vibration monitoring system	To monitor the vibration in the system during process and control should be provided.		14	Vibration monitoring system	To monitor the vibration in the system during process should be provided.	
3.	**Point no. 2.1.3 Liquid Discharge area**: feed once separated must be conveyed out of the Continuous Centrifuge, without any change of temperature in process and other required parameters. Provision for two open outlets (TC ended) in T shape shall be considered One outlet will be used for transferring liquid out of the Continuous Centrifuge tanks to the collection tank / process drain.				**Point no. 2.1.3 Liquid Discharge area**: feed once separated must be conveyed out of the Continuous Centrifuge, without any change of temperature in process and other required parameters. Provision for two open outlets (TC ended) in T shape shall be considered One outlet will be used for transferring liquid out of the Continuous Centrifuge tanks to the collection tank / process drain.			

S. No.	Clarifications on URSs / Data sheets	
	Other will be used to recirculate the supernatant discharge back to the feed input vessel. Both the outlets shall be provided with pneumatic valves which shall be controlled by the readings of the Turbidity sensor. • If Turbidity Reading ≤ set point – Output of the tank will be routed to the collection tank / process drain. • If Turbidity Reading > set point – Output of the tank will be recirculated back to the feed vessel. Turbidity sensor reading shall provide input to control the back pressure for product inlet and outlet. **Note: It must also be possible to operate the valves manually based on visual observations in the view glass.**	Other will be used to recirculate the supernatant discharge back to the **feed line.** Both the outlets shall be provided with pneumatic valves which shall be controlled by the readings of the Turbidity sensor. • If Turbidity Reading ≤ set point – Output of the tank will be routed to the collection tank / process drain. • If Turbidity Reading > set point – Output of the tank will be recirculated back to the feed vessel. **Note: It must also be possible to operate the valves manually based on visual observations in the view glass.**
4.	**Point no. 2.1.4** Solid Discharge area: After separation, the cell mass / solid gets collected in the sludge collection tank.	**Point no. 2.1.4** Solid Discharge area: After separation, the cell mass / solid gets collected in the solid cyclone.
5.	**Point no. 2.1.12** The installed wheels on control module must be made of material that does not damage the clean room floors.	**Point no. 2.1.12** Control module can be the part of the equipment skid
6.	**Point no. 2.1.14**	**Point no. 2.1.14** Point Deleted
7.	**Point no. 3.2.3** Turbidity meter and view glass must be installed for monitoring and controlling the discharge. If the turbidity is above the set point the outlet shall be recirculated to the 1200 L feed vessel.	**Point no. 3.2.3** Turbidity meter and view glass must be installed for monitoring and controlling the discharge. If the turbidity is above the set point the outlet shall be recirculated to the feed line.
8.	**Point no. 3.5.2** Turbidity meter and view glass must be installed for monitoring and controlling the discharge. If the turbidity is above the set point the outlet shall be recirculated to the 1200 L feed vessel.	**Point no. 3.5.2** Turbidity meter and view glass must be installed for monitoring and controlling the discharge. If the turbidity is above the set point the outlet shall be recirculated to the feed line.
9.	**Point no. 4.2.3** Turbidity meter and view glass must be installed for monitoring and controlling the supernatant. If the turbidity is above the set point the outlet shall be recirculated to the 800 L feed vessel.	**Point no. 4.2.3** Turbidity meter and view glass must be installed for monitoring and controlling the supernatant. If the turbidity is above the set point the outlet shall be recirculated to the feed line.
10.	**Point no. 4.3.3** The separated liquid will be recirculated to the feed vessel and collect in process vessel which shall be controlled through turbidity sensor.	**Point no. 4.3.3** The separated liquid will be recirculated to the feed line or collected in process vessel which shall be controlled through turbidity sensor

S. No.	Clarifications on URSs / Data sheets	
11.	**Point no. 7.1.1** Temperature , pressure , flow rate and Turbidity control	**Point no. 7.1.1** Temperature (only monitoring) , pressure , flow rate and Turbidity control
12.	**Point no. 7.1.2** It must be possible to manually change the CIP priority and CIP recipe.	**Point no. 7.1.2** It must be possible to manually change the CIP priority and CIP time.
13.	**Point no. 7.2.2**	**Point no. 7.2.2** -Deleted
14.	**Point no. 7.2.3** Emergency air pressure	**Point no. 7.2.2** Compressed air pressure
15.	**Point no. 7.2.6** Deviation from the set point flow during separation process	**Point no. 7.2.6** Deleted
16.	**Point no. 7.2.7** Temperature Alarm	**Point no. 7.2.7** Temperature Alarm -Deleted
17.	**Point no. 7.2.8**	**Point no. 7.2.8** -Deleted
18.	**Point no. 7.2.10**	**Point no. 7.2.10**-Deleted
19.	**Point no. 7.2.11**	**Point no. 7.2.11** -Deleted
20.	**Point no. 7.3.1** The flow through the Continuous Centrifuge must be regulated to a set point 50 to 500 LPH	**Point no. 7.3.1** The flow through the Continuous Centrifuge must be regulated as specified under section 2.0
21.	**Point no. 7.3.2** The back pressure for the Continuous Centrifuge at the supernatant outlet must be regulated to a set point range of 5-7 bar.	**Point no. 7.3.2** The back pressure for the Continuous Centrifuge at the supernatant outlet must be regulated to a set point range of 0-6 bar.
22.	**Point no. 7.3.4** The speed of rotation for the ball in the Continuous Centrifuge must be controlled to 7000 to 12000 rpm.	**Point no. 7.3.4** The speed of rotation for the bowl in the Continuous Centrifuge must be controlled in the specified range.
23.	**Point no. 7.3.6** Sanitization of Continuous Centrifuge, and connecting pipes must ensure a temperature of 100 °C for ≥30 min.	**Point no. 7.3.6** Sterilisation of Continuous Centrifuge, and all process pipings must ensure a temperature of >121 °C
24.	**Point no. 7.3.7** After CIP of Continuous Centrifuge, the inside surface (plates inside the Continuous Centrifuge) must be visually clean.	**Point no. 7.3.7** After CIP of Continuous Centrifuge, the inside surface (plates inside the Continuous Centrifuge) must be visually clean. Riboflavin test shall be used for FAT

S. No.	Clarifications on URSs / Data sheets	
25.	**Point no. 7.4** Level | in solid tank to monitor the amount of solids generated | Load cell / Vender to spec	**Point no. 7.4** Level | in solid tank to monitor the amount of solids generated | Level switch
26.	**Point no. 7.4** Flow rate | At upstream and downstream of centrifuge to monitor the flow of centrifuged bulk | Flow transmitt / indicator / controller.	**Point no. 7.4** Flow rate | At downstream of centrifuge to monitor the flow of centrifuged bulk | Flow transmitters / indicator / controller.
27.	**Point no. 7.4** Flow rate | To monitor flow rate of Seal cooling liquid / Operating liquid for bowl lifting | Flow transmitters indicator / controller.	**Point no. 7.4** Pressure | To monitor pressure of Seal cooling liquid / Operating liquid for bowl lifting | Pressure switch
28.	**Point no. 7.5.2** SS 304 Control panel (IPC) with 21 CFR the following (not limited to these) • Display of time, temperature, pressure, Turbidity, flow rate and RPM • Provision for manual operation, CIP/SIP time duration, Emergency stop Button Also refer IRS	**Point no. 7.5.2** HMI shall include of the following (not limited to these) • Display of time, temperature, pressure, Turbidity, flow rate and RPM • Provision for manual operation, CIP/SIP time duration, Emergency stop Button • Batch data to be stored in SD card/USB and also stripchat recorder, real time printer to be provided
29.	**Point no. 7.6.7** Continuous Centrifuge should meet ASME standards, ASME section VIII,DIV.1,ASME BPE 2012,bio-procecessing equipment, GAMP 5, a risk based approach to compliant ,US FDA 21 CFR part 11 for electronic records and electronic signatures, GAMP for validation of automation system, IEC 60529 standards for protection of panel enclosure.	**Point no. 7.6.7** Refer only IRS applicable points
30.	**Point no. 7.7.5** Emergency air connection to provide back up for the lubrication air system	**Point no. 7.7.5** Compressed air connection to provide back up for the lubrication air system
31.	**Point no. 7.7.6** Peristaltic pump is required for infeed of intermediate solution and for the outfeed of the fractions	**Point no. 7.7.6** Peristaltic pump is required to feed the centrifuge (vendor scope)
32.	**Point no. 7.7.10** User will provide the cleaning agents and supplier shall give the compliance report of the cleaning agents coming in product contact surfaces	**Point no. 7.7.10** Equipment supplier to provide the MOC of each component and user to check the compatible cleaning solutions
33.	**Point no. 7.7.11** Point included: Equipment shall be provided with Hydro hermitic design	

<table>
<tr><th>S. No.</th><th>Clarifications on URSs / Data sheets</th></tr>
<tr><td>34.</td><td>Point no. 7.7.1
Point included: Double mechanical seal in the neck bearing is must to separate the sterile area from non sterile area</td></tr>
<tr><td>35.</td><td>URS Annexure 2: List of preferred make of components
<table>
<tr><td>4</td><td>Temperature sensor</td><td>Negele/ Radix/E&H/Yocogawa</td></tr>
<tr><td>5</td><td>Turbidity sensor</td><td>Mettler Toledo/Hamilton/E&H</td></tr>
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<tr><td>20</td><td>Bowl</td><td>Zook/Elfab/ Fike</td></tr>
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<tr><td>20</td><td colspan="2">Deleted</td></tr>
</table></td></tr>
<tr><td colspan="2">IRS Points: All the points of the IRS except below mentioned points would be applicable for this equipment and the points mentioned as “Modified as” will be applicable for this equipment</td></tr>
<tr><td>36.</td><td>Insulation, cladding and civil work related points mentioned in the document are not related to this equipment</td></tr>
<tr><td>37.</td><td>Point no. 5.1, 3
FDA Guidance for Industry: For equipment used in sterilization such as autoclave / DHS etc</td></tr>
<tr><td>38.</td><td>Point no. 5.1, 6
ASME: For all pressure vessels / reactors / fermenters / autoclave / sterilizers etc</td></tr>
<tr><td>39.</td><td>Point no. 5.1, 7
ANSI / NSF 49-2008</td></tr>
<tr><td>40.</td><td>Point no. 5.1, 8
ISO 14664</td></tr>
<tr><td>41.</td><td>Point no. 5.1, 9
ISO 8362</td></tr>
<tr><td>42.</td><td>Point no. 5.4.1
“filling line and < 0.8µ Ra for Lyophiliser” is removed</td></tr>
<tr><td>43.</td><td>Point no. 5.6
21CFR Part11</td></tr>
<tr><td>44.</td><td>Point no. 5.9.6.42
Modified as : Only the sequence of operations to be provided</td></tr>
<tr><td>45.</td><td>Point no. 5.9.6.46
Modified as: Delivered software must be forwarded on suitable Storage medium in a format suitable for</td></tr>
</table>

S. No.	Clarifications on URSs / Data sheets
	installation. customization and minor modification to create new recipe shall be possible.
46.	**Point no. 5.9.6.51** Supplementing the P&I diagram: A valve position matrix must be developed for complex processes. The conditions of valves and engines must be described in the various process steps.
47.	**Point no. 5.10.1** Modified as: A special training for operators, supervisor, and maintenance, electrician staff has to be included in the offer.
48.	**Point no. 5.10.2** Modified as: Training must be carried out by qualified personnel. Training documents must be handed over to each participant (by the customer) at the beginning of the training. A training certificate describing the training subjects must be worked out.
49.	**Point no. 5.11.9** Air break for drain is not required (applicable for other pages of the document also)

For HLL Biotech Limited

Chief Executive Officer

nne pharmaplan®

NNE Pharmaplan India Limited, #.9, BEL Air Drive, 4th Floor, Bellary Road, Ganganagar, Bangalore - 560032, India

List of Attendees

Date: 19-01-2016

Client: M/s HLL Biotech Limited

Venue: M/s HLL Biotech Limited, Chennai

Project: Integrated Vaccine Complex, at Chengalpattu

Subject: Pre-bid Meeting for Continuous Centrifuge

SL NO.	NAME	COMPANY	CONTACT NO:	EMAIL ADDRESS	SIGNATURE
1	Atal Singh	GEA WESTFALIA	7738339393	atalsingh@gea.com	Atal
2.	S. LAKSHMANAN	ALFA LAVAL (I) LTD.	9741111382.	S.LAKSHMANAN@ ALFALAVAL.COM	
3.	S.T. Phansekar	ALFA LAVAL (I) LTD.	9822081032	Sameep.phansekar@ alfalaval.com	
4.	Abhilash.T	HBL	7303550556	abhilash.t@hllbiotech	
5	Ch. Rajesh	HBL	9440207523	rajeshch@hllbiotech	
6.	Dr. SUBRAHMANYAM V. MANTHA	HBL	9003431219	subrahmanyamvm@hllbiotech.com	
7	G. NARASIMHA REDDY	HBL	8754450128	narasimhareddy@hllbiotech.com	
8	YOGESHA-MJ	NNE	9740782605	mjy@nnepharmaplan.com.	
9	VIGNESHWARAN.T	HBL	9025041256	Vigneshwaran.t e hllbiotech.com	
10	S. G. Suresh	HBL	9500053552	Sureshsg@hllbiotech.com	19.01.2016