

MINUTES OF THE MEETING

PRE-BID MEETING

TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF CLEAN ROOM EQUIPMENT AT PII, COONOOR

Document No. : NPI/110831/EQP/TD/08

Venue : HLL Biotech Limited, Chennai

Date : 14th February, 2017

Project : Revival of DPT Vaccines manufacturing facility at PII, Coonoor

Attendees : See attached list of attendees

Issued on : 15th February, 2017

Issued by : Mr.Suresh .S (DGM – Procurement)

Agenda	
1.	Pre-bid Meeting for Supply, Installation, Commissioning and Validation of clean room equipment at PII, Coonoor.

Sl.No.	Amendments to tender & clarification on queries raised by vendors to tender document
1.	GIT Clause no. 10 in Page no 16 of 93, under Techno-Commercial Bid (Un priced Bid): point vii) Performance Statement as per section IX along with relevant copies of orders and its users' completion certificate, <i>This is amended as mentioned below:</i> vii) Completion certificate as per section IX along with relevant purchase order copies".
2.	This tender is the single schedule/package. So, Tenderer shall quote for all items.
3.	"C" Form will not be issued. Tenderer shall be entirely responsible for all taxes, duties, fees, levies etc. incurred until delivery of the contracted goods to the purchaser.
4.	Successful tenderer's earnest money will be returned, after receipt of performance security from that tenderer.
5.	Section IX Qualification Criteria in page no 53 of 93, point no 2. The vendor should have successfully supplied, installed, commissioned and validated at-least Ten (10) numbers of each clean room equipment's i.e. Bio Safety Cabinet, Laminar Air Flow (LAF) units, Ceiling Suspended Laminar Air Flow (CLAF) units, Dispensing/sampling Booth (RLAF) units) in last three years in the field of Pharma /Bio-pharma / Vaccine / Biotech facility. (Installation certificate or Completion certificate of equipment's to be attached). <i>This is amended as mentioned below:</i> 2. The vendor should have successfully supplied, installed, commissioned and validated at-least Ten (10) numbers of each clean room equipment's i.e. Bio Safety Cabinet, Laminar Air Flow (LAF) units, Ceiling Suspended Laminar Air Flow (CLAF) units, Dispensing/sampling Booth (RLAF) units) in last three years from the date of publish of this tender in the field of Pharma /Bio-pharma / Vaccine / Biotech facility. (Installation certificate or Completion certificate of equipment's & its purchase orders to be attached).
6.	The CMC will commence from the date of expiry of the Warranty Period.
7.	Cost of CMC will be added for Ranking/Evaluation purpose.
8.	The comments/approval from the client/purchaser on GA drawings of equipment will be provided in 3 working days, for starting the production of equipment.
9.	For Bio safety Cabinets as per technical specification: SS 304 exhaust duct for the height of 1.5 m to be provided (i.e. 300 mm above false ceiling from equipment)
10.	Bio Safety Cabinet shall be with double stage filtration as per technical specification.
11.	For Bio Safety Cabinet: Incinerator not required.
12.	Approved make for CFL & UV Light for all equipment: Philips & Crompton Greaves
13.	The cost of Comprehensive Maintenance Contract (CMC) which includes preventive maintenance including testing & calibration as per technical/ service /operational manual of the manufacturer, labour and spares, after satisfactory completion of Warranty period may be quoted for next 5 years on yearly basis for complete equipment
14.	Blower MOC for all equipment shall be powder coated GI.

15.	Instrument to be used for validation shall have master calibration certificate with traceable to NIST.
16.	All LAF worktable shall be with solid type work table designed to with stand 150 kg weight as per technical specification
17.	For all Dispensing/Sampling/RLAF: The size of dead work table (Capsule Perforation) shall be designed to suit the booth size & for required operation purpose.
18.	BSC Cabinets (Class II A2 type): Total quantity of 15 nos. <i>The Quantity & type is amended as mentioned below:</i> BSC Cabinet (Class II A2 type): Total quantity of 14 nos. BSC Cabinet (Class II B2 type): Total quantity of 1 no. Please refer the amended Technical data sheet of BSC-01 attached as “Annexure-01” with this pre-bid MOM.
19.	Henceforth, this minutes of pre-bid meeting will be part of the original tender document.

For HLL Biotech Limited




DGM (Procurement)


LIST OF ATTENDEES


Subject : Pre Bid Meeting for Supply, Installation, Commissioning and Validation of Clean Room Equipment at PII, Coonoor
Date & Time : 14.02.2017 @11.00 AM.
Venue : HBL Corporate Office, Chennai

S.NO	Name & Designation	Organization	Contact No	Signature
1	Ravnaak Pote Mktg. & Sales Engg.	Dyna Filters, Pune	8554022973	
2	T.abeuchulats hmeiah	Isolan	9382635463	
3.	Aneezuddin .R .S Senior Account Manager	TechBio Solution	9003900187	
4.	Dr. Ruban. Technical Director	TechBio Solution	9003900196	
5.	MILIND PUNWATKAR Mkt and sales	GMP Tech	9769258074	
6.	Dr. B. SEKAR Director	PII, Coonoor		
7.	Dr. B. SUNDARAN Deputy Director	PII, Coonoor	9442083803	 14/2/2017
8.	A. ANTO FELIX	HLL	9444486955	 14/2/2017
9	T. Lalitha	PII - Coonoor	9443091544	 14/2/17
10.	B. Annamalai	PII Coonoor	9443809913	 14/2/17
11.	Dr. N. Sivananda	PII, Coonoor	9486921166	
12.	Ragul. P. K	HBL	9952742712	 14/02/17
13.	S. Pandeyan	HBL	9751557706	

DATA SHEET			
HLL Biotech Limited, CHENNAI			
one pharmaplan	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR		 HLL BIOTECH LIMITED <small>(A subsidiary of HLL, a Public Limited Company, A Government of India Enterprise)</small>
	Biosafety Cabinet		
	PROJECT #:	110831	
	EQ. ID #:	See Annexure -1	
	DOCUMENT # :	DS/BSC 01	
1	Process requirements		Vendor Comments (Yes/No)
1.1	A Biosafety Cabinet (BSC) is the primary barrier protection for individuals working with bio hazardous materials. Procedures that could create airborne biohazards should always be performed in a BSC as it protects workers and the environment from aerosols or droplets that could spread biohazardous material.		
2	Technical Specification		
2.1	Model	cGMP BSC	
2.2	Type	Class II A2 type & Class II B2 type (See Annexure-1)	
2.3	Inner Area (mm)	See Annexure-1	
2.4	Overall Area (mm)	Vendor to specify exact dimension	
2.5	Type & Capacity	a) Recirculation & exhaust as per Class II A2 type & Class II B2 type b) Double Stage filtration	
2.6	Pre- Filter	EU - 6 Efficiency > 95% Size: 5 µ	
2.7	HEPA Filter	H -14 Efficiency >99.997% Size: 0.3 µ	
2.8	UV light	a) The UV lamp installed shall be mounted out of the operator's line of sight and the radiation output should not be less than 40 microwatts per square centimeter at a wavelength of 254 nanometers (nm). b) UV light with digital Hour Meter (Re-settable type)	
2.9	Air Velocity	0.45 m/s ± 20% from 6" below the HEPA filter	
2.10	Electrical Requirement	220-230 V, 50 Hz , Single phase	
2.11	Magnehelic Gauge	For pre-filter & HEPA filter	
2.12	Speed Control of motor	Manual speed adjustable with stepless regulator	
2.13	Quantity	Class II A2 type: 14 nos. (See Annex -1) Class II B2 type: 1 nos (See Annex -1)	
3	Material Of Construction		
3.1	Body Construction	SS 304 (1.2 mm)	
3.2	Support Stand	SS 304	
3.3	Coving	SS 304 in built	
3.4	Working Table	The work tray shall be integrated with the front air grille, for joint-free construction of SS304 (1.2 mm)	
3.5	Inner surface	SS 304 (1.2 mm)	
3.6	Side Panels	SS 304 (1.2 mm)	
3.7	Back Panels	SS 304 (1.2 mm)	
3.8	Front Glass	UV protected tempered glass with counter weight arrangement	
3.9	Wheels	PU castor wheels with lockable and level adjustment type (for floor variations)	
4	Specific requirement		
4.1	In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points.		
4.2	Unit shall be provided with 3 m long power cable with 16 Amps 3 Pin plug top.		
4.3	HEPA (H-14) (High-Efficiency Particulate Air) shall be provided : • The BSC Class II A2 type. Typical efficiency of 99.997% at MPPS, 0.3. • ISO Class 5 needs to be maintained during operation		
4.4	UV Protected glass front sash with counter weight arrangement • Optimum resistance to and filtering of germicidal UV radiation • Higher optical quality and less reflection and glare off of glass surface • High tolerance to heat • The interlayer should dampen the sound significantly		
4.5	2 no.- magnehelic gauges to be provided to monitor the differential pressure across the HEPA filter & Pre-filter		
4.6	Manual damper adjustment shall be provide to control in flow and exhaust (for class II A2 type)		
4.7	Manual speed control of motor (with manual stepless regulator) shall be provided to overcome the filter choking and to maintain the velocity of 0.45m/s ±20%.		
4.8	Two electrical sockets, (6/16A on 230 volt models), located one on each side and covered with stainless steel covers and two cock (for air & gas inlet) and drain valve to be provided.		

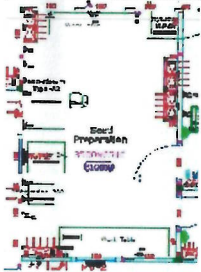


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	Biosafety Cabinet	
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	EQ. ID #:	See Annexure -1
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4.9	The interior work area is formed from a single piece of stainless-steel with large radius to simplify cleaning	
4.10	Integrated sash proximity contacts sensor shall be provided. So that, UV lamp shall be interlocked with blower, sash, fluorescent lamp and UV lamp can be switched on only when the front sash is completely closed, otherwise it should give alarm. Also, alarm shall be triggered if the front shash is raised more than the safe working height.	
4.11	PAO test port to be provided.	
4.12	SS 304 exhaust duct for the height of 1.5 m to be provided (i.e. 300 mm above false ceiling from equipment)	
4.13	All materials shall be made of durable type and have to be resistant against surface cleaning and wiping disinfecting using common detergents, disinfectants (chlorine free) and 70% Ethanol / IPA	
4.14	The work tray shall be integrated with the front air grille, for joint-free construction of SS 304 (1.2 mm)	
4.15	Feather touch touch keypad shall be provided at the top of the front glass for blower, lights & sockets. All switches ergonomically located for operator convenience.	
4.16	Blower: a) Blower shall be permanently lubricated b) Motor blower assembly MOC : Aluminum	
4.17	Approved make for motor blower assembly: EBM	
4.18	Approvedmake for filter : AAF/Freudenberg Approved make for Magnehelic Gauge : Dwyer	
4.19	UV light with digital hour meter (re-settable type) shall be provided.	
5	Other requirements	
5.1	Moving parts between the technical and the clean areas are not permitted. Necessary shafts and moving parts have to be tightly sealed.	
5.2	Cleaning shall be done manually.	
5.3	Illumination: i. Unit to be provided with adequate illumination at the work table by means of fluoresent light panel concealed at the upper portion of the unit. ii. The illumination at the work table is to be minimum 400 Lux	
5.4	Ultraviolet Light i. Optimal wattage of UV light to be incorporated for sanitization of the chamber area ii. The UV lamp installed shall be mounted out of the operator's line of sight and the radiation output should not be less than 40 microwatts per square centimeter at a wavelength of 254 nanometers (nm). iii. UV light with Hour Meter (Re-settable type)	
5.5	Vendor to give code numbers for each component	
5.6	In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points e. g. motors, filters, etc.	
5.7	The design shall be maintenance friendly for the ease of replacement of filters	
5.8	All parts of the machine exposed in A/B area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants	
5.9	Equipment design must realize zero contamination.	
5.10	Vendor to submit detailed fabrication drawing for approval before fabrication.	
5.11	The following test to be conducted at site during qualification 1. air velocity test 2. Filter Integrity Test 3. Flow Visualization Test (videography) 4. Non viable Particle Count 5. Recovery Test 6. Lux Level 7. Sound Level	
6	Regulatory guidelines / standards	
6.1	ISO 14644 – 1 (For Cleanliness Class)	
6.2	ISO 14644 – 3 (For HEPA filter integrity testing & Velocity testing)	
6.3	EU-GMP-Guideline Part 1, Annexes 1, 11 & 15	
6.4	Schedule M of Indian Drugs and Cosmetics Act	
6.5	Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing and Holding of Drugs	

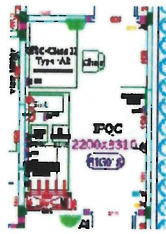
DATA SHEET						
HLL Biotech Limited, CHENNAI						
nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR			 HLL BIOTECH LIMITED <small>Subsidiary of HLL Lifecare Limited A Government of India Enterprise</small>		
	Biosafety Cabinet					
	PROJECT #:	110831				
	EQ. ID #:	See Annexure -1				
	DOCUMENT # :	DS/BSC 01				
7	Safety requirement					
7.1	NA					
7.2	Noise level below 75 decible.					
7.3	Appropriate closure of all the rotating parts.					
8	Documents					
	Vendor to submit detailed fabrication drawing for approval before fabrication.					
8.1	Phase 1: Post ordering and prefabrication stage of the equipment					
8.1.1	Functional design specification containing:					
8.1.2	Equipment descriptions					
8.1.3	Equipment operation steps					
8.1.4	List of failure indications and interlocks (as applicable)					
8.1.5	Critical list of major component, devices and instruments with their specific functions, specs and data sheets.					
8.1.6	GA/ Schematic diagram of the equipment					
8.1.7	DQ Specification					
8.1.8	IOQ specification					
8.2	Phase - 2					
8.2.1	Factory Acceptance Test not required for this equipment					
8.3	Phase - 3					
8.3.1	Vendor shall provide the following documents in the delivery package in minimum 2 sets. The delivery package shall reach the site of user at least 15 days before the delivery equipments for the engineering check of the documents.					
8.3.2	Shipping checklist.					
8.3.3	Operation and maintenance manuals; preventive maintenance instruction & schedule for equipment major component as well as the operating system. Control system operation manual. Cleaning procedures to be provided.					
8.3.4	Operation and maintenance manuals for the bought out items (as applicable).					
8.3.5	Drawings: Electrical, instrumentation, final GA drawing etc.					
8.3.6	Spare and/ or change parts list with ordering information.					
8.3.7	MOC certificates for all product contact surfaces.					
8.3.8	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.					
8.3.9	Comprehensive 1 year warranty from the date of completion.					
8.3.10	Types of Lubricant and Lubrication instructions. Food grade certificates.					
8.3.11	The Vendor shall provide start-up services through successful completion of the site acceptance test. The site acceptance test will be a repeat of the factory integration test performed at the Vendor's facility.					
9	Timelines					
	NA					
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.					
	AFI Approved for Enquiry			AFO Approved for Ordering		
02	2016-11-23	SECC	SDBB	L	L	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2
NNE Pharmaplan	Prepared By	Name: Designation:		Sign & Date:		
	Approved By	Name: Designation:		Sign & Date:		
HLL Lifecare Limited	Reviewed By	Name: Designation:		Sign & Date:		
	Approved By	Name: Designation:		Sign & Date:		
Pastuer Institue of India	Reviewed By	Name: Designation:		Sign & Date:		
	Reviewed By	Name: Designation:		Sign & Date:		
	Approved By	Name: Designation:		Sign & Date:		

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	Biosafety Cabinet					
	PROJECT #:	110831				
	EQ. ID #:	See Annexure -1				
	DOCUMENT # :	DS/BSC 01				
ANNEXURE - 01						
EQUIPME T ID	Block Name	Room Name	Room No	Quantity	Working Area Dimensions (WxDxH) mm	Remarks
CLASS II A2 TYPE						
B1-BSC 01	Diphtheria Block	Seed Preparation	B1G047	1	1200 x 600 x 750 mm	10L flask handling
B1-BSC 02	Diphtheria Block	IPQC	B1G057	1	900 x 600 x 600 mm	IPQC testing
B1-BSC 03	Pertussis Block	Seed Preparation	B1G008	1	1200 x 600 x 750 mm	10L flask handling
B1-BSC 04	Pertussis Block	IPQC	B1G018	1	900 x 600 x 600 mm	IPQC testing
B2-BSC 01	Tetanus Block	IPQC	B2G026	1	900 x 600 x 600 mm	IPQC testing
B2-BSC 02	Tetanus Block	Seed Preparation	B2G028	1	1200 x 600 x 750 mm	Seed preparation
M1-BSC 01	Microbiology and QC Lab	Media preparation	M1G022	1	1200 x 600 x 600 mm	QC Lab media preparation
M1-BSC 02	Microbiology and QC Lab	Micro lab	M1G028	1	1200 x 600 x 600 mm	QC Lab Testing
M1-BSC 03	Microbiology and QC Lab	Testing lab	M1G029	1	1200 x 600 x 600 mm	QC Lab Testing
M1-BSC 04	Microbiology and QC Lab	Challenge test	M1G033	1	1200 x 600 x 600 mm	QC Lab Testing
M1-BSC 05	Microbiology and QC Lab	Sterility lab -1	M1G037	1	1500 x 600 x 600 mm	Sterility testing
M1-BSC 06	Microbiology and QC Lab	Sterility lab -2	M1G038	1	1500 x 600 x 600 mm	Sterility testing
A1-BSC 01	Animal Breeding	Animal health monitor	A1G012	1	1200 x 600 x 600 mm	Animal testing/sampling
A1-BSC 02	Animal Breeding	Animal health monitor	A1F014	1	1200 x 600 x 600 mm	Animal testing/sampling
CLASS II B2 TYPE						
QC-BSC 01	Exsiting QC LAB	NA	NA	1	1200 x 600 x 600 mm	NA
	AFI Approved for Enquiry		AFO Approved for Ordering			
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Rev	Date	Completed By	Checked By	AFI	AFO	

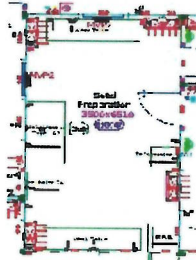
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Biosafety Cabinet		
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	DOCUMENT #:	DS/BSC 01



D-BSC 01



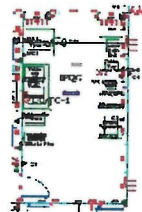
D-BSC 02



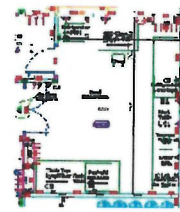
P-BSC 03



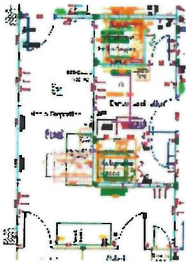
P-BSC 04



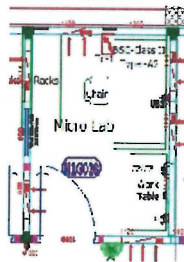
T-BSC 01



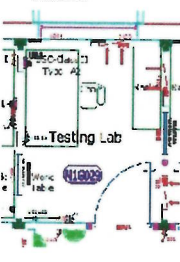
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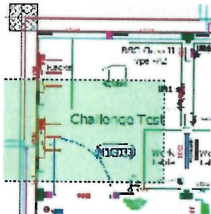
M-BSC 01



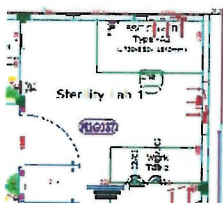
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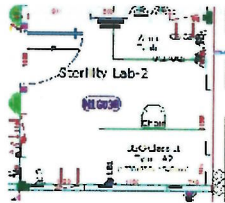
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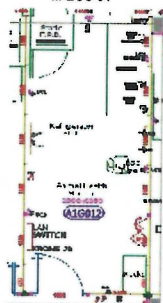
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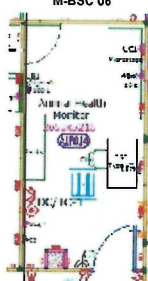
M-BSC 05



M-BSC 06



AB-BSC 01



AB-BSC 02

AFI Approved for Enquiry		AFO Approved for Ordering				
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Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2