# BID DOCUMENT FOR APPOINTMENT OF CONSULTANT (for providing Comprehensive CleanRoom/HVAC Consultancy for medical device manufacturing facility)

## IFB No.HLL/AFT/PROJECTS/2015-16/09/GFBBP/HVAC-CON/02



HLL Lifecare Limited Akkulam Factory, Sreekariyam P.O, Thiruvananthapuram – 695017, Kerala, India Ph: 0471-2442642/2445945 (D) URL: <u>www.lifecarehll.com</u> E-mail: <u>mukundr@lifecarehll.com</u>

# September 2015

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## DISCLAIMER

HLL Lifecare Limited, India (HLL) has prepared this document to give bidders background information on the project. The information is provided to bidders on the terms and conditions set out in this document and any other terms and conditions subject to which such information is provided.

This document is not an agreement, is not an offer or invitation to any other party. The purpose of this document is to provide interested parties with information to assist the formulation of their bid. The information is not intended to be exhaustive. Bidders are required to make their own inquiries and respondents will be required to confirm in writing that they have done so and they do not rely solely on the information in this document.

The information is provided on the basis that it is non – binding on HLL Lifecare Limited, any of its authorities or agencies or any of their respective officers, employees, agents or advisors.

HLL Lifecare Limited reserves the right to not proceed with the project or to change the configuration of the project, to alter the timetable reflected in this document or to change the process or procedure to be applied. It also reserves the right to decline to discuss the project further with any party submitting the tender.

While HLL Lifecare Limited have taken due care in the preparation of the information contained herein and believe it to be accurate neither HLL Lifecare Limited nor any of its authorities or agencies nor any of their respective officers, employees, agents or advisors gives any warranty or make any representations, express or implied as to the completeness or accuracy of the information contained in this document or any information which may be provided in association with it.

No reimbursement of cost of any type will be paid to persons or entities submitting their Tender.

## INVITATION OF OFFERS FROM CLEANROOM/HVAC CONSULTANTS

#### HLL LIFECARE LIMITED (A GOVT. OF INDIA ENTERPRISE) AKKULAM FACTORY, SREEKARIYAM P.O, THIRUVANANTHAPURAM – 695017, INDIA

OFFERS ARE INVITED FROM ELIGIBLE AND COMPETENT CONSULTANTS FOR PROVIDING COMPREHENSIVE CLEANROOM/HVAC CONSULTANCY SERVICES FOR MEDICAL DEVICE MANUFACTURING FACILITY. THE DETAILS ARE AVAILABLE AT OUR WEBSITE WWW.LIFECAREHLL.COM. THE LAST DATE AND TIME FOR RECEIPT OF OFFERS IS AT 15.00 HRS IST ON 25.09.2015.

DEPUTY GENERAL MANAGER (BLOOD BAG PROJECT)

## SECTION I

## NOTICE INVITING TENDER (NIT)

## **1.1 Brief Description of the Project**

HLL Lifecare Limited, a Govt. of India Enterprise, commenced manufacturing of Blood bags in 1995 at Akkulam, Thiruvananthapuram. Over the years, HLL has emerged as the market leader for Blood Bags in the domestic market as well as establishing firm footholds in more than 30 countries worldwide.

HLL is looking to establish a manufacturing facility for Blood bags at a Greenfield Location in Kerala. The facility shall be located at a distance of approximately 120 kms from Thiruvananthapuram Airport. HLL Lifecare Limited wishes to appoint competent Consultants for the GMP and Cleanroom/HVAC modules of this project. The nature of services to be provided by the Consultant will include, but will not be limited to, preparing Plant and process layout including concept design, process sizing, clean room design, Utility sizing, man/material movement planning, entry/exit procedure and Clean room layout planning, preparation of BOQ and provide supervisory support and coordination with HLL authorities at the Clean room Execution stage with due emphasis on quality of design and assistance during validation of the Clean room/HVAC system. The Consultant will be required to provide sufficient technically qualified and experienced staff for providing the required level of service.

## **1.2 TENDER DETAILS**

Approximate cost of the	Rs. 900 Lakhs
Cleanroom/HVAC project	
Earnest Money Deposit	Rs. 1,00,000.00 (Rupees One Lakh only)
Cost of Tender form (Non-refundable)	Tenders can be downloaded from HLL
	website www.lifecarehll.com free of cost.
Availability of Tender documents at	Available till 15.00 hrs IST on 24.09.2015
HLL website	at <u>www.lifecarehll.com</u>
Last date & time of submission of	15.00 hrs IST on 25.09.2015
Tender	
Date & Time of opening of technical	15.30 hrs IST on 25.09.2015
Bid	

## 1.3 POINTS TO BE NOTED

- 1.3.1 Tenderers shall submit a written Power of Attorney authorizing the signatory (ies) of the tender to commit the tender.
- 1.3.2 The authorized signatory of the Tenderer shall sign each page of tender.

1.3.3 Cancellation or creation of a document such as Power of Attorney, Partnership deed, Constitution of firm etc., which may have bearing on the Tender/Contract shall be communicated forthwith in writing by the Tenderer to HLL.

## 1.4 TENDER DOCUMENTS

The offers will be received in TWO PARTS – a) Technical Bid and b) Financial Bid in two separate sealed envelopes. The two envelopes shall be wrapped in an outer envelope addressed to Deputy General Manager (Blood Bag Project), HLL Lifecare Limited., AKKULAM FACTORY, SREEKARIYAM P.O, THIRUVANANTHAPURAM – 695 017, duly super scribing on top "Offer for providing Comprehensive Clean room/HVAC Consultancy Services for Medical Device Manufacturing facility", on or before the last date and time for submission. The envelope should also bear the name and address of the Tenderer.

The firm(s) must include in their Technical Bid the following information in the format given in the Terms of Reference:

1. The general and overall experience of the firm including the number of years of operations, in planning, designing, contract management, commissioning supervision of similar works as detailed in the "Scope of work" mentioned in this tender. The minimum period required for qualification is 3 years.

2. Annual turnover of the firm(s) by way of Professional Fees for Cleanroom/HVAC consultancy for pharmaceutical products/medical device projects for the last three years duly audited by a Chartered Accountant. The gross turnover per year should not be less than Rs.200 Lakhs.

3. Nature, cost, area, employer, location and specific services for works presently at hand and likely date of completion.

4. Experience of the firm(s) in Concept Design, Basic Engineering and Detailed Engineering of Clean rooms for manufacture of pharmaceutical products/Medical devices, including sub systems such as Power Systems, HVAC, Utility piping inside cleanroom, Fire Detection and fire protection Systems, over the past 3 years. It is mandatory that the firm(s) should have provided consultancy for at least one project, with similar scope, for facilities intended for manufacture of atleast any one among the following type of pharmaceutical products: LVPs, SVPs, Injectibles and Vaccines.

5. Summary of permanent professional employees and Key personnel indicating the nature of specialization, qualifications and experience considering requirements specified in earlier paragraph. The CVs of key personnel proposed to be deployed on this assignment along with documentary proof of qualification and experience; their written consent and availability.

## **1.5 TENDER EVALUATON**

The Technical Bids will be evaluated based on the eligibility criteria and responsiveness to the tender requirements. The Financial Bids of firm(s) who fulfill the technical tender requirements alone will be opened for further evaluation. HLL

Lifecare Limited reserves the right to reject any or all of the offers without assigning any reason.

The successful bidder shall be required to execute a Contract Agreement within fifteen days of issue of Letter of Acceptance/Purchase order, failing which the Earnest Money shall be forfeited and the offer cancelled.

The Terms of Reference and Conditions of Contract (Bid Document) can be downloaded from HLL website <u>www.lifecarehll.com</u>.

The Offers must be delivered to the address below on or before 15.00 hrs of 25.09.2015. The envelope should be duly super scribed as "Offer for providing Comprehensive Clean room/HVAC Consultancy Services for Medical Device Manufacturing facility", along with EMD in the form of a Bank Draft for Rs.1,00,000 in favor of *HLL Lifecare Limited payable at Thiruvananthapuram*. The Earnest Money Deposit of Rs.1,00,000 shall be refunded in case of firm(s) whose offers are not accepted.

Further information if any, may be obtained from the address and telephone no. given below:

Deputy General Manager (Blood Bag Project) HLL Lifecare Limited AKKULAM FACTORY, SREEKARIYAM P.O, Thiruvananthapurm – 695 017 Ph: 0471 – 2442642/2445945(D) Email: <u>mukundr@lifecarehll.com</u>

## SECTION II

## INSTRUCTION FOR BIDDERS (IFB)

## 1. Brief Description of Project

HLL Lifecare Limited, a Govt. of India Enterprise, commenced manufacturing of Blood bags in 1995 at Akkulam, Thiruvananthapuram. Over the years, HLL has emerged as the market leader for Blood Bags in the domestic market as well as establishing firm footholds in almost 30 countries worldwide.

HLL is looking to establish a manufacturing facility for Blood bags at a Greenfield Location in Kerala. HLL Lifecare Limited wishes to appoint competent Consultants for the GMP and Clean room modules of this project. The nature of services to be provided by the Consultant will include, but will not be limited to, preparing Plant and process layout including concept design, process sizing, clean room design, Utility sizing, man/material movement planning, entry/exit procedure and Clean room layout planning, preparation of BOQ and provide supervisory support and coordination with HLL authorities at the Clean room Execution stage with due emphasis on quality of design and assistance during validation of the Clean room/HVAC system. The Consultant will be required to provide sufficient technically qualified and experienced staff for providing the required level of service.

## 2. SCOPE OF WORK

The services to be provided by the Consultants shall inter alia include the following:

- a) Concept Design Visiting the site for discussing details with the Employer to understand the User Requirement Specifications (URS) and Develop concept design for the clean room module of the plant including process sizing, manpower sizing, ware-house sizing, Gowning philosophy, cGMP aspects, Man and Material movement philosophy. The above details shall be presented in the form of a report, which shall be reviewed and approved by the Employer.
- b) Basic Engineering Preparing preliminary drawings and designs for the conceptual layout, HVAC layout, Pressure zoning layout, Utility matrix, Process Equipment layout, Process utility layout, man/material movement layout, clean room entry/exit procedure and zoning, etc. in consultation with the Employer.
- c) Detailed Engineering This stage involves preparation of complete finalized working details, finalized schedules, finalized specifications and finalized bill of quantities in the manner prescribed by employer.

The following table illustrates the majority of the deliverables for this stage:

Sr. No.	DESCRIPTION
A : H\	AC (LIMITED FOR PRPOCESS AREA ONLY)
1	BASIS OF DESIGN
2	FINAL CLASSIFICATION (HVAC) ZONING
3	FINAL ROOM PRESSURE ZONING
4	AHU ZONING
5	LOCATION DRAWING OF RISER / HEPA
6	CONTROL SCHEMATIC
7	HEAT LOAD ESTIMATION
8	AIR FLOW SCHEMATICS FOR CLASSIFIED AREA AHU'S
9	SINGLE LINE DUCT LAYOUT
10	REFLECTED CEILING LAYOUT
11	SPECS FOR MAJOR ITEM
12	BOQ
13	Tender
B: ME	CHANICAL / PIPING: (WILL INCLUDE CLEAN
	TY PIPING WITHIN PROCES AREA ALSO)
	ITED FOR PRPOCESS AREA ONLY)
1	LOCATION DRAWING FOR UTILITIES REQUIRED WITHIN PROCESS
1	AREA
2	BASIS OF DESIGN - PIPING
	PIPE & PIPE ELEMENT SPECS
	PIPE SIZING
5	DISTRIBUTION P&ID
6	PIPING LAYOUT WITHIN PROCESS AREA
7	BOQ
8	TENDER
9	SIZING & SPECS FOR PUW/WFI/PURE STEAM
10	STORAGE & DISTRIBUTION SCHEME WITH SUGGESTED P&ID FOR
	PUW & WFI
11	DISTRIBUTION P&ID FOR PURE STEAM
12	PIPING LAYOUT FOR PUW/WFI & PURE STEAM DISTRIBUTION
	SYSTEM
13	BOQ & TENDER FOR PUW/WFI/PURE STEAM
C: EL	ECTRICAL: (LIMITED FOR PRPOCESS AREA
ONLY	
1	LOCATIONAL DRAWING FOR SWITCH / SOCKET / INPUT POWER FOR
_	PROCESS AREA
2	PROCESS AREA LIGHTING DESIGN FOR LUX LEVEL.
3	SLD FOR PROCESS AREA
4	SLD FOR HVAC SYSTEM OF PROCESS AREA
5	LDB/PDB SPECS FOR PROCESS AREA
6	CABLE SCHEDULE FOR PROCESS AREA INCLUDING LAN, CCTV & CAT 6
7	CABLE ROUTING DRAWING FOR PROCESS AREA INCLUDING LAN,
	CCTV & CAT 6
8	SPECS FOR MAJOR ITEM
9	BOQ
10	TENDER

d) Obtaining the approval of the employer to a, b & c above and to any

subsequent changes which the consultant will carry out on the advice of the employer

e) Supervision Support during Execution – The scope of service required by the Employer during the execution stages are shown in the below table:

Stage	Scope of service required by the Employer
Execution	<ul> <li>Support for supervision of execution activities carried out at site:</li> <li>1. The Engineers from consultant will, visit site during execution at least once in every two weeks. A duration of 8 months may be considered for the completion of supply, installation and commissioning of the Cleanroom/HVAC system.</li> <li>2. During each visit they will check the installation done for the quality attributes &amp; design done.</li> <li>3. Any discrepancies will be brought to the notice of HLL &amp; the contractor.</li> <li>4. The consultant shall coordinate with HLL and the contractor to ensure quality of the work being carried out</li> </ul>

- f) Validation assistance The consultant shall assist HLL in the following activities of the validation:
  - Preparation of DQ, IQ, OQ and PQ protocols for validation of entire cleanroom/HVAC system as per ISO 14644 standard and cGMP requirement
  - Overseeing validation by contractor and third-party validation of the cleanroom/HVAC system as per ISO 14644 and cGMP requirements.
  - Validation sign-off
- g) The Consultant shall indicate the name of his sub-consultants for various services with their organization, qualification and experience and shall obtain prior approval of the employer for the same. However, he shall be fully responsible for the correctness and accuracy of services design prepared by such sub-consultants and shall indemnify the employer for damage or loss caused due to negligence of sub-consultant.
- h) Prepare a three dimensional model of suitable scale as and when required by the employer, at no extra cost.
- i) Wherever in-house expertise for designing services/sub systems, is not available with the consultant, the agency whom the consultant proposes to engage for this purpose, shall need to be approved by the Employer. This agency shall be associated from the preliminary drawing stage to the final design work.

- j) Supply all the approved working drawings, specifications and details in the manner required by Employer for proper execution of the work. (In total 5 sets of approved drawings shall be supplied free of charge to Employer)
- k) Obtain Employer's approval for any material deviation in design or specifications.
- I) Shall inspect & certify correctness of the physical layout at site as per approved plans.
- m) Shall undertake periodical supervision and inspection as may be considered necessary to ensure execution of works in accordance with working drawings and specifications.
- Assist the employer in the validation of the commissioned facility including all associated accessories except the process machinery, process utilities and Plant utility.
- o) Shall provide necessary completion reports to the Employer for certifying final completion of the respective works along with four sets of as-built completion drawings and one set of reproducible drawings in A-0 size, and other connected documents. These drawings will be in addition to drawings and details mentioned in above clauses.
- p) All drawings shall be provided in hard-format as well as soft-formats (CAD & PDF)

## 3. Eligibility Criteria

- 1. The firm should be in the business of Clean room/HVAC Consultancy operations for Pharmaceutical products/medical device manufacturing facilities (including planning, designing, contract management, Execution supervision and validation of major works) for a minimum period of Three years.
- Annual turnover of the firm(s) by way of Professional Fees for Clean room/HVAC Consultancy services for pharmaceutical projects during at least the last three years duly audited by a Chartered Accountant. The desired gross turnover per year should not be less than Rs.200 Lakhs.
- 3. Experience of the firm(s) in Concept Design, Basic Engineering and Detailed Engineering of Clean rooms for manufacture of Pharmaceutical products/Medical devices including sub systems such as Power Systems, HVAC, Utility piping inside clean room, Fire Detection and fire protection Systems. It is mandatory that the firm(s) should have provided consultancy for at least one project, with similar scope, for facilities intended for manufacture of atleast any one among the following type of pharmaceutical products: LVPs, SVPs, Injectibles and Vaccines.

The Tenderers should submit satisfactory completion certificate from the client(s) for the above works.

## 4. Submission of Offer.

The intending Consultants shall submit their Offer in two parts, the Technical Bid and the Financial Bid.

## 4,1 TECHNICAL BID

- 4.1.1 The technical bid, clearly labeled as **"TECHNICAL BID"**, shall consist of following information /details for eligibility criteria of bidders.
  - a. Covering letter for the Bid in Form A.
  - b. Earnest Money Deposit in the form of a Demand Draft for Rs.1,00,000 in a separate sealed envelope duly marked "Earnest Money Deposit".
  - c. Income tax returns for the last three years
  - d. Attested Copy of Power of Attorney (in favour of the Authorised Signatory of the Bidder) to submit the Bid,
  - e. Relevant Experience for the projects
    - Length of time in business in the form attached as Form T-I along with list of similar pharmaceutical industry/medical device projects handled during the period (in bidder's format).
    - ii. Total number of projects, involving Concept Design, Basic Engineering and Detailed Engineering of Clean rooms for manufacture of any one among the following pharmaceutical products – LVPs/SVPs/Injectables/Vaccines should be indicated, in the format attached as Form T-II
    - iii. Performance certificate from client in the Form T-V in respect of Works above
  - f. Financial Data for the past three years
    - Annual Turnover from Concept Design, Basic Engineering and Detailed Engineering of Clean rooms for manufacture of pharmaceutical products/medical devices, as per the format T-IV.

The Bidder should validate the data provided as above using suitable documentary evidence such as client certificates, audited balance sheets, annual reports etc clearly giving the reference to the evidence in front of the relevant portion.

- g. Technical and organizational capability
  - i. Number of Technical staff (excluding support staff) proposed for this project in the Form T-III
  - ii. Academic qualification of the staff in the Form T-III
  - iii. Experience of the proposed staff in the Form T-III
- 4.1.2 In addition to above, following information shall also be furnished in Part-I of technical bid:
  - (a) An organization chart with assignment of each key staff member (identified by name), duration & timing together with clear description of the responsibilities of each key staff member within the overall work program.
  - (b) The name, background and professional experience of each key staff member to be assigned to the project, with particular reference to his experience of a nature similar to that of the proposed assignment. The majority of the key staff shall be regular members of the firm for at least six months (CV format in Form T-IV).

## 4.2 THE FINANCIAL BID

- 4.2.1 The financial bid, clearly labeled as "FINANCIAL BID" will contain the following:
  - i. Form of tender (Form A).
  - ii. Financial Bid of the Offer as per Form C.
- 4.2.2 The financial proposal should be separately completed and submitted in a separate sealed envelope in the Format prescribed in Form C. The final prices shall be entered in the Form of Tender. These prices should include all costs associated with the contract.

## 5 AWARD OF CONTRACT

## 5.1.1 AWARD CRITERIA

5.1.2 Subject to meeting the Eligibility Criteria stipulated in clause 3 above, HLL will award, the Contract to the Consultant, who's Offer has been determined to be substantially responsive, complete and in accordance with the Bid documents, and who's Price has been determined to be the lowest.

# 5.2 EMPLOYER'S RIGHT TO ACCEPT ANY TENDER AND TO REJECT ANY OR ALL TENDERS

Notwithstanding Clause 5.1, HLL reserves the right to accept or reject any offer, and to annul the tender process and reject all offers, at any time prior to award of Contract without thereby incurring any liability to the affected Bidder or Bidders or any obligations to inform the affected Bidder or Bidders of the grounds for HLL's action.

## 5.3 NOTIFICATION OF AWARD

- 5.3.1 Prior to the expiry of the period of offer validity prescribed by the HLL, HLL will notify the successful Bidder by Tele-fax or e-mail, to be confirmed in writing by registered post/ by courier, that his offer has been accepted. This letter (hereinafter and in the Conditions of Contract called 'the Letter of Acceptance') shall specify the fees which HLL will pay to the Consultant in consideration of the services to be provided for the works by the Consultant as prescribed by the Contract (hereinafter and in the conditions of Contract called 'the Contract Price'). The Letter of Acceptance will be send to the successful bidder. No correspondence will be entertained by HLL from the unsuccessful Bidders.
- 5.3.2 The Letter of Acceptance shall constitute a part of the contract.

## 5.4 SIGNING OF AGREEMENT

5.4.1 HLL shall prepare the Agreement in the Proforma (Form C) included in this Document, duly incorporating all the terms of agreement between the two parties. Within 10 days from the date of issue of the Letter of Acceptance the successful Bidder will be required to execute the Contract agreement. One copy of the Agreement duly signed by HLL and the Consultant through their authorized signatories will be supplied by HLL to the Consultant.

FORM A PAGE 1 OF 2

#### FORM OF BID

- Note : i. The Appendix forms part of the Bid
  - ii. Bidders are required to fill up all the blank spaces in this form of Tender and Appendix.

NAME OF WORK : \_\_\_\_\_

To,

Deputy General Manager (Blood Bag Project) HLL Lifecare Limited AKKULAM FACTORY, SREEKARIYAM PO, Thiruvananthapurm – 695 017, Kerala, India

- 1. Having examined the Terms of Reference and the terms of the Comprehensive Cleanroom/HVAC Consultancy Contract attached thereto and the NIT for providing Comprehensive Cleanroom/HVAC Consultancy for Medical Device Manufacturing facility we the undersigned, offer to provide comprehensive Cleanroom/HVAC Consultancy Services in conformity with the Terms of Reference and the terms of the Cleanroom/HVAC Consultancy Contract attached thereto.
- 2. We undertake, if our Offer is accepted, to commence the works within one week of signing the Contract Agreement to commence and to complete the whole of the Works comprised in the Contract within <u>the Time Schedules mentioned therein</u> calculated from the date of issue of the Letter of Acceptance.
- 3. We have independently considered the amount shown in Clause 6.3 of the Cleanroom/HVAC Consultancy Contract, appended to the Terms of Reference, as liquidated damages and agree that they represent a fair estimate of the damages likely to be suffered by you in the event of the work not being completed in time.
- 4. We agree to abide by this Offer for a minimum period of 150 days from the last date fixed for receiving the same and it shall remain binding upon us and may be accepted at any time before the expiry of that period or any extended period mutually agreed to.
- 5. We declare that the submission of this Offer confirms that no agent, middleman or any intermediary has been, or will be engaged to provide any services, or any other item of work related to the award and performance of this Contract. We further confirm and declare that no agency commission or any payment, which may be construed as an agency, commission has been, or will be, paid and that the tender price does not include any such amount. We acknowledge the right of Employer, if it finds to the contrary, to declare our Offer to be non-compliant and if the Contract has been awarded to declare the Contract null and void.
- 6. We understand that you are not bound to accept the lowest or any offer you may receive.

7. If our Offer is accepted we understand that we are to be held solely responsible for the due performance of the Contract.

DATED THIS......DAY OF......201

SIGNATURE .....

WITNESS – SIGNATURE ..... NAME ..... ADDRESS .... Occupation ....

## FORM B

PAGE 1 OF 2

#### FORMAT FOR FINANCIAL BID

(ON THE LETTER HEAD OF THE COMPANY)

DATE:

TO: HLL Lifecare Limited, AKKULAM FACTORY, SREEKARIYAM PO, THIRUVANANTHAPURAM – 695 017.

**SUB.:** OFFER FOR PROVIDING COMPREHENSIVE CLEANROOM/HVAC CONSULTANCY FOR MEDICAL DEVICE MANUFACTURING FACILITY.

DEAR SIR / MADAM:

(i) BEING DULY AUTHORIZED TO REPRESENT AND ACT ON BEHALF OF ....., AND HAVING REVIEWED AND FULLY UNDERSTOOD ALL THE REQUIREMENTS OF BID SUBMISSION PROVIDED VIDE THE BID DOCUMENT DATED ...... PERTAINING TO THE ABOVE MENTIONED WORK, WE HEREBY PROVIDE OUR FINANCIAL PROPOSAL FOR PROVIDING CLEANROOM/HVAC CONSULTANCY FOR THIS PROJECT ON A COMPREHENSIVE BASIS.

S NO	STAGE-WISE CONSULTANCY FEE	ALL-INCLUSIVE LUMPSUM AMOUNT (IN INR)	Remarks
1	CLEANROOM/HVAC CONSULTANCY CHARGES (FOR CONCEPT DESIGN, BASIC ENGINEERING AND DETAILED ENGINEERING)		(THE BID MUST CLEARLY INDICATE THE FULL PLAN INCLUDING THE NUMBER OF WORKSHOPS PLANNED)
2	FEES FOR SUPERVISORY SUPPORT DURING EXECUTION		(THE BID MUST CLEARLY INDICATE THE PLAN FOR SUPERVISORY SUPPORT AND EXECUTION)
3	FEES FOR VALIDATION ASSISTANCE		(THE BID MUST CLEARLY INDICATE THE PLAN FOR SUPPORT DURING VALIDATION)
TOTAL	ALL-INCLUSIVE LUMPSUM FEES (IN INR)		

#### FORM B

PAGE 2 OF 2

(II) WE CONFIRM THAT THE ABOVE INDICATED FEES ARE INCLUSIVE OF ALL APPLICABLE TAXES & LEVIES AS PER THE REGULATIONS OF KERALA & INDIA, ARE INCLUSIVE OF PROFESSIONAL FEES, AIR-FARE EXPENSES, LODGING EXPENSES, BOARDING EXPENSES, LOCAL CONVEYANCE EXPENSES, PRINTING CHARGES FOR DRAWINGS, REPORTS, ETC. THAT SHALL BE INCURRED BY US DURING ALL THE STAGES MENTIONED IN THE SCOPE OF THE WORK.

(III) WE CONFIRM THAT WE SHALL NOT CLAIM ANY EXTRA CHARGES OVER THE ABOVE-QUOTED PROFESSIONAL FEES.

WE AGREE TO BIND BY THIS OFFER IF WE ARE SELECTED AS CONSULTANT FOR THIS PROJECT.

FOR AND ON BEHALF OF:SIGNATURE:NAME OF THE PERSON:DESIGNATION:

Instructions:

- 1. No conditions should be attached.
- 2. In case of difference between the words and figures, words would prevail.

(Should be given in a sealed envelope).

## FORM T-I PAGE 1 OF 1

#### **GENERAL INFORMATION**

#### Notes:

- (i) Attach an attested photocopy of Certificate of Registration.
- 1. Name of the firm: .....
- 2. Legal Status of the Firm: Individual/Association/Joint Venture/Consortium
- 3. Registered Address, telephone, Tele-fax.

Contact Person, Designation and address including email id

- 5. Number of years in Cleanroom/HVAC Consultancy Business
- Number of Pharmaceutical product/medical device manufacturing facilities for which comprehensive cleanroom/HVAC design consultancy has been provided during the last three years with details
- 7. Number of LVP/SVP/Injectables/Vaccines manufacturing facilities for which comprehensive cleanroom/HVAC design consultancy has been provided during the last five years with details
- Names and Addresses of Associated Companies to be involved in the Project and whether Parent / subsidiary/ others.
- 9. If the company is subsidiary, what involvement, if any, will the Parent Company have in the Project?
- 10. State if in-house expertise is available for all services/sub-systems. If not details of subconsultants to be involved in the project.
- 11. State the Quality System followed in the Company. Does the company have an ISO 9001 certificate or it follows an internal quality system.

#### FORM T-II

#### NUMBER OF PHARMACEUTICAL PRODUCT/MEDICAL DEVICE MANUFACTURING FACILITY PROJECTS FOR WHICH COMPREHENSIVE CLEANROOM/HVAC CONSULTANCY WAS PROVIDED

SI. No.	Name and location of the Project	Name and address of the Client	Details of the Project		Year of Completion of Project	Whether the intended Product is LVP/SVP/Injecta bles/Vaccines	Remarks
			Built up Area	Cost*			
1							
2							
3							
4							
5							
6							

\*- VALUE OF THE WORK FOR WHICH SERVICES PROVIDED BY THE CONSULTANT ONLY SHALL BE PROVIDED

# FORM T-III PAGE 1 OF 2

#### KEY PERSONNEL PROPOSED FOR THE PROJECT

SI. No.	Sector	Number of	proposed	personnel	Education	Proposed	Designation	Total Years	of	Experience	Relevant	Experience	in vears	Details in	Annexure	on page no.
1.	Project Manager															
2.	Process Specialist in LVP manufacturing															
3.	Civil Engineer															
4.	Electrical Engineer															
5.	HVAC															
6.	MEP															
7.	GMP															
8.	Fire Detection & protection Systems															

Note :

- 1) A summary of the qualification and work experience of each key staff, to be attached.
- 2) **CVs** to be submitted for all the proposed personnel in the format provided

Form T-III

Page 2 of 2

## CVS OF KEY STAFF

Name of the Staff						
Designation						
Name of the firm presently e	employed					
Years with the firm						
Proposed position						
Details of task assigned						
Key Qualifications						
Education						
Employment Record						
Name of the Firm	Position Held		Years of Employment			

#### FORM T-IV

PAGE 1 OF 1

#### FINANCIAL DATA FOR ASSESSMENT

YEAR	2012-13	2013-14	2014-15
Annual Turn-over by way of Professional fees towards Comprehensive Clean room/HVAC consultancy provided for pharmaceutical product manufacturing facility projects			

Attach audited balance sheets in support of the data clearly marking the relevant portion. Also attach copies of Income Tax Returns filed.

#### FORM T-V

#### PAGE 1 OF 1

#### PERFORMANCE REPORT OF WORKS (On Clients' Letter Head)

- 1. Name of Project and location
- 2. Agreement No.
- 3. Product Manufactured
- 4. Estimated Cost
- 5. Built up area
- 6. Date of Start
- 7. Date of Completion
- 8. Amount of professional fees paid
- 9. Performance report
  - a. Quality of Services provided Very Good/ Good/ Fair/ Poor

DATE:

AUTHORISED SIGNATORY (WITH STAMP)

FORM C

## CLEANROOM/HVAC CONSULTANCY CONTRACT

This agreement ma	de on this	day
of Two	Thousand Fifteen between HLL	Lifecare Limited, a
Company incorporated	under the Companies Act, 19	56 and having its
Registered Office at HLL	Latex Bhavan, Poojappura, Thiruv	ananthapuram - 695
012 (hereinafter referred	to as Employer) which expression	unless excluded by
or repugnant to the conte	ext shall include their successors	and assignees of the
part		and
M/s		having their
Registered	Office	at

(Hereinafter referred to as Consultant) which expression unless excluded by or repugnant to the context, shall include their successors and assignees of the other part.

Whereas the employer is desirous of undertaking Comprehensive Cleanroom/HVAC Consultancy for Greenfield Blood Bag manufacturing facility in accordance with the general requirements and conditions hereinafter appearing and whereas the Consultant has agreed to perform the same.

## NOW THIS AGREEMENT WITNESSETH AS FOLLOWS

## TERMS AND CONDITIONS OF AGREEMENT

#### 1.0 DEFINITIONS:

1.1 For the purpose of this agreement, the following words and expressions shall have the meaning hereby assigned to them except where the context otherwise requires:-

i) "Approved" means approved by employer's representative in writing including subsequent confirmation of previous approval.

ii) "Employer" means the HLL Lifecare Limited, which expression shall unless excluded by or repugnant to the context include employer's representative.

iii) "Employer's representative" means Project Manager (hereinafter called PM) of HLL Lifecare Limited or any person authorized by him as designated in-charge of the work. (Please refer to Annexure I)

iv) "Consultant" Means M/s.\_\_\_\_\_

2.0 SCOPE OF WORK:-

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The services to be provided by the Consultants shall inter alia include the following:

- a) Concept Design Visiting the site for discussing details with the Employer to understand the User Requirement Specifications (URS) and Develop concept design for the clean room module of the plant including process sizing, manpower sizing, ware-house sizing, Gowning philosophy, cGMP aspects, Man and Material movement philosophy. The above details shall be presented in the form of a report, which shall be reviewed and approved by the Employer.
- b) Basic Engineering Preparing preliminary drawings and designs for the conceptual layout, HVAC layout, Pressure zoning layout, Utility matrix, Process Equipment layout, Process utility layout, man/material movement layout, clean room entry/exit procedure and zoning, etc. in consultation with the Employer.
- c) Detailed Engineering This stage involves preparation of complete finalized working details, finalized schedules, finalized specifications and finalized bill of quantities in the manner prescribed by employer. The following table illustrates the majority of the deliverables for this stage:

Sr. No.	DESCRIPTION						
A : H	A : HVAC (LIMITED FOR PRPOCESS AREA ONLY)						
1	BASIS OF DESIGN						
2	FINAL CLASSIFICATION (HVAC) ZONING						
3	FINAL ROOM PRESSURE ZONING						
4	AHU ZONING						
5	LOCATION DRAWING OF RISER / HEPA						
6	CONTROL SCHEMATIC						
7	HEAT LOAD ESTIMATION						
8	AIR FLOW SCHEMATICS FOR CLASSIFIED AREA AHU'S						
9	SINGLE LINE DUCT LAYOUT						
10	REFLECTED CEILING LAYOUT						
11	SPECS FOR MAJOR ITEM						
12	BOQ						
13	Tender						

	CHANICAL / PIPING: (WILL INCLUDE CLEAN
UTILI	TY PIPING WITHIN PROCES AREA ALSO)
(LIM	ITED FOR PRPOCESS AREA ONLY)
1	LOCATION DRAWING FOR UTILITIES REQUIRED WITHIN PROCESS
	AREA
2	BASIS OF DESIGN - PIPING
3	PIPE & PIPE ELEMENT SPECS
4	PIPE SIZING
5	DISTRIBUTION P&ID
6	PIPING LAYOUT WITHIN PROCESS AREA
7	BOQ
8	Tender
9	SIZING & SPECS FOR PUW/WFI/PURE STEAM
10	STORAGE & DISTRIBUTION SCHEME WITH SUGGESTED P&ID FOR
	PUW & WFI
11	DISTRIBUTION P&ID FOR PURE STEAM
12	PIPING LAYOUT FOR PUW/WFI & PURE STEAM DISTRIBUTION
	SYSTEM
13	BOQ & TENDER FOR PUW/WFI/PURE STEAM
C: EL	ECTRICAL: (LIMITED FOR PRPOCESS AREA
ONLY	
1	LOCATIONAL DRAWING FOR SWITCH / SOCKET / INPUT POWER FOR
	PROCESS AREA
2	PROCESS AREA LIGHTING DESIGN FOR LUX LEVEL.
3	SLD FOR PROCESS AREA
4	SLD FOR HVAC SYSTEM OF PROCESS AREA
5	LDB/PDB SPECS FOR PROCESS AREA
6	CABLE SCHEDULE FOR PROCESS AREA INCLUDING LAN, CCTV & CAT
	6
7	CABLE ROUTING DRAWING FOR PROCESS AREA INCLUDING LAN,
	CCTV & CAT 6
8	SPECS FOR MAJOR ITEM
9	BOQ
10	Tender

- d) Obtaining the approval of the employer to a, b & c above and to any subsequent changes which the consultant will carry out on the advice of the employer
- e) Supervision Support during Execution The scope of service required by the Employer during the execution stages are shown in the below table:

Stage	Scope of service required by the Employer	
Execution	Support for supervision of execution activities carried out at site: 1. The Engineers from consultant will, visit site during execution at least once in every two	

weeks. A duration of 8 months may be considered for the completion of supply, installation and commissioning of the Cleanroom/HVAC system.
<ol> <li>During each visit they will check the installation done for the quality attributes &amp; design done.</li> <li>Any discrepancies will be brought to the notice of HLL &amp; the contractor.</li> <li>The consultant shall coordinate with HLL and the contractor to ensure quality of the work being carried out</li> </ol>

- f) Validation assistance The consultant shall assist HLL in the following activities of the validation:
  - Preparation of DQ, IQ, OQ and PQ protocols for validation of entire cleanroom/HVAC system as per ISO 14644 standard and cGMP requirement
  - Overseeing validation by contractor and third-party validation of the cleanroom/HVAC system as per ISO 14644 and cGMP requirements.
  - Validation sign-off
- g) The Consultant shall indicate the name of his sub-consultants for various services with their organization, qualification and experience and shall obtain prior approval of the employer for the same. However, he shall be fully responsible for the correctness and accuracy of services design prepared by such sub-consultants and shall indemnify the employer for damage or loss caused due to negligence of sub-consultant.
- h) Prepare a three dimensional model of suitable scale as and when required by the employer, at no extra cost.
- i) Wherever in-house expertise for designing services/sub systems, is not available with the consultant, the agency whom the consultant proposes to engage for this purpose, shall need to be approved by the Employer. This agency shall be associated from the preliminary drawing stage to the final design work.
- Supply all the approved working drawings, specifications and details in the manner required by Employer for proper execution of the work. (In total 5 sets of approved drawings shall be supplied free of charge to Employer)
- k) Obtain Employer's approval for any material deviation in design or specifications.

- I) Shall inspect & certify correctness of the physical layout at site as per approved plans.
- m) Shall undertake periodical supervision and inspection as may be considered necessary to ensure execution of works in accordance with working drawings and specifications.
- Assist the employer in the validation of the commissioned facility including all associated accessories except the process machinery, process utilities and Plant utility.
- o) Shall provide necessary completion reports to the Employer for certifying final completion of the respective works along with four sets of as-built completion drawings and one set of reproducible drawings in A-0 size, and other connected documents. These drawings will be in addition to drawings and details mentioned in above clauses.
- p) All drawings shall be provided in hard-format as well as soft-formats (CAD & PDF)

## 3.0 PAYMENT OF REMUNERATION

3.1) The employer agrees to pay to the consultant the following fee for the professional services to be rendered by him as hereinabove described in clause 2 and its sub clauses.

S No	STAGE-WISE CONSULTANCY FEE	All-inclusive lumpsum Amount (in INR)
1	CLEANROOM/HVAC CONSULTANCY CHARGES (FOR CONCEPT DESIGN, BASIC ENGINEERING AND DETAILED ENGINEERING)	
2	FEES FOR SUPERVISORY SUPPORT DURING EXECUTION	
3	FEES FOR VALIDATION ASSISTANCE	
TOTAL ALL-INCLUSIVE LUMPSUM FEES (IN INR)		

a) The fees shall be **inclusive** of applicable taxes, levies, travel and lodging expenses for the consultant's employees during the course

of the various stages of the contract and other relevant miscellaneous expenses.

b) The above fees mentioned at clause 3.1 (a) shall be deemed to be inclusive of fees payable by the Consultant to his any other subconsultant and associates, needed to accomplish the job and nothing extra, whatsoever, shall be payable by the Employer.

## 4.0 PAYMENT SCHEDULE:-

The fees will be paid in installments as specified below:-

Payments to the consultant shall be "on account" and shall be adjusted against the final bill. The various stages of payment shall be as follows:-

STAGE I:- On getting the preliminary concept drawings/ designs approved by the Employer. (Compliance sub-clauses a of clause 2.1 and other relevant subclauses of clause 2.1)	10 % of the fee for "Cleanroom/HVAC consultancy " finalized after negotiation on the quoted fees
STAGE II:- On completion of basic engineering stage as approved by the Employer. (Compliance sub-clauses b of clause 2.1 and other relevant subclauses of clause 2.1)	20% of the fee for "Cleanroom/HVAC consultancy" finalized after negotiation on the quoted fees
STAGE III:-On completion of Detailed engineering stage, as approved by the Employer (Compliance sub-clauses c of clause 2.1 and other relevant subclauses of clause 2.1)	30% of the fee for "Cleanroom/HVAC consultancy" finalized after negotiation on the quoted fees
STAGE IV:-On Completion of detailed estimates, drawings and specifications required for finalizing the tender document, as approved by the Employer (Compliance sub-clauses d and e of clause 2.1 and other relevant subclauses of clause 2.1)	30% of the fee for "Cleanroom/HVAC consultancy charges" finalized after negotiation on the quoted fees
STAGE V:- On completion of installation and commissioning work of entire cleanroom/HVAC system including MEP relevant to the scope of the contract, as certified by the Employer.	90 % of the fee for "Supervision Support during execution" finalized after negotiation on the quoted fees
STAGE VI:- On completion of validation work of the entire cleanroom/HVAC	90% of fee for "Validation assistance" finalized after negotiation on the

system including MEP relevant to the	quoted fees	
scope of the contract, as certified by the		
Employer.		
STAGE VII:- On completion of work as	Balance 10 % of fees for	
certified by HLL and submission of as-	"Cleanroom/HVAC consultancy",	
built drawings	"Supervision Support during	
	execution" and "Validation assistance"	
	making the total equivalent to 100% of	
	fees payable finalized after negotiation	
	on the quoted fees.	

## 5.0. ADDITIONS AND ALTERATIONS

- (i) The employer shall have the right to request in writing for changes, additions, modifications or deletions in the design and drawings or any part of the work and to request in writing additional work in connection therewith and the consultant shall comply with such request.
- (ii) The consultant shall not make any deviations, alterations, additions, to or omissions from the work shown/described and awarded to the contractor except through and with proper approval of the Employer.

## 6.0. TIME SCHEDULE

6.1 The day of commencement of project will be reckoned from the date of acceptance of offer.

6.2 The following is the table indicating the Completion timelines of various activities as indicated in para 2.1

S No	Activity	Timeline for completion	
1	Concept Design	completionWithin 20 daysfrom date ofacceptance ofoffer (expected tobe completedaround end ofOctober 2015)	
2	Basic Engineering	Within 30 days	

		frame data (
		from date of
		acceptance of
		offer (expected to
		be completed
		around mid of
		November 2015)
3	Detailed Engineering	Within 50 days
		from date of
		acceptance of
		offer (expected to
		be completed
		around end of
		November 2015)
4	Providing finalized and	Within 75 days
	approved estimates, drawings	from date of
	and specifications including	acceptance of
	BoQ for tendering purpose	offer (expected to
		be completed
		around mid of
		December 2015)
5	Validation assistance	Till completion of
		cleanroom/HVAC
		system validation
		(expected to be
		completed around
		April 2017)
6	Providing as-built drawings of	Within 30 days
	all components of	from the
	cleanroom/HVAC systems	completion of
		validation of
		cleanroom/HVAC
		system (expected
		to be completed
		around May 2017)
		·····; ····;

6.3 The work shall be carried out with all due diligence and as per the time schedule specified above. In case of any delay/default, of the consultant to adhere to the agreed time schedule, (Decision of the PM shall be final and binding) the employer shall recover the liquidated damages from the consultant at the rate of 0.5% (zero decimal point five percent) of the total amount of fee payable per day of delay of any activity subject to a maximum of 5% (five percent) of the total fee payable.

## 7.0 EXTENSION OF TIME

- 7.1 To adhere to the above mentioned time schedule the consultant shall be provided on demand necessary documents, information and certificates/undertakings by the employer. Any delay in supplying the requisite documents and delay due to any other cause beyond the control of the Consultant shall be considered for grant of extension of time. If the Consultant requires extension of time, they shall intimate in writing to Employer within 10 days of the occurrence of such hindrance/delay.
- 7.2 The Employer after satisfying himself about the reasonableness of grounds, may grant extension of time as in his opinion be justified and communicate the same in writing. (The decision of PM shall be final and binding). Whenever such extension of time is granted, it would be without prejudice to the rights of Employer. Any extension of time granted as stated above shall neither entitle the Consultant to any claim for increase in their fees nor shall it release him from any of the obligations under the said agreement.

## 8.0 ABANDONMENT OF WORK

8.1 That if the consultant abandons the work for any reason whatsoever or becomes incapacitated from acting as Consultant as aforesaid, the Employer shall cancel the contract. The employer shall be at liberty to make full use of all or any of the drawings prepared by the Consultant. The Consultant shall also be liable to refund all the fees paid to him up to date plus such damages as may be assessed by the employer (Decision of PM shall be final and binding) subject to a maximum of 10% of the total fee payable to the consultant under this agreement including the recovery of liquidated damages under clause 6.3 hereinabove.

8.2 Provided, however, that in the event of the termination of the agreement under proper notice as provided in the clause hereinafter, the Consultant shall be liable to refund any excess payment made to him over and above which is due to him in accordance with the terms of this agreement, for the services rendered by him till the date of termination of agreement.

## 9.0 SUPPLY OF DRAWINGS AND COPY-RIGHT

9.1. All the estimates, bill of quantities, detailed designs with calculations, and any other details envisaged under this agreement shall be supplied in triplicate. All drawings and details of services/utilities (internal and external) shall be supplied by the Consultant as per requirements of local bodies and other authorities. The employer shall be supplied with

five sets of such drawings along with one reproducible copy in A-0 size. If there is any revision of any detail in any drawing for any reason whatsoever, same number of drawings shall be reissued after such corrections without any extra charge. Five sets of drawings and other details of completion plans along with the relevant soft formats (CAD & PDF) shall be supplied to the Employer.

9.2. All these drawings shall become the property of the Employer and he shall have the right to use the same anywhere else. Such drawings and designs shall not be issued to any other person firm or authority or used by the Consultant for any other project. No copies of any drawings or documents shall be issued to any one except the Employer and/or his authorized representatives.

## **10.0 GUARANTEE**

10.1.The consultant shall agree to redesign at his cost any portion of his engineering and design work, which due to his failure to use a reasonable degree of skill shall be found defective within two years from the date of start of regular use of the portion of the work affected. The Employer shall grant right of access to the consultant, of this portion of the work claimed to be defective for inspection.

## **11.0 DETERMINATION AND RESCISSION OF AGREEMENT**

11.1.The employer without any prejudice to its right against the Consultant in respect of any delay by notice in writing absolutely determine the contract in any of the following cases:-

i) If the Consultant, being a firm/company shall pass a resolution or the court shall make any order that the firm/company shall be wound up or if a receiver or a manager on behalf of the creditor shall be appointed or if circumstances shall arise which entitle the court to appoint a receiver or a manager or which entitles the court to make up a winding order.

ii) If the Consultant commits breach of any of the terms of agreement.

11.2. When the Consultant has made himself liable for action under any of the clauses aforesaid, the Employer shall have powers:

a) To rescind the agreement.

b) To engage another Consultant to carry out the balance work debiting the Consultant the extra amount, if any, so spent for

getting the balance work done. This amount would be in addition to the recovery of liquidated damages under Clauses 7 and 8 herein above.

## 12.0 GENERAL

- i. The Consultant shall be fully responsible for the technical soundness of the work including those of specialists engaged if any, by him and also ensure that the work is carried out generally in accordance with drawings, specifications and his conception.
- ii. The employer will have the work of Consultant and/or his sub-consultants supervised/inspected at any time by any officer, check estimates and designs.
- iii. The appointment of Employer's own supervisory staff, if any, does not absolve the Consultant of his responsibility of general supervision. The Consultant shall be responsible for designs of structures and all provisions/services of the work entrusted to him so as to satisfy their requirements.
- iv. The Consultant hereby agrees that the fee to be paid as provided herein (clause 3) will be in full discharge of functions to be performed by him and no claim whatsoever shall be made against the employer in respect of any proprietary rights or copy right on the part of any other party relating to plans, models and drawings.
- v. The consultants shall indemnify and keep indemnified the Employer against any such claims and against all costs and expenses paid by the Employer in defending himself against such claims.
- vi. The consultant hereby agrees that the employer shall have the right to take out any of the activities, which in the opinion of the employer is not being performed by the consultant with due diligence, and within the agreed time schedule, and which can be performed independently. The fees or the expenses incurred shall be debited to the consultant.

#### 13.0 ARBITRATION

All disputes or differences whatsoever arising between the parties out of or relating to the consultancy services, meaning and operations or effect of this contract or the breach thereof shall be settled by arbitration. Matters to be arbitrated upon shall be referred to a sole Arbitrator, to be appointed by the Employer and the award made in pursuance thereof shall be binding on the parties. Such arbitration shall be governed by the Indian Arbitration and Conciliation Act 1996.

It is hereby further agreed between the parties that the stamp duty payable under the law in respect of this agreement shall be borne by the Consultant.

The contract shall be deemed to have been concluded at Thiruvananthapuram, Kerala and suits and proceedings, if any, shall be only in the courts of competent jurisdiction in Thiruvananthapuram.

In witness whereof the parties	s hereto have set their	hands and
seals the	day of	Two
Thousand Fifteen above written.	-	

## ANNEXURE I

Various parts of the contract agreement shall be operated upon as follows:-

- 1. All the preliminary drawings, working drawings and other related details shall be monitored and approved by PM. Also the activities under clause 2.1 shall be monitored by PM.
- 2. Design and drawings of services' (internal), cleanroom/HVAC project estimate & bills of quantities (BOQ'S) for cleanroom/HVAC and MEP components shall be monitored and approved by the PM.
- 3. Electrical design & arrangement, BOQ'S for Electrical components and all the related activities shall be monitored & approved by PM.
- 4. The contract agreement shall be signed by the concerned PM on behalf of HLL and he shall also coordinate other remaining activities of the agreement.