PRE-BID MEETING

TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF FILLING LINE AT PII, COONOOR

Date: 30.07.2013

Venue: HLL Lifecare Ltd., Chennai



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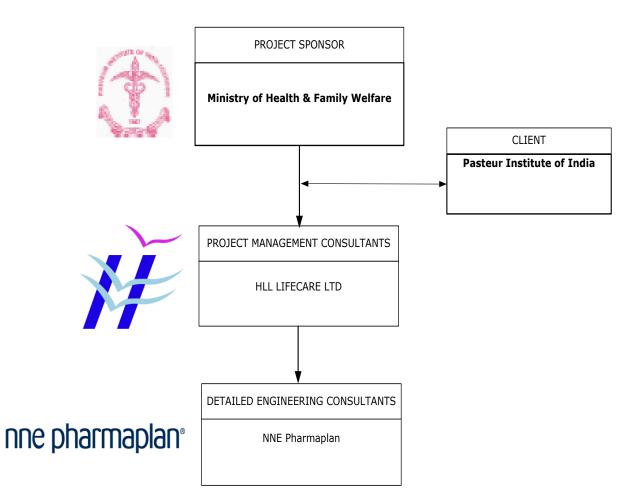
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PROJECT ORGANOGRAM





The primary objective of this project is the Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

This facility shall be built as per the latest International trends and upon completion, shall be in compliance with Indian

FDA (Schedule M), WHO/GMP regulations.





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INTRODUCTION

The Institute started functioning as Pasteur Institute of Southern India, on 6th April 1907 and the Institute took a new birth as The Pasteur Institute of India (registered as a society under the societies Act 1860) and started functioning as an autonomous body under the Ministry of Health and Family Welfare, Government of India, New Delhi since the 10th of February, 1977.

Pasteur Institute of India (PIIC), Coonoor is one of the leading organization which is in to the production of Antirabies Vaccine and DPT group of Vaccines for the EPI of Govt. of India.

The scope of this project is for the revival of the existing DPT Vaccine Manufacturing facility according to cGMP norms along with the increase in the production capacity.

Ministry of Health and Family Welfare (MOHFW) has appointed HLL Lifecare Limited as Project Management Consultant (PMC) for the revival of DPT Vaccine Manufacturing Facility. Further, HLL Lifecare Limited has associated with NNE Pharmaplan India Limited, which has been appointed as "Engineering Consultants". NNE Pharmaplan shall design and engineer this facility, incorporating the latest GMP Standards and best practices.



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Schedule . No	ITEM (PACKAGE)	EQUIPMENTS	Capacity / Size	QTY	EMD	
	FILLING LINE	Vial Washing & Depyrogenation	200 vials/min	1	Rs. 19,00,000/- (Rupees	
'	[200vials/min]	Vial Filling and Stoppering	200 vials/min	1	Nineteen Lakhs only)	
		Vial Sealing Machine	200 vials / min	1		



1."The tenderer:

Has to be a manufacturer of all the tendered equipments.

OR

Has to be an authorised Indian representative of the equipment manufacturer/s of all the tendered equipments."

2. In case the manufacturer of any of the tendered equipment is of foreign origin, the manufacturer should have a Permanent Establishment or Authorised Representative in India for carrying out the activities of Clearing, Forwarding, Transportation, Installation, Commissioning, Qualification, Training, Warranty and CMC obligations



MINIMUM ELIGIBILTY CRITERIA

3. The Tenderer should have supplied ,installed & commissioned successfully at-least two integrated vial filling lines (vial washing & depyrogenation, vial filling & stoppering and vial sealing machine having CE certification) with minimum capacity of 200 vials/min in the last five years from the date of Tender Opening in the field of human vaccines. (purchase order, Completion certificate of the integrated vial filling line equipments to be attached).

4. The Tenderer should have supplied and installed successfully at-least one integrated vial filling lines (vial washing & de-pyrogenation, vial filling & stoppering and vial sealing machine having CE certification) in India for the field of human vaccines (Purchase order, installation certificate of the integrated vial filling line equipment to be attached).



5. Minimum 3 Nos. of Client's performance satisfactory certificate in the field of Human vaccines should be provided in the client's official letter head with their seal ,Signature & contact details.

6. Their Client's list must include at-least two facilities approved from national regulatory body (NRA) or international regulatory bodies (viz., US-FDA / UK-MHRA / WHO / EU). List-out the experience under section C

7. Turnover of the company must be minimum INR. 475 Lakh (or equivalent in Foreign Currency) during the last three financial year. Furnish the information under section B.

8. Net worth of the Tenderer and its authorised Indian representative (if any) should be positive during the last three financial years.



Note:

1. In support of above the Tenderer shall furnish the details in the below tables.

2. The manufacturer as well as the Tenderer/ Indian Agent shall furnish Satisfactory Performance cum Installation Certificate/purchase orders/bill of entry in respect of above, duly translated in English and duly notarized in the country of origin, along with the tender.

3. The Tenderer shall furnish a brief write-up, packed with adequate data explaining and establishing his available capacity/capability (both technical and financial) to perform the Contract (if awarded) within the stipulated time period, after meeting all its current/present commitments. The Tenderer shall also furnish details of Equipment and Quality Control in the enclosed Section below.

4. The Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of Tender opening certified by a Chartered Accountant should be submitted as part of the tender

5. Notwithstanding anything stated above, the Purchaser reserves the right to assess the Tenderer's capability and capacity to perform the contract satisfactorily before deciding on award of Contract, should circumstances warrant such an assessment in the overall interest of the Purchaser. The Purchaser reserves the right to ask for a free demonstration of the quoted equipment to similar/identical specification at a pre determined place acceptable to the purchaser for determining technical responsiveness, before the opening of the Price Bid.



SECTION – XI A PRICE SCHEDULE i) PRICE SCHEDULE FOR DOMESTIC GOODS OR GOODS OF FOREIGN ORIGIN LOCATED WITHIN INDIA

1	2	3	4				5			6	
					Price per unit (Rs.)						
Schedule	Brief Description of Goods	Country of Origin	Quantity (Nos.)	Ex - factory/ Ex -warehouse /Ex- showroom /Off - the shelf (a)	Excise Duty (if any) [%age & value] (b)	Sales Tax/VAT(if any) [% age & value] ©	Packing and Forwarding charges (d)	Incidental Services (including Instal lation & Commissioning, Supervision, Demonstration , Training, Documental on and Qualification) at the Consignee's site e)	Unit Price (at Consignee Site) basis (g) =a+b+c+d+e	Total Price (at Consignee Site) basis (Rs.) 4 x 5(g)	



SECTION – XI B PRICE SCHEDULE i) PRICE SCHEDULE FOR GOODS TO BE IMPORTED FROM ABROAD

1	2	3	4					5						6
					Price per unit (Currency)									0
Schedule	Brief Description of Goods	Country of Origin	Quantity (Nos.)	Gross FOB price at sea air port of Lading (indusive of Agency commission) Amount and percentage of Agency	Commission	Net FOB (excluding Agency Commission) (a-b)	Insurance & Freight	Net CIP Port of destination by Air/sea (c+d)	Custom Duty amount as % of Net CIP (as applicable)	Custom Clearance & Handling Charges	Loading / unloading / inland transportation / insurance & incidental cost till consignee's site	Installation, commissioning, supervision, Demonstration,training Documentaion and Qualification at the consignee's site	Unit price on DDP basis at consignee's site (a+d+f+g+h+i)	Total price on DDP basis at consignee's site 4X 5 (j)
				(a)	(b)	(C)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)



SECTION XI C: PRICE BID FORMAT – COMPREHENSIVE MAINTENANCE CHARGES –

1	2	3	4				5	
Schedule	Brief description of	Quantity. (No.)	Mair	nual (itenan Each	ce Co	ntract	Total Annual Comprehensive Maintenance Contract	
No.	No. goods		1 st	2 nd	3 rd	4 th	5 th	Cost for 5 Years
			Α	В	С	D	E	[3 x (4A+4B+4C+4D+4E)]

* After completion of Warranty period



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SUPPLY SCHEDULE:

TO BE COMPLETED WITH IN <u>14 MONTHS</u> FROM THE DATE OF ISSUE OF PURCHASE ORDER

INSTALLATION, COMMISSIONING AND VALIDATION SHOULD BE COMPLETED : <u>2 MONTHS</u> FROM THE DATE OF DELIVERY AT SITE

WARRANTY : 24 (TWENTY FOUR) MONTHS FROM THE DATE OF COMPLETION (Final Acceptance Certificate).



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 20% of the contract value shall be released against Bank guarantee equivalent to 110% of the advance amount and submission of 10 % of the contract value as Security Deposit/ Performance Security in the form of Bank Guarantee from any scheduled commercial bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.

b) On delivery at site:

60 % of the contract price shall be paid on receipt of goods in good condition and upon the submission of the following documents:

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;

(ii) Consignee Receipt Certificate as per Section XVII in original issued by the authorized representative of the consignee;

(iii) Two copies of packing list identifying contents of each package;

(iv) Dispatch Clearance from Purchaser or authorized agent

(v) Inspection certificate issued by the nominated Inspection agency, if any.

(vi) Insurance Certificate as per GCC Clause 11

(vii) Certificate of Country of origin.



c) On Installation Qualification (IQ) & Submission of IQ report by client/ purchaser 5% of the net CIP price

d) On Operational Qualification (OQ) & submission of OQ report by client/ purchaser 5% of the net CIP price

e) On validation and Final Acceptance Certificate by Client/ Purchaser:

Balance 10 % of the net CIP price payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.

f) Payment of custom duty amount, customs clearance and handling charges, loading/ unloading, inland transportation, incidental costs till consignee site & incidental services (including installation & commissioning, supervision, demonstration and training) will be paid in Indian Rupees to the Manufacturer's Authorized Indian representative at actual on intimation to purchaser with Bill of Entry and supporting documents.

g) Payment of Indian Agency Commission:

Indian Agency commission will be paid to the manufacturer's agent in Indian rupees indicated in the relevant Price Schedule (as per prevailing rate of exchange ruling on the date of Contract) and shall not be subject to further escalation / exchange variation. 100% Payment shall be paid in Indian Rupees to the Indian Agent after 100 % payment to the foreign principal.



TWO BID SYSTEM COMPRISING OF TECHNICAL BID AND FINANCIAL BID in 2 separate envelopes.

The two envelopes must be enclosed in a single envelope super scribing : "TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF FILLING LINE AT PII, COONOOR"



Technical bid (Un-priced Bid)

- Earnest money furnished in accordance with GIT clause 18.1 alternatively, documentary evidence as per GIT clause 18.2 for claiming exemption from payment of earnest money.
- Tender Form as per Section X (Un priced).
- Documentary evidence, as necessary in terms of GIT clauses 4 and 16 establishing that the tenderer is eligible to submit the tender and, also, qualified to perform the contract if its tender is accepted.
- Tenderer/Agent who quotes for goods manufactured by other manufacturer shall furnish Manufacturer's Authorisation Form.
- Power of attorney in favour of the signatory of the tender document.
- Documents and relevant details to establish in accordance with GIT clause 17 that the goods and the allied services to be supplied by the tenderer conform to the requirement of the TE documents.
- Performance Statement as per section IX along with relevant copies of orders and end users' satisfaction certificate.



Technical bid (Un-priced Bid)

•Price Schedule(s) as per Section XI filled up with all the details including Make, Model, etc. of the goods offered with prices blank (without indicating any prices).

•Certificate of country of origin by the bidder from abroad. (Chamber of commerce)

•Checklist as per Section XIX.

•IRS,URS (Technical Specification) and Layouts given as Annexure- I, II & III, should be duly filled , signed and stamped.



Account Payee Demand Draft or Bank Guarantee

-The demand draft shall be drawn on any commercial bank in India or in case of foreign tenderer, the DD must be routed through a nationalized Indian Bank, in favour of the "**HLL Lifecare Limited**" payable at Trivandrum.

- If the EMD is in the form of bank guarantee, the same is to be provided from any scheduled commercial bank in India or in the case of foreign tenderer, the same should be routed through a Nationalized Indian Bank as per the format specified under Section XIII of the tender.



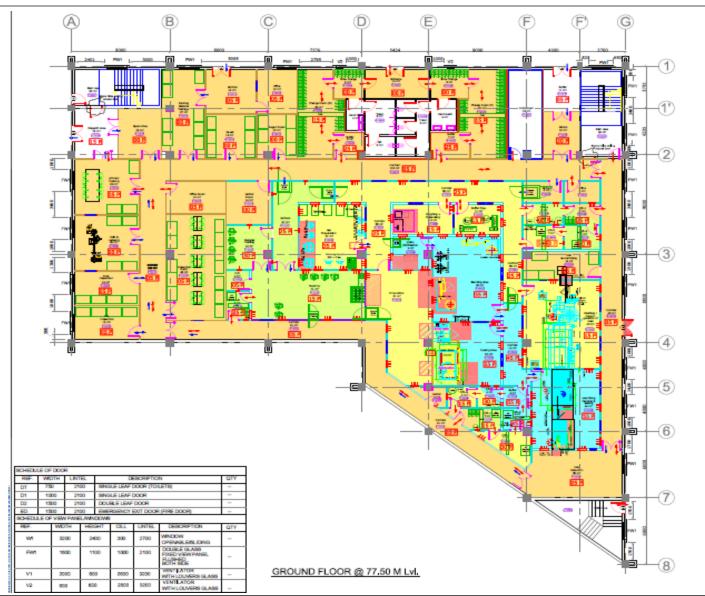
Integrity Pact has to be signed and submitted by the Tenderer along with the filled up Tenders, failing which the Tender is liable to be rejected. Integrity Pack is enclosed in Section-XXI



SI No.	Description	Schedule					
1	Closing date & time for receipt of Tender	On or before 20.8.2013 at 15:00 Hrs					
2	Time and date of opening of Technical Bids	20.08.2013 at 15:30 Hrs					
3	Venue of Opening of Techno Commercial Tender	HLL Lifecare Limited C/o HLL Biotech Limited, Ticel Biopark Campus (Module no. 013- 015), CSIR Road, Taramani, Chennai- 600 113					



Layouts



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PII, Coonoor- Revival DPT Vaccine/ cGMP Compliance

QUESTIONS / CLARIFICATIONS ????



PII, Coonoor– Revival DPT Vaccine/ cGMP Compliance



