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**Minutes of Pre-Proposal Conference held on 02.06.2011 at 10.00 AM at National AIDS Control Organization (NACO) Ministry of Health and Family Welfare, Govt. of India , 9<sup>th</sup> Floor, Chandralok Building, 36, Janpath, New Delhi – RFP Ref.: NACO/BS/2011/01 for Selection of Project Management Consultant to setup Plasma Fractionation Centre at Chennai, India**

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The following were present:

**Client**

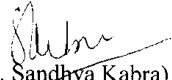
- 1 Dr. Mohammed Shaukat, ADG(CST)
- 2 Dr. Sandhya Kabra, ADG(LS&BS)
- 3 Dr. Zaren S. Bharucha, Consultant Model Blood Bank, NACO
- 4 Dr. Ranjeet S Ajmani, Consultant
- 5 Dr. Chandra Viswanathan, PFC-Reliance
- 6 Dr. Rajiv Mahajan, NPFC, Mumbai
- 7 Mr. Satya P. Verma, Procurement Specialist

**Consultants**

- 1 Mr. Vijay Bakhru, Director, Bideco Limited, Gurgaon
- 2 Mr. Rohan Bakhru, Country Business Manager, Bideco Limited, Gurgaon
- 3 Mr. Anuvrat Singal, Manager, Glatt (India) Pharma Engineering Pvt. Limited, New Delhi
- 4 Mr. Bernd Kreyer, Director, Glatt (India) Pharma Engineering Pvt. Limited, New Delhi
- 5 Mr. E.A. Subramanian, Vice President (Projects), HLL Lifecare Limited, Thiruvanthapuram
- 6 Mr. Tarun Handa, HLL Lifecare Limited, Noida
- 7 Mr. Narendra Prasad, Director-Technical, NNE Pharmaplan India Ltd., New Delhi

The following are the proceedings the Pre-proposal conference:

1. The Client briefed the Consultants representatives about the intent of organizing this pre-bid conference and selection process.
2. The Consultants were requested to ask clarifications with regard to provisions given in the RFP Documents, including Instructions to Consultants, Terms of Reference, technical and financial proposal forms and draft contract.
3. The clarifications asked by the Consultants were responded by the Client appropriately. The clarifications so asked from Consultants and the NACO's response is enclosed as **Annexure-A**.

  
(Dr. Sandhya Kabra)  
Asst. Director General (Blood Safety)

**Annexure-A**

Sr. No.	Reference from RFP Document	Particulars of Clarification	NACO's Response
1	--	What is the area of land available for the Project?	Approx. 1.5 Acre
2	--	What is the estimated cost of Project?	Rs. 250 Crores
3	--	Has the technology been finalized?	Please refer Terms of Reference- Sub-para (a) of Para 2). It has been decided to use Cohn & Chromatography (Integrated) technology for the PFC.
4	--	What would be the mechanism of approval by NACO	<p>The progress of project would be monitored by NACO based on the milestones agreed during contract negotiations with the selected PMC.</p> <p>The stages of approvals required from NACO shall also be agreed during contract negotiations. Broadly, the PMC shall complete all the documentations for approvals on critical stages and submit recommendations for approval by NACO, such as selection of technology provider, award of contract for civil and allied works and services and award of contract for supply and/or installation of plant and equipment etc.</p> <p>All the key activities need to be itemized and captured in a chronological manner. Project management software can be used for better monitoring. Timelines will be agreed upon with NACO ahead of time, and follow up will be purely based on that.</p>
5	--	Who will handle the issues related with intellectual property	It is the responsibility of PMC to ensure that the intellectual property related matters are (thought thru with the technology provider ahead of time. Technology Providers must also see the freedom to operate in this country as far as plasma process production goes) taken care as per applicable laws and regulations. There should be no infringement of intellectual property rights whatsoever.
6	Instructions to Consultants – Data Sheet Para 3.3(b)	There seems inappropriate conversion of INR to USD.	The USD equivalent of Rs.212 Lakh provided between parenthesis may be read as [USD 471,111 (approx)]

7	Terms of Reference-Sub-para 3. of Para 3)	What level of involvement is required from PMC	<p>The PMC is expected to act as an extended arm of NACO. The PMC has to carryout selection of various contractors/service providers / technology providers through open and competitive bidding process. enter in to contract with them on behalf of NACO and do contract monitoring during all stages of setting up PFC, including overseeing operation and management of PFC for an initial period of 2 years and assist in handing over operation and maintenance of the PFC to NACO or its designated entity in phased manner.</p> <p>All steps must be done in accordance with the required regulations, e.g. both FDA and statutory laws for building a biopharma plant.</p>
8	Terms of Reference-Sub-para 14. of Para 3)	Please re-consider the responsibility for clinical evaluation of products	<p>The level of clinical evaluation required may depend upon the technology provider selected for setting up of PFC. It may be required to perform only comparability evaluation only, in case the product is registered for use in India. In case otherwise, full clinical evaluation may be required. In such case, third party CRO services may be taken by PMC. In such case, the cost of evaluation shall be reimbursed separately.</p> <p>In addition, PMC has to perform validation of PFC facility for 3 consecutive batches of production.</p> <p>The PMC is expected to only cover cost towards comparability evaluation in its proposal.</p>
9	Terms of Reference-Sub-para 17. of Para 3)	Please clarify the role of PMC in operation and management of the PFC for an initial period of 2 years. Is it 'overseeing' function or the PMC is expected to employ its own personnel during this period?	<p>Please also refer sub-para 15. The PMC is only expected to provide oversight in operation and management of PFC during the initial period of 2 years. The PMC is not required to employ its own personnel for operation and management of PFC, instead, it is expected to assist NACO in initial recruitment of key personnel.</p>
10	Terms of Reference-Sub-para 18. of Para 3)	<p>Whether the risk coverage shall also include the risks associated with use of plasma product?</p> <p>Who will be the beneficiary of the insurance claim</p>	<p>No. The risk insurance coverage under the scope o PMC shall only cover risks associated with setting up and operation of PFC.</p> <p>NACO will be the beneficiary of the insurance claim.</p>

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11	Instructions to Consultants – Data Sheet Para 4.5	Proposal submission date may be extended further for 7	No change as adequate time has already been given. The proposals are to be submitted not later than June 20, 2011 up to 3:00 PM.
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