TENDER NOTICE

NATIONAL INSTITUTE OF PATHOLOGY-ICMR

(Indian Council of Medical Research)
"Sriramachari Bhawan"
Safdarjang Hospital Campus
Post Box No. 4909, New Delhi-110029
(Tender No.: Tender Store/Clean Room/F-381/2012-2013)

Tender Notice inviting Expression of Interest

The National Institute of Pathology (ICMR), Sriramachari Bhawan, Safdarjang Hospital Campus, New Delhi, invites expression of interest from reputed firms which have executed GMP oriented production facilities in a pharmaceutical setup elsewhere. The proposed activity will include creation of a GMP Facility on turn key basis suitable for sterile Ex-vivo maintenance and propagation of human and xenogeneic cells/tissues/materials towards formation of organs or any of their structural elements for their ultimate clinical application. The out line of the proposal along with terms and conditions may be obtained from the Director, National Institute of Pathology (ICMR), Safdarjung Hospital Campus, New Delhi-110029 by paying a **non - refundable sum of Rs.500/- (by DD drawn in favor of Director, National Institute of Pathology, payable at New Delhi) towards the cost of such documents/details.** If the 'Outline of the proposal' is downloaded from **NIOP (www.instpath.gov.in) ICMR (www.icmr.nic.in)** the amount is payable at the time of submitting the Proposal.

The interested firms may visit the site at the institute. Contact person: Dr. L. K Yerneni, Scientist D, **National Institute of Pathology (NIP) between 10.00 AM and 4.00 PM. Tel No: 26198402-8, Ext.411, yernenilk@icmr.org.in.**

Issue of the Documents:	**From 15th June to 5th July, 2012** **(From :** 10.00 AM to 4.00 PM)
The last date for submission of the offers:	**12.07.2012 upto 4.00 PM**
Date of Opening of Proposal:	**16.07.2012** at **2.00 PM**, in the Conference Room, 2nd Floor, National Institute of Pathology, Safdarjang Hospital Campus, Post Box No. 4909, New Delhi-110029

This invitation of expression of interest is for short listing of eligible firms as per GOI guidelines and not to be treated as an agreement with NIP (ICMR). The Director, NIP reserves full rights to accept or reject any or all Proposals without assigning any reason.

DIRECTOR
NATIONAL INSTITUTE OF PATHOLOGY (New Delhi)

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OUTLINE OF THE PROPOSAL

The National Institute of Pathology (ICMR), New Delhi, invites expression of interest to bring up a "GMP Facility" on turn key basis suitable for sterile in vitro maintenance and propagation of human and xenogeneic cells/tissues/materials towards formation of organs or any of their structural elements, e.g., epidermis, skin etc. for their ultimate clinical application. This facility will be used to manufacture cultured epithelial autograft for undertaking clinical trials in Burns patients.

Scope of Work:

1. The GMP facility to include Clean areas for Bio Safety Level - 1 and 2 operations with ISO Class 7 (class 10,000) rated cleanrooms, peripheral non-clean areas having Comfort AC and integrated equipments: The facility should comply with personnel-safety, cGMP & cGood Tissue Practices norms, and appropriate bio-safety levels.

2. The total plinth area is about 830 sq ft.

3. The job includes Design, supply, installation, fabrication and commissioning of ductable HVAC systems, air-conditioning systems, validation, interior decoration, provision of various fixtures, electrical work including provision of Generator backup etc.

4. The layout for the proposed facility depicting the design and location of various labs/rooms should be in view of process of manufacturing and cover clean and non-clean areas having Comfort AC, flow of materials and personnel, utilities and location of various equipments and accessories.

5. The firm should be able to undertake the necessary civil and other miscellaneous works in addition to the main work.

6. The Facility should have independent clean rooms for (1) Media preparation, (2) Maintenance, cryo-banking and preparation of Feeder cells (characterized and certified murine cells), (3) Isolator for handling biopsy & propagating cells of patient origin and (4) Gowning of ISO Class 7 (CLASS 10,000) with Standard air locks, Interlocking doors, independent HEPA filtered air supply and exhaust systems and appropriate pressure differentials.

7. The firm should be able to provide a 'self-contained' isolator based multi-chambered aseptic class 100 cell culture workstation having integrated incubators, process stations, appropriate neutralizing/buffer zones, microscope chamber and biosafety benches for handling human tissues with programmable, user defined and self regulatory control of internal clean and sterile environment towards GMP end-points.

8. The firm should be able to integrate into the facility equipments like autoclave (stand alone and across the wall panel), CO_2 incubators (across the wall panel), microscope (integration into isolator), detectors for humidity, temperature, pressure, environmental O_2 level and gas cylinders for medical-grade CO_2 gas and air with appropriate gas regulators.

9. The facility to include dedicated areas/cubicles for sterilization, washing, staff, cryo-facilities, quality control & packing of finished product etc with sufficient measures for waste disposal.

10. There should be **controlled access** to labs/rooms through biometric electronic keycards.

11. Provision of smoke detection & alarm system to be linked with the existing fire fighting system.

12. The firm should be able to provide 'Building management system (BMS)' for on-line monitoring and control of the environmental conditions (particle count, temperature, humidity, pressure etc.) in class 100 and class 10,000 zones.

13. The firm should be able to provide relevant literature and operation & maintenance manuals of the supplied equipments.

14. The firm should also be able to provide calibration certificates for test & measurement equipments from the Original Equipment Management (OEM).

15. The firm should provide **validation** and also allow 3rd party validation for particle counts, temperature, humidity, air velocity, air volume, differential/absolute pressure and any other relevant validations, as per compliance to design specifications.

16. The firm should be able to extend appropriate **training** to our staff towards operation, maintenance, validation / documentation or on any other related topics.

17. The firm should be able to formulate relevant SOPs necessary towards validation and guide & assist in obtaining approval by competent authorities.

Terms and Conditions:

1. The proposal should have 4 hard copies + a soft copy, enclosed in sealed envelopes inscribed with 'Expression of interest for GMP facility'.

2. The proposal should accompany an **EMD of Rs.1,00,000/- in the form of Demand Draft in favour of the Director, National Institute of Pathology payable at New Delhi.** The proposal without the EMD will be summarily rejected. No interest is payable on EMD.

3. Only vendors who have successfully executed pharmaceutical and/or cell therapeutic GMP oriented projects during last 4 years should only quote.

4. The vendors should indicate Indian clientele pertaining to experience of establishing clean rooms in 'exclusively pharmaceutical and/or cell therapeutic' GMP oriented production facilities in public and private sectors. Proof of such execution should be submitted with the Proposal along with details of the work i.e., summary of technical details (clean room size, class), cost and completion certificate.
5. The firm should submit the essential qualifications of the concerned team-members involved in the commissioning of such facilities and whosoever are going to undertake the said project. The vendors should indicate their Annual Turnover.

6. The vendors may inspect the commissioning site for clean-room facility and the necessary supporting systems by contacting **Dr. L. K Yerneni, Scientist D, National Institute of Pathology, Safdarjung Hospital Campus, between 10.00 AM and 4.00 PM. Tel No: 26198 402-8 Ext.411**, yernenilk@icmr.org.in

7. The vendors should understand our basic manufacturing process and submit preliminary designs, drawings as per building bye-laws in the existing building.

8. The vendors should be able to make a detailed presentation of their proposal in the presence of our Technical Committee at National Institute of Pathology, the exact timing will be notified to the firms and the presenting team should be competent enough to clarify any technical and other related queries raised during such presentation.

9. The short listed firms should be able to submit a final 'Techno-commercial & Price bid' as per the discussion with the committee within 4 week's time.

10. **Turn –Key Project : The work has to be undertaken as a turn-key project** and the firm should submit timescale for execution of the project.

11. Entire facility and all the items to be supplied/commissioned by the vendor should be under 5 year comprehensive warranty from the date of handing over of the facility.

12. The Director, National Institute of Pathology, New Delhi, reserves the right to accept or reject any or all Proposals the tenders without assigning any reason.

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DIRECTOR
NATIONAL INSTITUTE OF PATHOLOGY (New Delhi)