

**CENTRAL RESEARCH INSTITUTE
KASALI (HP)
MINISTRY OF HEALTH & FW**

REQUEST FOR EXPRESSION OF INTEREST

FOR

**REVIVAL OF VACCINE MANUFACTURING
FACILITY AS PER cGMP NORMS**

EOI DOCUMENT NO.

20-1/95-Admn. (Part VIII)

DATE OF ISSUE:

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Central Research Institute, Kasauli (HP)
Ministry of Health & Family Welfare
Government of India

EXPRESSION OF INTEREST (EOI)

Notice No.: 20-1/95-Admn. (Part VIII)

Date: 13..07.2009

Request for "Expression of Interest" from Firms/Vendors for participating in national bidding for "**Revival of Triple Vaccine Manufacturing Facility at Central Research Institute, Kasauli (HP) as per cGMP norms.**"

Interested Firms having experience of working with Pharmaceutical industry and Vaccine Manufacturing facility are hereby invited to submit their "Expression of Interest (EOI)" as per the prescribed proforma addressed to the Director, Central Research Institute, Kasauli (HP)

The prescribed proforma containing the details regarding the Vendor selection criteria etc. can be obtained in person on any working day from 18.07.2009 to 10.08.2009 up to 1.00 PM from HSCC (I) Ltd, E-6A, Sector 1 Noida, (U.P) on payment of Rs 2000/- in cash or in the form of Demand Draft / Banker's cheque in favour of HSCC (I) Ltd payable at Noida /Delhi or may be downloaded from HSCC and MOH&FW websites www.hsccltd.co.in/tender.html/ www.mohfw.nic.in respectively and submitted along with a demand draft of Rs 2,000/- in favour of Director, Central Research Institute, Kasauli Payable at Kasauli. The last date of submission of sealed EOI document complete in all respects is 10.08.2009 up to 13.00 hrs. CRI reserves the right to accept or reject any/all applications without assigning any reason thereof. The prospective firms are requested to visit the HSCC website regularly for any further announcement / clarifications /addendum/ corrigendum.

Director

EXPRESSION OF INTEREST

SECTION I

1. GENERAL

1.1 BACKGROUND

Central Research Institute, Kasauli was established in 1905 and ever since then is a pioneer institute of Government of India for manufacturing life saving vaccines and Sera. The institute is of national importance in the country and is well spoken and recognized internationally.

Central Research Institute is located in a naturally pollution free area with cool temperature climate. As such, the facilities in the institute were found in compliance with acceptable International Standards even after several years of its establishment. However, due to evolution of sophisticated environment and infections control system and also due to advance construction materials and techniques, the current manufacturing practices (cGMP) for production of immunobiologicals have been upgraded by Drug Controller General of India (DCGI), the World Health Organisation (WHO) and other international agencies.

1.2 NEED FOR MODFICATION OF LAYOUT PLAN

Directions have been received from Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India to upgrade the existing facilities as per current cGMP norms and develop it to the standard of international standards and accordingly a concept layout plan showing the proposed layout for the Diptheria, Pertussis, Tetanus and filling facility for DPT group of vaccines has been prepared. The facilities are to be renovated by the firm by providing/modifying panel partitions, false ceilings, flooring, doors / windows and various internal services like electrical,HVAC, plumbing, Firefighting etc. as per the concept layout plan in order to make the facilities cGMP compliant for manufacturing of DPT group of Vaccines.

1.3 Proposed Vaccine Manufacturing facility

The building for the facilities already exists with internal services like plumbing, electrical, HVAC, Cold rooms, DG Sets, ETP etc. The internal partitions, False ceiling, door/ windows are now being dismantled to renovate the building as per aforesaid concept plan in order to make the facility cGMP compliant for manufacturing of DPT group of vaccines and is to be commissioned by 30.06.2010 within an approximate cost of Rs. 15 crores. Copies of Concept layout plan are enclosed as Annexure- I placed at page-20.

1.4 Role / Scope of the Firm/Vendor

The selected firm/vendor shall be required to install clean room and Utility systems in existing building of Triple Vaccine Laboratory at Kasauli. The broad specifications are as under:

Manufacturing Area

Level 0

- Total Covered Area – 1617.88 Sqm
- Tetanus Facility Covered Area - 819.87 Sqm
- Diptheria Pertusis Facility Covered Area – 798. 01 Sqm

Level 1

- Total Covered Area – 1962.16 Sqm
- Filling Line Area – 1067.08 Sqm
- Utility Area – 895. 08 Sqm

Issued Addressed in Designing the Plant

- Cross contamination
- Mix ups
- Cleaning and Sanitization
- Viable & Non- viable Particle Control
- Surfaces
- Product Safety
- Personnel and environmental safety
- Water Systems
- Ease of Operation
- Optimal use of available space

Cross Contamination and mix ups

- Pressure differentials
- Appropriate classification of rooms to meet current WHO cGMP classifications
- Proper segregation of manufacturing Areas
- Unidirectional process flow
- Air locks
- Change rooms
- Dynamic Pass Boxes

Cleaning and Sanitization

- Facility designed to provide easy cleaning and sanitization of the manufacturing facility.
- Use of Vinyl Flooring to provide cost effective highly chemical resistant (resistant to all disinfectants and cleaning agents used in clean rooms) and non supportive surface for microbial growth.
- Crevices free facility
- Aseptic drains in clean room areas.

Viable and non viable Particle Control

- Appropriate air changes (Grade D-40, C-60, B-90)
- Terminal HEPA Filters (> 99.97 efficiency)
- Non particle shredding and chemically resistant material
- Temperature & Humidity Control
- Differential Pressure (15 Pa)
- Recovery Time (less than 20 min)
- Non particle Shredding

Surfaces

- Easy maintenance
- Easy to install
- Resistant to chemicals
- Smooth Finish
- Cost effective

Other Features

- Maximum Use of available resources
- Optimized for high Production Outputs
- Strategic location of formulation and filling facility for minimization of labor during transport of intermediate bulks.

1.5 VENDOR SELECTION CRITERIA FOR CLEAN ROOM AND UTILITY SYSTEM

1. The vendor should have good experience of at least 8-10 years working with pharmaceutical industry.
2. The vendor should have previous experience of working for a Vaccine manufacturing company.
3. The vendor should have provided such services to WHO GMP pre- qualified manufacturing company.
4. The Vendor should have the experience of working with Diptheria, Pertusis and Tetanus production Units.
5. The Vendor must be technically competent to provide cGMP solutions.
6. The Vendor should be aware of current GMP practices.
7. Preferably the manufacturing site /office of the vendor shall be nearby Delhi NCR region to facilitate the ease of maintenance.
8. The vendor should have sufficient capacity/resources to take such projects within a short period of time.

Vendors/ Firms of repute fulfilling the selection criteria mentioned above are hereby invited to submit their "expression of interest" for participating for national competitive bidding for revival of Vaccine manufacturing facility at Central Research Institute, Kasauli (HP).

Central Research Institute, Kasauli (HP), Ministry of Health& Family Welfare (MOH&FW), Government of India (GOI), reserves the right to reject any or all the applications without assigning any reason or incurring any liability thereof.

SECTION-II

INFORMATION & INSTRUCTIONS FOR BIDDERS

1. GENERAL:

1.1 Tender Document Fee

All bidders are required to pay **Rs. Two Thousand only (Rs 2, 000)**, towards EOI document fee in the form of Demand Draft from any **Nationalized/Scheduled Bank** drawn in favour of "Director, Central Research Institute, Kasauli and payable at Kasauli. The Expression of Interest document fee is Non-Refundable.

1.2 Letter of Transmittal and Forms 'A' to 'C' seeking information /documents are given in Section -III.

1.3 All information called for in the enclosed forms should be furnished against the relevant columns in the forms. If for any reason, information is furnished on a separate sheet, this fact should be mentioned against the relevant column. Even if no information is to be provided in a column, a 'nil' or 'no such case' entry should be made in that column. If any particulars/ query is not applicable to the applicant, it should be stated as 'not applicable'. The applicants are cautioned that not giving complete information called for in the application forms or not giving it in clear terms or making any change in the prescribed forms or deliberately suppressing the information shall result in the applicant being summarily disqualified. Applications made by telegram or telex and also those received late will not be entertained.

1.4 The application should be type written. The applicant should sign each page of the application.

1.5 The applicant may furnish any additional information, which is deemed necessary to establish capability to successfully complete the envisaged project. Superfluous information need not be furnished and no information shall be entertained after submission of EOI document unless specifically called for.

1.6 Any information furnished by the applicant found to be incorrect either immediately or at a later date, would render him liable to be debarred from taking up the project. The EOI document in prescribed form duly completed

and signed should be submitted in a sealed cover. The sealed cover super scribed "**Expression of Interest for revival of Vaccine manufacturing Facility at Kasauli (HP)**" shall be **received in the office of HSCC (India) Limited, Plot No. 6(A), Block-E Sector 1, NOIDA - 201 301 (U.P), INDIA up to 1.00 p.m. on 10.08.2009.** A soft copy, MS-Word compatible, shall also be submitted in the same sealed cover. Documents submitted in connection with EOI will be property of Central research Institute, Kasauli.

- 1.7 Prospective bidders can seek any clarification regarding project requirements and EOI document from the office of Director CRI, Kasauli/ Chief General Manager (PG-II), HSCC (India) Limited, E- 6(A), Sector 1, NOIDA - 201 301 (U.P), INDIA (Phone: 0091-120-2542436-40, Fax: 0091-120-2542447/2540399,

Ministry of Health & Family Welfare reserves its right not to respond to any question raised or provide clarification sought in its sole discretion.

- 1.8 Jurisdiction

All disputes arising shall be subject to the jurisdiction of the appropriate court at Kasauli (HP) alone and be governed by laws of India.

- 1.9 The discretion and decision of CRI, Kasauli /MOHFW-GOI in respect of the EOI shall be final and shall not be open to be challenged in any Court of Law.

2. **FINAL DECISION MAKING AUTHORITY:**

Central Research Institute, Kasauli/ Ministry of Health & Family Welfare, Government of India reserves the right to accept or reject any application and/or to annul the selection process and reject all applications at any time without assigning any reason or incurring any liability thereof to the applicants.

3. **ORGANIZATIONAL STRUCTURE**

The applicant should have sufficient number of Engineers and other technical professionals. The applicant should submit a list of key professionals stating clearly how they would be deployed in this project The in- house capability of the firm should be brought out, clearly indicating the disciplines for which the firm will need to appoint sub-contractors.

Even though an applicant may satisfy the above requirements, he would be liable to disqualification, if he has:-

- a) Made misleading or false representation or deliberately suppressed the information in the forms, statements and enclosures required in the EOI document.
- b) Record of poor performance such as abandoning project, not properly completing the assigned project, or financial failures/weaknesses etc.

4. INFORMATION TO BE GIVEN IN THE REQUIRED FORMATS:

Bidders should furnish the following:

4.1 ORGANIZATION INFORMATION

Bidders are required to submit the following information in respect of their organization (Form - 'A').

- a) Name & postal address, Telephone & Fax Number etc.
- b) Year of establishment and commencement of practice.
- c) Copies of original documents defining the legal status, place of registration and principal places of business.
- d) Name & title of Directors
- e) Name and designation of officers to be associated with the project and authorized to act for the organization.
- f) Information on any litigation in which the applicant was involved during the last seven years including any current litigation.
- g) Brochures and Annual reports of last seven years.

4.2 List of Projects

List of similar assignments/ projects successfully completed/ongoing in the vaccine manufacturing sector during the last Eight to Ten years (Form 'B').

5. **LETTER OF TRANSMITTAL**

The applicant should submit the Letter of Transmittal attached under Section-III of the EOI document.

6. **DISCLAIMER**

The information in this document has been prepared to assist the applicants in preparing the EOI and it is clarified that:

- i. It does not constitute an invitation to offer or an offer in relation to the transaction.
- ii. This document does not constitute any contract or agreement of any kind whatsoever.
- iii. This document does not purport to contain all the information that interested parties and their advisors would desire or require in reaching decisions as to the transaction. Interested applicant should form their own view as to what information is relevant to such decisions and make their own independent investigations in relation to any additional information.
- iv. Neither the information in this document nor any other written or oral information in relation to the transaction or otherwise is intended to form the basis of or the inducement for any investment activity or any decision to enter into any contract or arrangement in relation to the transaction and should not be relied on as such. Neither CRI, Kasauli/ MOHFW-GOI nor their employees or advisors shall be liable to any interested party or any entity under any law including the law of contract, tort, the principles of restitution or unjust enrichment or otherwise for any loss, expenses or damage which may arise, or be incurred, or suffered, in connection with this document, or any matter that may be deemed to form part of this document, or any other information supplied by or on behalf of CRI Kasauli/ MOHFW-GOI or their employees or advisors or otherwise arising in any way from the selection process mentioned herein.

- v. CRI, Kasauli/ MOHFW-GOI is not bound to accept any or all the EOI. CRI, Kasauli/ MOHFW-GOI reserves the right to reject any or all EOI without assigning any reasons. No applicant shall have any cause of action or claim against CRI/ MOHFW- GOI or its officers, employees, advisors, agents, successors or assignees for rejection of this EOI.
- vi. Failure to provide information that is essential to evaluate the applicant's qualifications or substantiation of the information supplied, shall result in disqualification of the applicant.
- vii. It shall not be assumed that there shall be no deviation or change in any of the herein mentioned information. While this document has been prepared in good faith, neither CRI, Kasauli /MOHFW-GOI nor any of their respective officers or employees or advisors or agents make any representation or warranty or shall have any responsibility or liability whatsoever in respect of any statements or omissions here from. Any liability is accordingly expressly disclaimed by CRI, Kasauli /MOHFW-GOI or any of their respective officers, employees, advisors or agents, whether negligent or otherwise.

Section - III

LETTER OF TRANSMITTAL

FROM:

To:

The Director,
Central Research Institute
Kasauli (H.P.)

SUBJECT: Submission of EOI for Revival of Vaccine Manufacturing Unit at CRI, Kasauli (HP).

Sir,

Having examined the details given in EOI Notice and EOI document for the above project, I/We hereby submit the relevant information.

1. I/We hereby certify that all the statements made and information supplied in the enclosed forms 'A' to 'C (i)' and accompanying statements are true and correct.
2. I/We have furnished all information and details necessary for EOI and have no further pertinent information to supply.
3. I/We also authorize Central Research Institute, Kasauli, Ministry of Health & Family Welfare, Govt. of India or their authorized representatives to approach individuals, employers and firms to verify our competence and general reputation.
4. I/We submit the following certificates along with details in prescribed format in support of our suitability, technical know-how and capability for having successfully completed the following projects :

Name of project

Certificate from

Enclosures

Signature(s) of Applicant(s)

Seal of applicant
Date of submission

ORGANISATIONAL STRUCTURE

1)	Name & Address of the applicant with Telephone No./Fax No/Email, Website etc.	
2)	a) Year of Establishment b) Date & Year of commencement of practice.	
3)	Legal status of the applicant (attach copies of original document defining the legal status)	
	a) A proprietary firm	
	b) A firm in partnership	
	c) A limited company or Corporation / Joint venture / Consortia	
4)	Names of Directors & other executives with designation	
5)	Designation of individuals authorized to act for the organization.	
6)	Total No. of professional staff:- Vaccine Manufacturing Unit Planners: HVAC Engineers: Quantity Surveyors: Others:	

7)	Was the applicant ever required to suspend the project for a period of more than six months continuously after commencement of planning? If so, give the name of the project and reasons of suspension of project.	
8)	Has the applicant or any constituent partner in case of partnership firm, ever abandoned the awarded project before its completion? If so, give name of the project and reasons for abandonment.	
9)	Has the applicant or any constituent partner in case of partnership firm, ever been debarred/ black listed for competing in any organization at any time? If so, give details.	
10)	Has the applicant or any constituent partner in case of partnership firm, ever been convicted by a court of law? If so, give details.	
11)	Any other information considered necessary but not included above.	

Signature

FORM – B

Details of Similar Projects completed in the Last Eight to Ten Years

Name of assignment & location			Page No. of EOI for cross referencing and verification of information
Project Cost (Rs. in Crores)	Project Cost		
Commencement date	Scheduled	Actual	
Completion Date	Scheduled	Actual	
Reasons for delay, if any			
Services provided			
No. & Staff involved and functions performed	Staff involved (Discipline-wise)	Staff-Months	
Name of Associated firm(s), if any			
Services provided by the Associated firm(s)			
No. & Staff of associated firms involved and functions performed	Staff involved (Discipline-wise)	Staff-Months	

Name of Senior Staff (Project Director, team leader) involved & functions performed		
Narrative description of project including size, features etc.	Use up to a quarter page	
Description of actual services provided	Use up to a quarter page	
Proof of having completed the work to the satisfaction of Client		
Name & address of Clients Officer to whom reference may be made		

Signature

Note:

1. Applicants are required to page no. their EOI submission document and for cross referencing and verification of information mentioned in the above matrix, the page no. at which the details are enclosed in their EOI
2. Use Separate sheet for each project
3. Only those projects shall be considered for evaluation for which verifiable letter of award and successful completion /occupancy certificate issued by the Client are enclosed.
4. The evaluation shall be based on the qualitative aspects of the applicants work, therefore, please indicate the salient features of the work undertaken including all such factors like time / Cost / quality aspects. You may also enclose photographs etc. to substantiate on the same.

FORM – C

DETAILS OF QUALIFYING PARAMETERS

Sr. No.	RFP particulars requirement	(Ref. Page No. in Proposal)	Details of Particulars provided
1.	Tender document fee Rs. 2,000/- in the form of DD from Nationalized / Scheduled bank		
2.	Qualifying Projects <i>[As per Form –B]</i>		
3.	Power of Attorney for authorized signatory of firm		

ANNEXURE -I