भारत सरकार
GOVERNMENT OF INDIA
केंद्रीय अनुसंधान संस्थान/CENTRAL RESEARCH INSTITUTE
कसौली/KASAULI

Registered/Speed Post/E-mail

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Tel. No. : 01792-273105, 273189
E-mail : director-crik-hp@gov.in
Website : www.crikasauli.nic.in

संख्या / No.: 25-16/2023-Admn

दिनांक /Dated : 14/06/2024
14 JUN 2024

प्रेषक / From :

निदेशक/ **DIRECTOR,**
केंद्रीय अनुसंधान संस्थान कसौली
CENTRAL RESEARCH INSTITUTE, KASAULI

सेवा में /To,

Subject: - **Invitation of Non- Financial Expression of Interest (EOI) in respect of planning, creation and execution of cGMP compliant facility for Antisera Production and Other Allied Facilities at Central Research Institute, Kasauli.**

Sir,

Central Research institute, Kasauli, is engaged in the production & testing of human life saving vaccines, antisera and diagnostic reagents etc since 1905. In order to implement Good Manufacturing Practices, the Institute is in the process of creation of cGMP compliant manufacturing facility for Antisera products and other Allied Facilities (Quality Control Unit, Animal House Facilities- Breeding & Experimental, Ware House Facilities- Raw materials & finished products).

For this purpose Expression of Interest for planning, creation and execution of cGMP compliant facility for Antisera Production and Other Allied Facilities at Central Research Institute, Kasauli from the Government/PSU etc. are invited from the interested organization by 05.07.2024 at 2:00 PM in the sealed cover. The EOI shall be opened on 05.07.2024 at 2:30PM in the conference Hall of the Institute. The detailed format for EOI for participation is enclosed herewith.

The firms can visit the site/laboratories on any working day with prior intimation to this office before submitting the final Non- Financial EOI.

It is therefore requested to submit Non-Financial EOI proposal on or before scheduled date and time. In case of any clarification, feel free to contact us.

Yours faithfully,

Encl. As above.

(Dr. Dimple Kasana)
Director

Government of India

Ministry of Health & Family Welfare

Expression of Interest (Non Financial)

for

Planning, creation and execution of cGMP compliant facility for Antisera Production and other Allied Facilities

at

Central Research Institute,

Kasauli, Himachal Pradesh

(DGHS/MoHFW reserves the right to accept/reject the request for EOI and / or invite afresh with or without amendments to this request for EOI, without liability or any obligation for such request for EOI and without assigning any reason. Information provided at this stage is indicative and DGHS/MoHFW reserves the right to amend/ add further details in the RFP document).

IMPORTANT INSTRUCTIONS

Prospective bidders who wish to participate in bid process need to notify CRI with their contact details (Name, Designation, Organization details with address, Contact Number and Official Email ID) to *director-crik-hp@gov.in, directorcri@gmail.com,* immediately after receiving the EOI document.

Details to be shared in below format –

1) Bidder Name :

2) Designation :

3) Organization Details with Address :

4) Contact Number :

5) Official Email ID :

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SNAPSHOT

Name of Project	Planning, creation and execution of cGMP compliant facility for Antisera Production and other Allied Facilities at Central Research Institute, Kasauli, Himachal Pradesh
Name of Authority	Ministry of Health & Family Welfare
Last date for submission of EOI	**05/07/2024** by 02:00 PM
Date for RFP	*Will be intimated later only to shortlisted firms*
Eligible Entities	Government/PSU agencies
Signature Authority	Authorised Representative/Signatory
Selection Process	**Two stage process** 1. EOI 2. Request for proposal (RFP) stage and Financial bid of shortlisted vendors
Tentative cost of project	**Rs.150 crores**

Qualification Criteria

Technical Criteria:

1) Experience in development/construction of pharmaceutical/biopharmaceutical (preferably immunobiologicals) cGMP projects, either as a single entity or as a consortium

2) Experience of the key personnel with respect to above mentioned pt.1.

Contact person

Director
Central Research Institute
Kasauli -173204
Himachal Pradesh
Tel No. 01792-273105,272114 Email:*director-crik-hp@gov.in*
directorcri@gmail.com

INSTRUCTIONS TO ORGANIZATIONS

i. Organizations are hereby invited for non-financial Expression of Interest for planning, creation and execution of cGMP compliant facility for Antisera Production and other Allied Facilities (Quality Control Lab, Animal facilities [Experimental and Breeding] and Central Warehouse) at Central Research Institute, Kasauli, Himachal Pradesh. Preference will be given to organizations having relevant experience in designing, constructing and validating GMP compliant pharmaceutical/biopharmaceutical facilities preferably immuno-biologicals.

ii. An applicant shall be a Government/PSU agency. The tentative duration of the project is forty-two months from the date of award of contract. During the contract, the organizations shall work for execution of project as per scope of work. The scope of work also includes obtaining approvals/permits from all applicable Government/statutory authorities during various stages of the project.

iii. The EOI should be submitted in accordance with the procedure detailed herein:

   a) The duly filled and completed application form along with all documents (as annexures) shall be enclosed in a single sealed envelope of appropriate size.

   b) All pages of this instruction booklet should be signed and stamped by the authorised signatory as a proof of having read the terms and conditions and submitted along with the EOI.

   c) The Envelope should be super-scribed as*"EOI for Planning, creation and execution of cGMP compliant facility for Antisera Production and other Allied Facilities" to be opened on 05.07.2024 at 2:30 pm,* at Conference Hall, CRI, Kasauli.

   d) The EOI completed in all respects must be submitted in sealed envelope which must be either delivered by hand at Receipt/General Section, CRI, or *sent by registered/speed post to "The Director, Central Research Institute, Kasauli, Dist. Solan, (H.P.), India PIN-173204", to reach not later than 05.07.2024, by 2:00 pm.*

iv. The institute in no case will be held responsible for late receipt or postal delays. EOI proposal received after due date and time, will not be considered.

v. Institute shall hold no responsibility for misplacement/damage or premature opening of unsealed and unmarked envelopes as required.

vi. The EOI received through E-mail/Fax, or not in proper format, or without; appropriate and supporting documents will be summarily rejected.

vii. Bribing/canvassing/influencing by any means shall be deemed as a serious offence and would lead to disqualification of bidder. Central Research Institute

will shortlist eligible firms based on the selection criteria for the second stage of Request for Proposal (RfP).

viii. The organization must ensure that they have people engaged in their organization with relevant experience to take care of all aspects of the projects especially cGMP compliance.

ix. It is the responsibility of organization to identify and declare all possible conflicts of interest that may affect services.

x. The organisation should not have been blacklisted or debarred by any central or state government organizations.

xi. Applicant/Organisation must be free of any legal proceedings for any type of irregularities.

xii. Submission of any wrong/misleading information on any aspect mentioned in the EOI by the organizations shall lead to disqualification at EOI or later stage.

xiii. The shortlisted Organisation(s) is/are required to deliver technical presentation before submission of the RfP.

xiv. The progress of the project shall be monitored by a team of officials decided upon by MoHFW/DGHS/DCGI/CRI, Kasauli etc.

SCOPE OF WORK

Background

The Central Research Institute (CRI) is situated in Kasauli, Himachal Pradesh. Founded in 1905, the Institute is a subordinate office of the Directorate General of Health Services (DGHS), Ministry of Health & Family Welfare (MoHFW), Government of India. The Institute is engaged in the manufacturing of Immuno-biologicals along with other activities. Antisera Division of CRI is engaged in production of Anti-Snake Venom Serum (ASVS) since 1906 while the production of two other products, Diphtheria Anti-Toxin Serum (DATS) and Anti-Rabies Serum (ARS) was started in 1950's. The Antisera Division is currently engaged in the production and supply of equine based ASVS, ARS and DATS that caters to the antisera demand of various central and state-run health units across the country.

The Quality Control Division has been engaged in *in vitro* and *in vivo* quality testing of immuno-biologicals (vaccines, antisera and diagnostic reagents) manufactured at CRI, Kasauli. The division is also associated with testing of raw materials used in production of various immuno-biologicals.

Purpose/Objective:

The Institute is in the process of construction/upgradation of its Antisera production and allied facilities as per cGMP requirements of Schedule "M", Committee for Control and Supervision of Experiments on Animals (CCSEA) guidelines and other international standards such as WHO etc.

Services to be provided by the organization:

The nature of services to be provided by the organizations will include, but will not limited to, preparing the facility and process layout including concept design, equipment design and qualification. The firm shall also provide process sizing, utility sizing, man/material movement planning, entry/exit procedure and clean room layout planning. Human resource estimation, preparation of bill of quantity (BOQ), supervisory support and coordination with CRI officials shall also be provided by the firm at the facility execution stage with due emphasis on quality of design and assistance during validation of the facility.

The organizations will provide sufficient technically qualified and experienced staff for:

1. Designing & monitoring of the project
2. Obtaining necessary clearances including regulatory and non-regulatory
3. Planning and monitoring of Civil, Modular, Electrical, Mechanical and HVAC systems
4. Equipment design, procurement, installation, qualification, calibration and validation
5. Process design and validation as per our products requirements
6. Getting the project approved from DCGI and WHO for schedule "M"/cGMP compliance.

The execution of the project from the start to its completion shall be monitored by a team of project engineers of the firm who shall possess relevant experience and qualification. The progress of the project shall also be monitored by a team of officials decided upon by MoHFW/DGHS/DCGI/CRI, Kasauli. The term "completion of the project" shall be mutually agreed upon.

BROAD SCOPE

The broad scope for creation/upgradation of all facilities are:

1. Designing & monitoring of the project.
2. Getting necessary clearances.
3. Civil, Electrical, Mechanical and HVAC work design and monitoring.
4. Modular work and equipment design.
5. Qualification of facilities and utilities

6. Qualification/Validation and calibration of equipment.
7. Building monitoring systems
8. Getting the facilities approved from DCGI and WHO pre-qualification

In addition to above, other requirements also need to be fulfilled in the proposed facilities as detailed below:

I. Antisera Manufacturing Facility:

1. Planning, Creation and execution of cGMP compliant facility for Antisera Production:

This entails planning, creation and execution of a building(s) from scratch to house the labs, production areas and utilities for development of the latest state of art cGMP production and testing facility for Anti Snake Venom Serum (ASVS), Diphtheria Antitoxin Serum (DATS) and Anti Rabies Serum (ARS). Encumbrance-free land earmarked for the project will be provided for this purpose by the institute. The organization will have to obtain necessary clearances, provide essential equipments, lab furniture etc. for the facility. The firm shall also design and equip suitable utilities for the lab as per the regulatory requirements. Rain water harvesting system to provide potable quality water will also have to be provided. All necessary provisions shall be made to meet the current norms set by the Himachal Pradesh State Pollution Control Board.

Annual Production Capacity:

S. No.	PRODUCT	NEW EQUINE FARM (400 equines)	
		No. of Equines	No. of vials/year
1	Anti-Snake Venom Serum (ASVS)- 10 ml Vials	175	42,000
2	Anti-Rabies Serum (ARS)- 5 ml Vials	175	1,57,000
3	Anti-Diphtheria Serum (DATS)- 10 ml Vials	50	12,000
	Total		2,11,000

2. **Equine Stables:** Upgradation of the existing stables is required to house about 400 equines from the present capacity of 150. It is proposed to construct buildings for housing and bleeding of equines that shall comply with & guidelines of Schedule M, WHO CCSEA (as applicable) used for hyperimmune sera raising.

II ALLIED FACILITIES

All allied facilities need to be constructed/upgraded as per cGMP requirements in the existing building of Quality Control Division, Animal House facilities (Experimental and Breeding) and Warehouse facility.

1. **Quality Control Laboratory**: **Construction/upgradation** of the Quality Control Lab to create:
   a. Sterility testing lab
   b. Media preparation lab
   c. Biochemistry /Raw Material testing lab: Laboratory for biochemical and physiochemical testing of immunobiologicals and raw materials.
2. **Laboratory Animal Facility:** Renovation/upgradation of the existing laboratory animal breeding and *in vivo* testing facility as per Indian Pharmacopoeia, cGMP and CCSEA guidelines.
3. **Central Warehouse**:
   a. The existing Stores department (Raw material warehouse) will have to be upgraded as per the latest GMP guidelines.
   b. The existing Stock and Supply department (Finished product warehouse) also needs to be upgraded as per the latest cGMP guidelines.

In addition to the above, imparting personnel training is also part of the project.

TIME-FRAME

The tentative timeline for completion of the project is forty-two months which may be broadly categorized as under:

S. No.	EVENT	TIME FROM START
1.	Preliminary short listing based on EOI for hiring of organization	1 month
2.	Assessment of Technical and financial bids and finalization of organization	3 months
3.	Submission of plans by organizationfor approval	6 months
4.	Finalisation of plans for the project	9 months
5.	Tendering for construction and equipment procurement	12 months
6.	Completion of civil work	30 months
7.	Commissioning & validation of equipments	36 months
8.	Process validation & submission of design qualification documents	36 months
9.	Manufacturing of trial and commercial batches followed by necessary regulatory approvals	42 months

Graphical representation of tentative time line for completion of project work:

S.No	Activities	1st Year*	2nd Year*	3rd Year*	4th Year*
1.	Preliminary short listing based on EOI for hiring of organization				
2.	Assessment of Technical and financial bids and finalization of organization				
3.	Submission of plans by organizationfor approval				
4.	Finalisation of plans for the project				
5.	Tendering for construction and equipment procurement				
6.	Completion of civil work				
7.	Commissioning & validation of equipments				
8.	Process validation & submission of design qualification documents				
9.	Obtaining regulatory permission from CDSCO				

*Activity execution time on quarterly basis at CRI, Kasauli

**Personnel training will ensue throughout S.No 7 & 9*

SHORTLISTING CRITERIA

1. EXPERIENCE OF THE FIRM (60 %)					
S. No	**Parameters**	**Weightage**	**Max. Marks**	**Criteria**	**Marks**
1.1	Number of years of experience in consultation services for pharmaceuticals/ bio-pharmaceuticals GMP facility	20%	15	Upto 5 years	5 Marks
				5-10 years	10 Marks
				10 years and above	15 Marks
1.2	Experience (in no. of years) in carrying out projects in related field	50%	30	Less than 2 projects	Zero Marks
				Upto 2 Projects	10 Marks
				Upto 3 Projects	20 Marks
				More than 3 Projects	30 Marks
1.3	Experience in consultancy for bio-pharmaceutical projects	20%	10	If one of the projects carried out in Bio-pharmaceuticals	5 Marks
				If more than oneprojects carried out in Bio-pharmaceuticals	10 Marks
1.4	Studies carried out in India.	10%	5	Upto3 years	3 Marks
				More than 3 years	5Marks

2. FINANCIAL STRENGTH OF THE ORGANIZATION (15 %)					
2.1	Annual turnover figure for last Three Years.	50%	7.5	5cr to 10 Crores	**4 Marks**
				Above 10Crores	**7.5 Marks**
2.2	Net Profit figure for last three years	50%	7.5	Up to 1Crore	**3 Marks**
				Above 1Crore Up to 3 Crores	**5 Marks**
				More Than 3 Crores	**7.5 Marks**

3. QUALIFICATION AND EXPERIENCE OF KEY PERSONNEL (25 %)				
S. No.	**Expertise of Key Personnel**	**Qualification**	**Marks for qualification**	**Marks for experience in relevant field (3 years or more)**
1	Project manager	Master's degree in management or equivalent	2	2
2	Architect	Bachelor's degree in architecture or equivalent	1	1
3	Civil Engineer	Bachelor's degree in civil engineering or equivalent	1	1
4	HVAC/Refrigeration engineer	Bachelor's degree in mechanical engineering or equivalent	1	1
5	Electrical Engineer	Bachelor's degree in electrical engineering or equivalent	1	1
6	Instrumentation engineer	Bachelor's degree in engineering or equivalent	1	1
7	Production Specialist	Master's degree in life sciences/ bio-medical engineering	1	1
8	GMP Expert	Master's degree in life sciences/ bio-medical engineering	2	2
9	Experts in Utilities, Validation and Documentation	Minimum Bachelor's degree in engineering/ Master's degree in life sciences or equivalent	2	3

*Only those Bidders shall be shortlisted who secure a minimum aggregate of **60%** marks based on above allocation and minimum **50%** marks in each of the three categories to be eligible for taking part in the further Bidding Process.

FORMAT FORSUBMISSION OF EXPRESSION OF INTEREST

The EOI document duly signed by Head of organization is to be submitted in the following format only:

1	Name of the Bidder	
2.	Office Address	
3.	E-mail	
4.	Website	
5.	PAN No., TIN No., GST No.	
6.	**Authorized Representative** a) Designation b) Mobile /Phone No. c) FaxNo. d) E-mail	
7.	Key Personnel to be designated for the said project along with their designation, qualifications and relevant experience (See Annexure II)	
8.	Registration No. and date of registration of organization, if applicable	
9.	Principal Place of Business	
10.	Act/Rule under which the organization was registered	
11.	Type of Organization (Government/PSU agency)	
12.	Whether any criminal case was registered against the organization or any of its promoter since the past or was the organization blacklisted	Yes/No
13.	Number of offices/centres in India	
14.	Total Experience of the organization in creation of cGMP compliant facilities	
15.	List of projects completed in which the firm has delivered services similar to that in this project (See Annexure III)	
16.	Turn-over of the organization during last three years (year wise)	
17.	Any other relevant information deemed suitable (Add as Annexure IV)	

LIST OF ANNEXURES

Information and documents required to be attached as Annexures with the EOI:

Annexure I	Covering Letter
Annexure II	Key Personnel to be designated for the said project along with their designation, qualifications and relevant experience
Annexure III	List of projects completed in which the firm has delivered services similar to that in this project.
Annexure IV	All other relevant information

Annexure I

Format for Covering Letter
(On the Letter head of the Applicant)

Date:

To

The Director,
Central Research Institute,
Kasuli,
Himachal Pradesh -173204

Ref: Expression of Interest (EOI) for Planning, Creation and execution of cGMP compliant facility for Antisera Production and other Allied Facilities

Sir,

Being duly authorized to represent and act on behalf of..... (Hereinafter referred to as "the Applicant"), and having reviewed and fully understood the evaluation criteria and information provided, the undersigned hereby apply in response to the EOI document for hiring of organization for creation of cGMP compliant Antisera and Allied Facilities project. We are enclosing our Expression of Interest with the details as per the requirements of the EOI document, for your evaluation.

Yours faithfully,

_____

(Signature of Authorised Signatory)

(Name, Title and Address)

ANNEXURE II

Key Personnel to be designated for the said project along with their designation, qualifications and relevant experience:

S. No	Name, Designation and Qualifications	Permanent/ contract basis	Period of engagement		Work Experience (No. of years)	Summary of work experience (Project/ role/ tasks)	Whether person shall be involved in current project
			From	To			

ANNEXURE III

A list of projects completed in which the organization has delivered services similar to that in this project.

Name of the assignment	Date of award of assignment	Date of completion of assignment	Country	Value	Client's Name	Short-description of assignment