National Institute of Pharmaceutical Education and Research – Guwahati
(*Dept. of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt. of India*)
Vill : Sila Katamur (Halagurisuk), P.O. Changsari, Dist. Kamrup (Assam) 781101

NOTICE FOR APPOINTMENT OF CONSULTANT

Ref No. NIPERG/01/EOI/2020-21 **Dated: 13/04/2020**

Director, NIPER-G, (An autonomous Institute under the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers, Govt. of India), Changsari, Guwahati, Assam invites, Bids in sealed envelope from Consultancies / Agencies either Individual or in group for Expression of Interest (EOI) for providing state-of-art solution for detailed Engineering, Design, Planning, Procurement & Execution of these following projects

1. To establish a GMP accredited Pilot Scale Extraction facilities for the development of Herbal or Phytopharmaceutical products from the Medicinal Plants of North Eastern India funded by Dept. of Biotechnology (DBT), Govt. of India.

2 Quality Assessment & Value Addition Centre for the herbal industry in the North Eastern States of India, by Ministry of Commerce, Govt. of India under TIES Programme.

Document related to Notice for appointment of a Consultant with details can be downloaded free of cost from Institute's website.

Last date of submission of EOI at NIPER-G : 11/05/2020 at 13.00 hours (1 P.M.)

Opening of Envelope (Expression of Interest): 11/05/2020 at 15.00 hours (3 P M)

The quotations received after the above indicated date and time will be rejected, treating them as late quotations.

Date of discussion & presentation in front of the committee: Bidders will be intimated about the suitable date and venue of the presentation later.

The Institute reserves the right to reject any or all tenders without assigning any reason thereof.

For details please visit NIPER-G website http://niperguwahati.ac.in

Introduction:

NIPER-Guwahati is one of the premier institutes under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. NIPER-Guwahati started functioning from the month of September, 2008. This institute is "Institute of National Importance" in the North Eastern Region of our country for providing high quality education and research in Pharmaceutical Sciences. It is also a place where knowledge in science and education stimulates technological innovation to inspire the student community to pursue scientific or industrial careers.

NIPER-G is an autonomous grant-in-aid institution of the Department of Pharmaceuticals (DoPs), Min. of Chemicals & Fertilizers, Govt. of India), Changsari, Guwahati, Assam.

NIPER-G new campus comprises three major structures i.e., Administrative Block (Block-A), remaining two (Block-B & C) are for basic/applied pharmaceutical research. NIPER-G also has fully equipped state-of-the-art instrumental facilities. Research investigations currently focus on drug discovery, development & production of herbal based products for major human diseases relevant to NER. It is envisaged that in the future, NIPER-G will play a greater role in drug development and emerging therapies for treatment and prevention of high-priority diseases of NER like cancer, lung fibrosis, asthma, etc.

On the said background, NIPER-G is planning to set up these two facilities for the development of Herbal or Phytopharmaceutical products from the Medicinal Plants of North Eastern India which are to be produced/manufactured in clean environment as per the GMP herbal guidelines as set in Schedule M/WHO GMP heading as "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products". On the other hand, other facilities Quality Assessment & Value Addition Centre for the herbal industry in the North Eastern States of India, by Ministry of Commerce, Govt. of India under TIES Programme will be focused to include following units:

1. *Extraction Unit (GMP):* The extraction unit will be following the WHO-Good Manufacturing Practices (GMP) guidelines and will provide support to the companies and entrepreneurs in the production of value-added products such as standardized herbal extracts at the pilot level to mimic the exact condition of the herbal industry.

2. *Quality Control and Quality Assessment Lab:* The lab will provide support to companies and entrepreneurs in testing herbal raw materials before purchase, testing quality of processed herbs before packaging and testing quality of standardized herbal products (extracts and formulations) before packaging as per the export standards. The intention is to get the Quality Control Lab & NABL accredited in due course of time.

3. *Formulation & Packaging Unit (GMP):* The formulation unit will be following WHO -Good Manufacturing Practices (GMP) guidelines and will provide support to companies and entrepreneurs in the production and packaging of value-added formulated products (solid and liquid dosage forms) for consumption such as capsules, tablets, liquid syrups etc., The formulation unit will have a small pilot scale unit with a capacity to produce 30,000 tablets & capsules per hour.

These facilities will be built to meet its upcoming research, production & export needs and will be located behind the B & C-Blocks of NIPER-G, Changsari campus. Exact requirement and selection of the clean room system and various protocols to be followed shall be based on cGMP Guidelines as specified by Schedule M of Drugs & Cosmetics Act/WHO/other acceptable standards. NIPER-G, Assam, in view of this, wants to Appoint a Consultant from reputed firms/Individuals belongs to India to provide state-of-art solution for design, planning, Engineering, Procurement & Execution of CGMP (Current Good Manufacturing Practices) Grade facility at NIPER-G campus, Assam.

Brief requirements:

As an alternative to allopathic medicine, NIPER-G has ventured into the research & development of herbal/phytopharmaceutical based extraction, production & export facilities for the treatment of most prevalent diseases of the North Eastern Region. Such treatment can be highly effective and also have minimal side effects on the patient's community. However, herbal/phytopharmaceutical based extraction, production & export facilities are currently unavailable in North Eastern Region, India due to high cost of installation & maintenance of such a facility. To improve the standards of herbal products to make them commercially viable as per the international standards, we are planning to set up these two facilities under a single umbrella behind the B & C-Block at NIPER-G, Changsari campus. The approximate area for setting up of "GMP accredited Pilot Scale Extraction facilities for the development of Herbal or Phytopharmaceutical products from the Medicinal Plants of NE India" including production rooms and offices and "Quality assessment & value addition centre for the herbal industry in the North Eastern States of India" would be around 5000 sq. ft., and 1568 square meters (G + 1) respectively . The proposed infrastructure will host suitably designed production rooms and offices for support staff of ~ 30 people and should be designed with all the required respective international standards detailed later in the document. The Basic requirements of the rooms is described with details in the scope of work. Necessary civil work, cooling system approach with various options, clean room infrastructure including physical security with firefighting facility and office space with necessary civil and furniture work, electrical works (including distribution of mains, lighting, LT panels, and UPS), cooling system are need to be designed as per the regulatory requirement. The bidder needs to plan space for all the rooms as mentioned above. Connection to the existing DG sets and other HT equipment are to be planned in the external areas available just adjacent to the archival building. Bidders have to survey the site and

participate in EOI with a suitable solution with detailed BOQ and specifications of every possible segment of the solution proposed. The bidder may submit multiple suitable solutions in detail in EOI with their possible merits independently.

OBJECTIVE

The purpose is to shortlist the prospective competent consultant, for the issue of RFP/RFQ based on their suggested comprehensive solutions endorsed by the benchmark suite for detailed Engineering, Design, Planning, Procurement & Execution of cGMP (Current Good Manufacturing Practices) Grade facility for these two facilities. The resultant finalized RFP would be based on the best suitable available technology/design proposed by Bidders, supported by the benchmark results/assessment by the NIPER-G technical committee.

Facility 1: "To Establish a GMP accredited Pilot Scale Extraction facilities for the development of Herbal or Phytopharmaceutical products from the Medicinal Plants of NE India

Extraction Unit (GMP): The extraction unit will follow WHO-Good Manufacturing Practices (GMP) guidelines and other established standards and will provide support to the companies as well as entrepreneurs in the production of value-added products such as standardized herbal extracts at the pilot level to mimic exact condition of the herbal industry. (Funded by Department of Biotechnology, Govt. of India).

Facility 2: "Quality Assessment & Value Addition Centre for the herbal industry in the North Eastern States of India"

The proposed Centre will include following units:

1. *Quality Control and Quality Assessment Lab*: The lab will provide support to the companies and entrepreneurs in testing of herbal raw materials before purchase, testing quality of processed herbs before packaging and testing quality of herbal products (extracts and formulations) before packaging as per the export standards. The intention is to get the Quality Control Lab accredited by NABL in due course of time.

2. *Formulation & Packaging Unit (FPU-GMP):* Under the proposed facility the extraction and formulation units will be established by following GMP guidelines and will provide support to the companies and entrepreneurs in production and packaging of standardised herbal extracts as well as value-added formulated products for its consumption such as capsules, tablets, liquid syrups etc., The formulation unit

will have a small/pilot scale capacity to produce 30,000 Nos tablets & capsules per hour. GMP extraction facility should be with input capacity of 20-25 KG extractor.

Built-up area: approx. 6000 square meters (G + 1)

Scope of Work FOR FACILITY 1 & 2

1. CONCEPTUAL DESIGN

- Project Goal & Objective should be defined.
- Proposed capacities, Batch sizes, Inventory norms for warehouse and provision for expansion also should be identified.
- Finalization of Process Flow Diagrams in consultation with the Client.
- All Equipment, related systems with specifications are to be identified and documented.
- Development of Concept layouts with cGMP, man material movement.
- Project TimeLine should be clearly defined

2. BASIC AND DETAIL ENGINEERING:

- The equipment Layout shall be developed along with Specifications & Room Data.
- HVAC DESIGN - Classification along with zoning has to be done.
- UTILITIES DESIGN with P&ID & Specifications.
- Generation of Energy Load data for Design of the Electrical system.

3. ARCHITECTURAL SCOPE

- To Develop floor Interior Layouts and sectional heights based on Data provided by the client and all the drawings shall be as per actual measurements.
- Door windows and sanitation/ drainage points to be shown clearly in layout.
- Working Drawing of sites to be prepared.
- Finalize technical specifications, discuss, suggest makes/ type, sizes for the material to be used as per the provided data sheets.
- Bill of quantities & specifications as per final design.

4. ELECTRICAL SCOPE

- Design of electrical layout, cabling layout drawings including lighting and allied services.
- Preparation of Single Line Diagram
- Preparation of Technical specification and Bill of Materials for Panels, Transformer, Illuminations etc.,
- Preparation of cable schedule

5. PROCUREMENT ASSISTANCE, if required

- Preparation of detailed Vendor list in consultation with the Client
- Techno-commercial evaluation of offers / bids and recommendation for supply of plant & machinery.
- Follow-up for GA drawings and documents & approval of GA drawings.

6.SITE SUPERVISION.

- The Consultant shall supervise the Project work at site as and when required.

7.DOCUMENTATION

- The consultant shall guide and assist in the preparation of the relevant cGMP documentation.

8.TIME FRAME

- The facility should be completed in 10 months (ready for commissioning) time from the date of signing of the agreement and receipt of advance as stipulated.

9. EXCLUSIONS

- Any items not covered by points 1 to 8

Required Clearances

1. All the municipal and environmental clearances have already been taken by NIPER Guwahati for its new campus construction. Therefore, no separate clearances will be required for the facility.

2. Civil and related works will be done by the existing PMC (identified by Department of Pharmaceuticals, Govt. of India for the construction of NIPER Guwahati campus.) after finalisation of layouts and drawings.

General terms and conditions –

1) The Technical bid must be accompanied with duly filled information sheets and sufficient documentary evidence. Expression of Interest without complete information or sufficient documentary evidence are liable for rejection.

2) Bidder or firm/Agency should have past expertise of at least two Projects in the establishment of WHO-GMP extraction facility, establishment of formulation units at least two of which shall be for QA & QC facility for the production of herbal or nutraceutical products.

3) NIPER-G reserves the right to modify, expand, restrict, scrap and re-float the expression of Interest, depending on the need of the institute

4) Bidders should submit the tender in two bid systems i.e., Technical and Financial bids separately in a sealed envelopes, super scribing clearly on each envelope as Technical Bid for……. and Commercial Bid for…….. Both Technical and Commercial Bid sealed covers should be kept in an outer cover super scribing the bid for…… due on…….. The covers without any indication of contents of the cover will be liable for rejection. The last date for submission of bids is 11th May 2020 at 13.00 Hours (1 P M) and the same will be opened at 15.00 Hours (3 P M).

5) On the due date of opening, Covers containing the technical bids only be opened and the corresponding commercial bids of short-listed consultants/Agencies will only be opened at a later date with intimation to them.

6) *Clarification:* Clarification, if any, about the requirement can be obtained by visiting the purchase section with prior information on any working day on or before 5th may 2020 ,17.00 Hours (5 P M). Queries /Enquiries made after this date will not be entertained.

7) It will be the sole discretion of NIPER-G to accept or reject any changes in the requirement based on feedbacks/inputs/suggestions received during the process of finalisation of the Consultant. The decision of NIPER-G committee regarding acceptability of any suggestion shall be final in this regard. NIPER-G reserves the right to modify, expand to form resultant RFP based on the latest technology/power efficiency/process flow/reliability, Interior design of office space etc.,

8) In the Process of Technical evaluation

a) The bidders can be asked to clarify/provide additional required information and relevant documents.

b) The Authorised Representatives of the Bidders May be invited to give a presentation of their plan of action to handle the assignment.

c) The Constituted committee from Niper(G), if found necessary, may visit customers premises to get feedback of performance of the bidder.

9) Payment Terms: As a matter of Institutes' policy No request for Advance Payment will be considered. The institute will make Payment as Indicated below.

a) 20% Payment after submission of Designs, Drawings, Proposed plan for Execution of contract etc. and acceptance by the committee and ensuring receipt of Security deposit amount.

b) 30% payment as a Second Instalment after assessing the progress of the work by the committee.

c) 30% payment as a Third Instalment against certification of progress of work by the committee.

d) The balance 20% after Successful completion of contractual obligations and final certification by the committee.

10) Security Deposit: The Successful bidders are expected to Deposit 5% value of contract as a Security Deposit through a demand draft in favour of the Director, NIPER-G,within 21 days of receiving the Contract assignment letter issued by the Institute. The Security Deposit amount will be refunded to the bidder after completion of Contractual obligations and certification by the Authorised committee.

11) Disputes, if any, shall be resolved mutually or shall be referred for arbitration to the Director, NIPER-G and his decision shall be final and binding on the firms. If arbitration fails, the dispute arising out of this shall be subjected to jurisdiction- courts of Guwahati only.

12) NIPER-G requires that there should be a single point of contact (SPOC) from a firm who is responsible for all the issues between NIPER-G and the Consultant.

13) Timing and sequence of events resulting from this appointment shall ultimately be determined by NIPER-G.

14) The covering letter and the Proforma given in the documents should be submitted on bidder's Letterhead, along with the technical proposal as well as financial proposal in separate envelopes.

15) In the Technical Bid ,the bidders shall submit a list of clients for whom they have executed similar types of projects. This list should clearly enunciate the address of the premises, with phone nos. /fax nos. /email and the names of the contact persons. NIPER-G technical committee shall visit these sites, if required, interact with the end users to establish the credibility of the bidder.

NB: During evaluation, the committee may summon bidders and seek clarification/ information or additional documents or original hard copy of any of the documents already submitted. If these are not produced within the stipulated time frame, the bid may be liable for rejection.

Group/Consortium related conditions

The bidder shall have the option to submit the proposal either alone or along with other partner companies. Maximum two more partners i.e. in totality consortium of three are allowed. Prerequisites for bidder have been specified in the qualifying requirement and other parts of the tender document. The lead partner will have the prime and sole responsibility for the execution of the scope of work. Any information/clarification submitted to the lead partner by NIPER-G will mean that the same has been conveyed to all partners. However, the partner companies should not

be involved in any major litigation that may have an impact of affecting or compromising the delivery of services. The bidder or any of the partner companies should not have been black-listed by any Central / State Government or Public Sector Undertakings. If at any stage of tendering process or during the currency of the contract, any suppression / falsification of such information is brought to the knowledge, NIPER-G shall have the right to reject the proposal or terminate the contract, as the case may be, without any compensation to the tenderer.

Prequalification criteria – to be furnished in the cover containing the Technical bid.

The committee will carry out a detailed evaluation of the proposals. Only those who qualify all pre-qualifications criteria, are eligible and notified accordingly. The firm must possess the requisite experience, strength and capabilities in providing the services as described in the document. The bidder must possess the technical know-how that would be required to successfully provide the support services sought for the entire period of the contract. The Notice for Appointment of Consultant is open for all bidders who qualify for the eligibility criteria as follows –

Sr. no.	Basic requirement	Criteria	Documents required
1	Legal Entity	The bidder should be an individual or if it is a Private/Public Limited company should be registered under the companies Act, 1956 or a registered firm. In case of a company, it should be in existence for more than 5 years as on 31.03.2018. The individual/ Firm should be based and operated in India. The company must be registered with appropriate authorities for all applicable statutory duties/taxes. In the case of an individual, he should have good experience in establishment of proposed facilities. Evidence of such experience must be mentioned which may be verified by NIPERG.	Valid documentary proof: - Certificate of Incorporation (if applicable), GST number. PAN number.
2	Mandatory requirement	The bidder should have executed at least Two similar comprehensive projects using the architecture and technologies similar to those being proposed in this bid.	To submit
3	Experience	The Agency interested in bidding should have sufficient experience in the similar works during the last 3 years.	To submit

To

The Director,
NIPER-G,
Changsari-781103, Assam.

Ref: Notice for Appointment of Consultant No.TMC/NIPER-G/

We, the undersigned, declare that:

A) We have examined and have no reservations to the Notice documents, including Addenda (if any) issued in accordance with Instructions to the Bidders.

B) We offer to extend Consultancy in conformity with the Notice for appointment Of Consultant for Execution of cGMP (Current Good Manufacturing Practices) standard facilities as per the regulatory criterion.

C) We also declare that Government of India or any other Government body has not declared us ineligible or black listed us on charges of engaging in corrupt, fraudulent, collusive or coercive practices or any failure / lapses of serious nature.

D) We also accept all the contents, terms and conditions of this Notice document and undertake to abide by them, including the condition that you are not bound to accept the bid that does not fulfil criteria specified in the Notice.

Yours sincerely,

(Authorized Signatory)

Note: Authorized person shall attach a copy of Authorization for signing on behalf of bidding company.

Full Name and Designation

(To be printed on Bidder's letterhead)

Annexure II

Non- Black Listing Self Certificate

This is to certify that I / M/s._____has / have not been blacklisted by any Central / State Government Department / organization in last 3 years.

Authorized Signatory Name: _____

Designation: _____

Note: In case of company, authorized person shall attach a copy of Authorization for signing on behalf of bidding company.

Full Name and Designation

(To be printed on Bidder's letterhead)

Annexure III

Undertaking

This is to certify that I have gone through all the pages of the document. The applicant company undertakes to abide by all the terms & conditions mentioned in the Notice document. It is further certified that the information furnished in the Notice documents is true and correct.

In the Event of any of above information found to be false, we understand that our proposal can be rejected and not considered.

Date:	Signatures:
Place:	Name:
Seal	Designation:

Note: Authorized person shall attach a copy of Authorization for signing on behalf of bidding company.

Full Name and Designation

(To be printed on Bidder's letterhead)

AGENCY CHECKLIST AT THE TIME OF SUBMISSION OF EOI		
Sl. No	Information Sought	Information Provided
1	Name of the Individual / Agency	
2	Name of Parent/Partner Organization	
3	Legal Status of Individual / Agency	
4	Year of Incorporation Agency/Parent/Partner or year of execution of first project in case of individual	
5	Local Address	
6	Number of years of Operation	
7	Document and Duration of Association (Parent / Partner)	
8	Name of Chief Functionary and Contact Details	
9	No of employees in the Agency	
10	GST No.	
11	PAN No.	
12	Experience in the relevant field	
13	Description and Value of Works executed	
14	In case of Company Annual Turnover (please provide audited Balance Sheets for previous 3 financial years)	
15	Site Visit and Review of Plans	