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Tender Details

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Basic Details														
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Organisation Ch		·			iticals Nation	nal Insti	tute of Pha	rmaceutical E	ducation	and Resea	arch (N	IIPER) Gu	wanati	
Tender Referen	ce Num			GMP-Consu	IIT/23-24									
Fender ID		2023_M	CF_/0/	/69_1										
Tender Type EOI					Form of contract EOI									
Fender Categor		Services				No. of Covers 1								
Payment Mode		Not Applicable				Is Multi Currency Allowed For BOQ No								
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Cover Details	<u>s, No. (</u>	Of Covers -	1											
Cover No	C	Cover Document Type					Description							
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Critical Dates	5													
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Documents	S.No	Document Ty	ument Type			Document Name			Description			Document Size (in KB)		
	1 Т	ender Docume	ler Documents			EOI GMP.pdf			Expression of Interest to engage a GMP Consultant at NIPER- Guwahati to install a Herbal			. ,		
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Designation	Assistant Registrar
Created Date	17-Apr-2023 02:04 PM



EXPRESSION OF INTEREST TO ENGAGE A GMP CONSULTANT AT NIPER-GUWAHATI TO INSTALL A HERBAL EXTRACTOR FACILITY UNDER A GMP PILOT-SCALE PLANT

<u>No.: NIPER-G/S&P/8/GMP-Consultant/2023-24/...3</u> Date: 17/04/2023

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH-GUWAHATI

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India SilaKatamur, Halugurisuk, Changsari, Kamrup, Assam-781101, India

Ph: 7099007822 Email: *purchase@niperguwahati.ac.in*



राष्ट्रीय औषधीय भिक्षा तथा अनुसंधान संस्थान गुवाहाटी NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCHGUWAHATI

(Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India) SilaKatamur (Halugurisuk), P.O.: Changsari, Dist: Kamrup, Assam, Pin: 781101.

No. NIPER-G/S&P/GMP-Consultant/2023-24/.13

Date: 17/04/2023

EXPRESSION OF INTEREST TO ENGAGE A GMP CONSULTANT AT NIPER GUWAHATI TO INSTALL A HERBAL EXTRACTOR FACILITY UNDER A GMP <u>PILOT-SCALE PLANT</u>

National Institute of Pharmaceutical Education and Research (NIPER)-Guwahati is an Institute of National Importance set up by an Act of Parliament under the aegis of Dept. of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt. of India, to impart higher education and undertake advanced research in the field of Pharmaceutical Sciences and Technology. NIPER-G is establishing a GMP accredited Pilot Scale extraction facilities to develop herbal or phytopharmaceutical products from the medicinal plants of NE India with financial support from the Department of Biotechnology, Ministry of Science & Technology, Government of India.

NIPER-Guwahati intends to install an Herbal Extractor Facility under a GMP pilot-scale plant and intent to call expressions of interest (EoI) from any consultancy agencies or registered entities or any individuals having relevant experience to guide the team of NIPER Guwahati in the following duties and responsibilities. The Consulting registered Organizations or registered entities, or any interested individuals may fill the application in two parts *i.e* (a) Technical details and (b) Commercial details as per the formats enclosed in Annexure 1 and Annexure 2 in separate sealed envelopes.

The information in sealed envelope is hereby invited by the undersigned, on behalf of Director, NIPER Guwahati from reputed vendors so as to reach in this office on or before 8th May 2023 (Monday) up to 2:00pm and shall be opened on the same day at 3:30pm in Stores and Purchase Department, NIPER Guwahati. Sealed cover/envelop must be super scribed with "GMP CONSULTANT AT NIPER-GUWAHATI TO INSTALL A HERBAL EXTRACTOR FACILITY UNDER A GMP PILOT-SCALE PLANT".

Duties & Responsibilities

- 1. Checking the designs of the herbal extractor facility provided by the supplier and providing his suggestions, if any, for improvement to NIPER-G.
- 2. Monitoring the progress of the fabrication of the extractor and its associated accessories at the site of the supplier/ vendor finalized by the NIPER-G and submitting weekly progress reports to the NIPER-G Coordinator. The consultant will be responsible for appropriate equipment for the herbal extractor facility that meets the requirements of GMP. The consultant will also need to ensure that the equipment is qualified and validated before it is put into use.

- 3. Check the partitions of the plant proposed by the civil contractor of NIPER-G, as per the designs of the fabricator, and suggest if any modifications are required with GMP compliance.
- 4. Monitoring and guiding of installation of the above equipment at the site of NIPER-G
- 5. Get the demonstration of the herbal extraction process from the vendor after installing the equipment at NIPER-G.
- 6. Helping with the documentation for getting approvals from the State FDA license for GMP (Only documentation and guidance and the process at the local bodies will be taken care of by NIPER-G)
- 7. Standard Operating Procedures (SOPs): The consultant will need to develop and implement standard operating procedures for all aspects of the herbal extraction process. This includes procedures for equipment operation, cleaning, and maintenance, as well as for the testing and release of finished products.
- 8. Training: The consultant will be responsible for training the plant personnel on the GMP requirements, the facility design, and the standard operating procedures. This ensures that all personnel understand their roles and responsibilities in maintaining GMP compliance. Minimum 3 programs to be conducted.
- 9. Quality Control: The consultant will also be responsible for developing and implementing a robust quality control program to ensure that the herbal extract produced meets the quality standards set by the regulatory agencies. The financial implications connected with this aspect are to be quoted separately and the Institute reserves the right to take a decision on its inclusion during the contact period.
- 10. Documentation: The consultant will need to ensure that all aspects of the herbal extractor facility are properly documented. This includes documenting equipment qualification, standard operating procedures, and quality control procedures. Good documentation practices are essential to maintaining GMP compliance.
- 11. Audits: The consultant will be responsible for conducting internal audits to ensure that the herbal extractor facility meets GMP requirements. This includes conducting regular self-inspections to identify and correct any potential compliance issues.
- 12. Any other Assignment given by the Director, connected with above assignment.

Essential Requirement:

- 1. Consulting registered Organizations (CRO) or registered entities registered under any Indian law and applying in response to this advertisement should have relevant experience in undertaking this kind of job and should be in this line for a period of at least five years. Individuals having relevant experience may also apply.
- 2. The applicant should be a well-qualified and experienced scientist/engineer, capable of executing the responsibilities required for completing the job detailed through this document.
- 3. The applicant must be a doctorate in a relevant field with a minimum of 8-10 years of experience to establish a GMP-accredited pilot scale extraction facility. In case CRO or registered entity is participating, the firm or registered entity should have at least one staff with the minimum qualification as specified for individual applicants.
- 4. Proven record in establishing a GMP-accredited pilot scale extraction facility either in the capacity of an individual or registered entity or CRO (enclose the proof of GMP training certificate).

- 5. Should have proven record to impart training ON GMP principles.
- 6. If bidding as an individual is participating for the EoI. The maximum age should not be more than the 63 years as on last date of the application (Proof either birth certificate or SSC must be enclosed only for individual applicant).

Tenure of engagement: Initially for a period of one year, that may be extended based on the need and performance the identified bidder.

The Director reserves the right to withdraw above EOI at any stage without assigning any reason. Director further reserves the Right to Relax any of the conditions, in the best Interest of the Institute.

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Annexure-1

Technical Details for the EoI as consulting firm/consultant to install an herbal extractor facility under a GMP pilot-scale plant.

- 1. Name of the applicant/registered entity/CRO: (in case if the applicant is CRO, furnish the details of the concerning authority with designation, furnish the details of company registration, Pan details, and enclose the GST filing for minimum of three years)
- 2. (a) Date of Birth (b) Age as on the last date of application (Proof should be attached if an individual applicant)
- 3. Adress for correspondence
- 4. Essential qualification

a) Qualification (proof of certificates may enclose)

S.no	The subject of master degree/University/Institute	Subject of Ph.D/University/Institute			
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b) Experience in Terms of Duties & Responsibilities mentioned in the EoI

S.no	Name of the organisation/Designation	from	То	Total experience

c) Detail of the organization served as an individual consultant/registered entity or as CRO:

d)Furnish the detail(s) of the organization that obtained GMP certification as an individual/registered entity or CRO consultant. (GMP certificate-Proofs should be attached)

Note: (a) For Those who qualify technically as per the essential requirement in the EoI, a financial envelope will be opened for the respective consultant/CRO only. The entity quoting the lowest amount per month would be considered for the award of work (b) If an individual applicant /CRO fails to submit or furnish the details as per the essential requirement will be technically rejected.

Annexure-2

1.50

Financial Details for the EoI as consulting firm/consultant/registered entity

- 1. Name of the applicant/CRO/registered entity:
- 2. Amount quoted per month (in Rupees): as consolidated based on the quantum of the work specified in the duties and responsibilities. (*Statutory taxes as applicable would be loaded extra and paid to the entity and same may not be included in the quote*)
- 3. The above quote should be exclusive of TA. NIPERG will provide air tickets and accommodation in the guest house of NIPERG as and when required with the approval of the competent authority. The local transport needs at the places of prospective bidder to be bear by the consultant.

Most of the meetings will be preferred online only. As per the decision by the competent authority or upon request by any of the faculty of NIPERG, the consultant/registered entity or any representative of CRO must attend physical meetings as when required.

4. Any missing component may be quoted as optional apart from the monthly charges.