S.A.S. Nagar

राष्टीय औषधीय शिक्षा एवं अनसंधान संस्थान (नाईपर), एस.ए.एस. नगर
National Institute of Pharmaceutical Education and Research (NIPER) S.A.S. Nagar
Sector 67, S.A.S. Nagar (Mohali)-160062, Punjab (India).

6. APPOINTMENT OF CONSULTANT/AGENCY FOR cGMP PILOT PLANT (API)(T1/2023)

National Institute of Pharmaceutical Education and Research (NIPER) invites online e-tenders in two –bid format for **Appointment of Consultant/Agency for cGMP Pilot Plant/ (API)** at the Institute as per the specification and other details given in the tender documents can be obtained from the website: CPP Portal : https://eprocure.gov.in/ and official website of the NIPER http://www.niper.gov.in.

1	Date of submission of e-tender	Start Date 18.02.2023 at 10.00 AM
		End Date : 11.03.2023 at 05.00 P.M
2	Opening of Technical Bid (online)	13.03.2023 at 11.00 A.M

Director, NIPER reserves the right to reject any or all tenders without assigning any reasons. Corrigendum/Addendum or Cancellation of this advertisement, if any, shall be published on NIPER Website www.niper.gov.in and CPP Portal : https://eprocure.gov.in/**.**

Officiating Registrar

APPOINTMENT OF CONSULTANT/AGENCY FOR cGMP PILOT PLANT (API)

Ref No. NIPER

National Institute of Pharmaceutical Education and Research (NIPER) SAS Nagar (Mohali), (An autonomous Institute under the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers, Govt. of India), SAS Nagar, Mohali Punjab invite bids in a online tender from Experienced 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 at DSIR-CRTDH at NIPER Mohali.

1. To establish a cGMP accredited Pilot Scale facilities for the development of API & Chemicals/ herbal as per ICH Topic Q 7 Good Manufacturing Practice (Key starting materials(KSMs)/Intermediate/finished for pharmaceutical products) by financial support under BIRD-crf scheme of DSIR for creation of Common Research and Technology Development Hubs (CRTDHs) in SECTOR- Chemical Process (Active Pharmaceutical Ingredient) (Target Area-5)
2. To establish a kilogram laboratory of innovation Quality for the API industry
3. To Set-up of R&D Laboratory for R&D innovation for the API industry
4. To Set-up of an Analytical Laboratory with NABL compliance

All projects 1-4 will be financial supported under BIRD-crf scheme of DSIR for creation of Common Research and Technology Development Hubs (CRTDHs)

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.

CRITERIA OF ELIGIBILITY

1. Consultant fulfill the following criteria shall be considered by NIPER, Mohali for technical evaluation

(a) The complete company profile including registration with appropriate authority with documentary evidence.

(b) Bio Data of key personnel on the roll of the Firm/Agency.

(c) A list of customers for whom similar jobs have been executed.

(d) Certificate of successful completion of similar jobs issued by at least two different customers.(Similar job Mean “establishment of approved WHO-GMP Facility, establishment of API units at least two of which shall be for QA & QC facility for the production of API”

(e) Proof of PAN No.

(f) Documentary evidence of GST No.

(g) List of works in hand with value, Name and address of the clients.

Introduction:

National Institute of Pharmaceutical Education and Research (NIPER) SAS Nagar (Mohali) is the first national level institute in pharmaceutical sciences with a proclaimed objective of becoming a centre of excellence for advanced studies and research in pharmaceutical sciences. The GoI has declared NIPER as an “Institute of National Importance”. It is an autonomous body under the aegis of Department of Pharmaceuticals, Ministry of Chemical & Fertilizers, GoI. NIPER SAS Nagar is fully equipped state-of-the-art instrumental facilities. Research investigations currently focus on drug discovery, development & production of herbal & API based products for major human diseases relevant to the country. It is envisaged that in the future, NIPER-Mohali will play a greater role in drug development and emerging therapies for treatment and prevention of high-priority diseases of country like cancer, lung fibrosis, asthma, etc. On the said background, NIPER SAS Nagar is planning create a new current Good Manufacturing Practice (cGMP) pilot plant within this complex along with laboratories with the assistance of DSIR under CRTDH scheme. This newly created advanced GMP certified DSIR-CRTDH facility will be useful for pharmaceutical/chemical MSMEs for research, scale-up and validation of processes. The proposed advanced facility will fulfil the gap of research and innovation which is absent in MSMEs for the development of new process technologies for APIs. Further, Pilot plant and scale-up techniques are both integral and critical to drug discovery and development process for new medicinal products. These facilities are for the development chemical processes for Key starting materials(KSMs)/Intermediate/APIs) which are to be produced/manufactured in clean environment as per the GMP-API guidelines as per Schedule M/ ICH Topic Q 7 /WHO cGMP under heading as “Current Good Manufacturing Practices and Requirements of premises, Plant and Equipment for Pharmaceutical Products”. On the other hand, other facilities for quality assessment (IPQC) & value addition laboratories (Kilogram and R&D) for the chemical/pharmaceutical industry. Thus the facility will be focused to include following units:

1. Pilot plant scale up facility (GMP): The Pilot Plant scale up facility will be following the WHO- Current Good Manufacturing Practices (cGMP-U/ ICH Topic Q 7) guidelines and will provide support to the companies and entrepreneurs in the production of value-added products such as standardized API, Chemical, herbal at the pilot scale level to mimic the exact condition of the industry.

Skill development trainings for MSMEs/chemical startups and refresher courses for other industry employees.

The intention is to get the pilot-plant cGMP scale up facility accredited by second year of the project

2. **Kilogram Laboratory:** The Kilogram laboratory will provide support to companies and entrepreneurs in scale up of API, Chemicals and herbals with capacity of 10gm to 1 kg level. Laboratory will provide customized R&D troubleshooting for MSMEs, process quality of processed chemicals/APIs standardized products. The intention is to get the accreditation compliant laboratory kilogram laboratory which may be accredited in due course of time.
3. **Research and Development Laboratory:** R&D laboratory will be support the development of sustainable, cost effective, industry feasible processes for APIs/KSM/Intermediates and extraction & isolation process of high value herbals**.** The lab will provide support to institutional experts, startup companies, institutional incubate and entrepreneurs for the standardization of the chemical processes from mg to 10 gm level.
4. **Analytical Labs:** Quality Control and Quality Assessment Lab: The lab will provide support to companies and entrepreneurs in testing API & herbal product raw materials before purchase, testing quality of processed API & herbs before packaging and testing quality of standardized API & herbal products (Intermediate & finish) before packaging as per the export standards. The aim is to get the NABL Compliant Quality Control Lab/Analytical lab which may be accredited in due course of time

Brief requirements

Pilot plant scale up facility (cGMP): The pilot plant facility will be as per the WHO -Good Manufacturing Practices (GMP) guidelines and will provide support to companies and entrepreneurs in the validation, scale up, production, and technology transfer of value-added chemical processes for Key starting materials(KSMs)/Intermediate/APIs. The pilot plant facility unit will have a capacity ranging from 50 ltr to 1000 ltr (volume) for scale up. These facilities will be built to meet its upcoming research, production & technology transfer and will be located Technology development centre –Pilot- Plant (Synthetics hall & drying area, R&D and analytical labs) of NIPER-SAS Nagar Mohali, Punjab. 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-

SAS Nagar in view of this, wants to appoint a Consultant/Reputed firms/Individuals belongs to India to provide state-of-art solution for design, planning, Engineering, Procurement & execution of CGMP (Current Good Manufacturing Practices) ICH Topic Q 7 Grade facility at NIPER SAS Nagar.

NIPER SAS Nagar has set up a state of the art pilot plant facility i.e. Technology Development Centre (TDC) -Pilot Plant to cater to the needs and support APIs, herbals, generic Indian Pharmaceutical Industry by offering the facility and technology to the industry. TDC-Pilot Plant was inaugurated by Dr. APJ Abdul Kalam (the then President of India and Visitor of the Institute) in 2003 and became functional in May 2004. The facility has a build up area of 1867 sqm (G + 1) with 20 reactors of different capacity and 2 sections to carry out pilot scale work for Active pharmaceutical ingredient and herbals. The Institute is already working in the non-GMP facility with MSMEs and it has been a common feedback from the companies to strengthen the facility as per cGMP requirements. The MSME's needs to create a model facility which can act as showcase of GMP requirement & trainings as well as a place wherein process development or process simulation in the regulated environment can be executed. The aim is to create a new current Good Manufacturing Practice (cGMP) pilot plant within this complex with the assistance of DSIR under CRTDH scheme. This newly created advanced GMP certified DSIR-CRTDH facility will be useful for pharmaceutical/chemical MSMEs for research, scale-up and validation of processes. The proposed advanced facility will fulfil the gap of research and innovation which is absent in MSMEs for the development of new process technologies for APIs. Technology gap, sustainability, cost effectiveness and regulatory clearances are the major hurdles for APIs manufacturing especially for MSMEs. Creation of regulatory compliant facility, R&D lab with technology expert will accelerate the research and subsequent KSMs/DIs/APIs manufacturing. NIPER SAS Nagar is working towards the creation of a self-sufficient healthcare ecosystem in the country. Institute will also work with internal experts and external institutes for development of cost effective synthesis of APIs for import substitution and export promotion. Further APIs which are going to be off patented, the new technologies can be developed with MSMEs. Chemical and molecules of export importance will also be developed in the regulated environment and samples from the same can be submitted to export company by MSMEs before starting its production. Thus MSMEs can work in the GMP certified facility and use this data for regulatory filing (wherever necessary) for domestic or export purposes. Once developed at DSIR-CRTDH the technology can be transferred to their respective facilities. Further, drug discovery and development process wherein New drug application(NDA) or Investigational Drug Application is required will be also accelerated with the creation of GMP facility. Thus DSIR-CRTDH funded new facility as per cGMP requirement would help MSMEs as well as academia in prototype development and technology transfer. The new DSIR-CRTDH facility will be created within the existing 1867sqm., (G + 1) space wherein dedicated space will be allocated to the pilot plant and other proposed laboratories

respectively. The proposed infrastructure will host suitably designed production rooms and offices for support staff and should be designed with all the required respective international standards detailed later in the document. The Basic requirements of the rooms are to be described with details in the scope of work. Necessary civil work, Utility, mechanical, electrical 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 participates 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 and proposed laboratories. 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 SAS Nagar technical committee.

Facility 1: GMP PILOT PLANT:- To establish a cGMP accredited Pilot Scale facilities for the development of API & Chemicals/ herbal as per ICH Topic Q7 Good Manufacturing Practice (Key starting materials(KSMs)/Intermediate/finished product) Unit (GMP): The pilot-plant unit will follow WHO-Good Manufacturing Practices (GMP)/ ICH Topic Q7 Grade guidelines and will provide support to the companies and entrepreneurs in the production of value-added products such as standardized API, Chemical, herbal at the pilot scale level to mimic the exact condition of the industry.

Facility 2 Kilogram Laboratory: The Kilogram laboratory will provide support to companies and entrepreneurs in scale up of API, Chemicals and herbals with capacity of 10gm to 1 kg level. Laboratory will provide customized R&D troubleshooting for MSMEs, process quality of processed chemicals/APIs standardized products. The intention is to get the accreditation compliant laboratory kilogram laboratory which may be accredited in due course of time.

Facility 3 Research and Development Laboratory: R&D laboratory will be support the ddevelopment of sustainable, cost effective, industry feasible processes for APIs/KSM/Intermediates and extraction & isolation process of high value herbals**.** The lab will

provide support to institutional experts, startup companies, institutional incubate and entrepreneurs for the standardization of the chemical processes from mg to 10 gm level.

Facility 4 Analytical Labs: Quality Control and Quality Assessment Lab: The lab will provide support to companies and entrepreneurs in testing API & herbal product raw materials before purchase, testing quality of processed API & herbs before packaging and testing quality of standardized API & herbal products (Intermediate & finish) before packaging as per the export standards. The aim is to get the NABL Compliant Quality Control Lab/Analytical lab which may be accredited in due course of time.

Scope of Work for facility

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 with certification of HEPA filters.
- UTILITIES DESIGN with P&ID & Specifications treated water supply, charging & sewage
- Generation of Energy Load data for Design of the Electrical system firefighting controller & etc.

3. ARCHITECTURAL SCOPE

- To develop floor Interior Layouts and sectional heights based on Data site provided by the client and all the drawings shall be as per actual measurements as per site available.
- 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 tentative equipment's loads, HVAC load

● Preparation of Single Line Diagram

● Preparation of Technical specification and Bill of Materials for wiring, Panels, Transformer, Illuminations etc.,

● Preparation of cable schedule

5. PROCUREMENT ASSISTANCE

● Preparation of detailed Vendor list in consultation with the NIPER

● 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/agency 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

All the municipal and environmental clearances to be suggested to be the consultant/firm

2. Civil and related works will be done by the existing PMC (identified by Department of Pharmaceuticals, Govt. of India for the after finalization of layouts and drawings.

10. <u>PAYMENT</u> : As a matter of Institutes` policy No request for Advance Payment will be considered. The Institute will make Payment as Indicated below.

i) 20% Payment after submission of Designs, Drawings, Proposed plan for Execution of contract etc. and acceptance by the committee.

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

iii) 30% payment as a Third Installation against certificate of progress of work by the Committee.

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

11. **<u>Security Deposit</u>**: The successful bidders are expected to deposit 5% value of contract as a Security Deposit through a Demand draft in favor of the Director NIPER Mohali with 21 days of receiving the order. The security Deposit amount will be refunded to the bidder after

completion of Contractual obligation and certification by the Authorized committee.

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 successfully completed of at least two Projects in the establishment of approved WHO-GMP Facility, establishment of API units at least two of which shall be for QA & QC facility for the production of API.
3) NIPER SAS Nagar reserves the right to modify, expand, restrict, scrap and re-float the expression of Interest, depending on the need of the institute
4) As plant site is planned for cGMP as per cGMP Q7 guidelines the complete work such as civil, mechanical, electrical, clean room, equipment, utilities, with certification of HVAC work etc. is required for the same.
5) The agreement may be terminated at any time by NIPER upon one month's notice in writing being given to the consultant, if the consultant's work is not found satisfactory according to the terms of the consultant's work not being satisfactory, NIPER will get the work done at the risk and cost of the consultant.
6) Arbitration In the event of any questions, dispute and or difference whatsoever arising under the agreement or any alleged thereof, the same shall be settled, as far as possible by mutual discussions and consultation between consultant and NIPER reference to and in context of the appointed by the Director, NIPER whose decision shall final and binding on both the parties subject to as aforesaid the Arbitration and Conciliation Act, 1996 and rules there under and any statutory modification thereof for the time being in force shall apply to arbitrator refuses or shall be supplied by Director, NIPER aforesaid. If arbitration fails, the dispute arising out of this shall be subjected to jurisdiction –courts of SAS Nagar Mohali Only.
7) FORECE MAJEURE CLAUSE The NIPER will not be responsible for any delay/ stoppage of work due to force majeure condition like natural calamities, evil disturbances, strikes, war etc and losses suffered, if any, by the consultant of this account. NIPER shall not be liable in any way to bear such losses and no compensation of any kind whatsoever will be payable by NIPER to the consultant