EXPRESSION OF INTEREST (EOI) FOR

cGMP pilot plant facility in PPP (Public-Private Partnership) mode

EOI No: ----------

Date. ----------

CSIR INDIAN INSTITUTE OF INTEGRATIVE MEDICINE
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Jammu- 180001, India
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Expression of Interest (EOI) for cGMP pilot plant facility in PPP (Public-Private Partnership)

1. CSIR-Indian Institute of Integrative Medicine (CSIR-IIIM), Jammu

The CSIR-Indian Institute of Integrative Medicine (CSIR-IIIM), Jammu, established in 1941, is a premier research institute under the Council of Scientific & Industrial Research (CSIR), New Delhi. With a strong focus on Natural Product-driven drug discovery, CSIR-IIIM addresses challenges faced by industry, government departments, and entrepreneurs through advanced research and process development. The institute is globally recognized for its contributions to biotechnology research and serves as a hub for translating research into commercial products, especially in fermentation technology.

CSIR-IIIM is known for its dynamic and innovative R&D activities and has successfully transferred several fermentation-based process technologies for commercialization. The institute continues to collaborate with leading academic and research institutions worldwide, maintaining its reputation as a trusted partner in natural product chemistry and biotechnology.

2. cGMP Plant

The cGMP (Current Good Manufacturing Practice) facility at CSIR-IIIM is licensed granted by Drug & Food Control Organization J & K Govt. [License No: JK/01/14-15/AY-UN/216] by the State FDA, Jammu & Kashmir, and authorized to manufacture tablets, capsules, and oral liquid products under licenses DFO/D-766/1097-99 and DFO/D-766/1383-85, valid until December 30, 2024. The facility complies with global GMP standards and is equipped to support pharmaceutical research, development, small-scale manufacturing for clinical trial bathes and commercial manufacturing on regular basis, making it ideal for collaboration under the Public-Private Partnership (PPP) model.

CSIR-IIIM invites Expressions of Interest (EOI) from qualified organizations for a strategic partnership to enhance pharmaceutical research and development utilizing the cGMP pilot plant facility. This partnership aims to leverage CSIR-IIIM's research capabilities and the partner organization's manufacturing and commercialization expertise to innovate, develop, and bring new pharmaceutical products and technologies to market.

3. Objectives of the Collaboration

The collaboration aims to achieve the following objectives:

1. **Operation of cGMP Facility:** cGMP-compliant pilot plant facility to support small-scale production on regular basis, process optimization, and scale-up activities.
2. **Innovation in Drug Development:** Create a collaborative environment for the development and refinement of novel drug formulations and technologies.
3. **Capacity Building and Knowledge Transfer:** Enhance technical expertise through skilled development training program, workshops, and collaborative research.
4. **Regulatory Compliance:** Ensure all developed products meet stringent national and international regulatory standards, guaranteeing their safety and efficacy.
5. **Ancillary Services:** CSIR-IIIM, Jammu also involved in NABL accredited laboratory (QA/QC testing facility), enriched instrumentation facility, GLP animal facility, and pharmacological studies for research and development work.

4. Eligibility Criteria

Interested organizations must meet the following criteria:

1. Reputed registered company under Indian Companies Act either partnership firm/Private limited/Trust/Limited company of Indian origin. The organizations involved in Hospital services/Medical Education are also eligible to apply with minimum experience of three years.
2. Valid GST registration and PAN card.
3. The average annual turnover of the company in last three financial years ending 31.03.2024 should be at least INR 50 Crore.
4. Copy of annual Income tax return filed for last three financial years i.e. 2021-2022; 2022-23; 2023-24 duly certified by CA and balance sheet of three financial years ending 31.03.2024.
5. Commitment to compliance with all relevant industry regulations and standards set by the state/central regulatory agencies.
6. Willingness to invest in joint R&D projects with CSIR-IIIM Jammu by hand holding together.

5. Submission Requirements

Interested parties are requested to submit the following:

7. **Detailed Proposal Report:** A comprehensive proposal outlining the organization's expertise, proposed areas of collaboration, and specific projects or technologies of interest.
8. **Company Profile:** Including relevant experience, key personnel, and financial statements.
9. **Statement of Intent:** Demonstrating the commitment to collaborate with CSIR-IIIM on pharmaceutical research and development.
10. **Last three years balance sheet** as well as GST filed at the portal of the GoI.

6. Evaluation Process

Submissions will be evaluated based on the following criteria:

1. **Strategic Alignment:** The aims and objective of the participating firms must align with the objectives of the collaboration by the institute. **(20 Marks)**
2. **Experience and Capability:** The applicant's experience and capability in running various business organizations especially in healthcare sector i.e. Pharmaceuticals (manufacturing of pharma herbal /API products & services), marketing & distribution, Hospital Research Center, etc. **(30 Marks)**
3. **Research and Development:** The potential bidder must propose a road map for CSIR-IIIM Jammu, for the benefit of the industry and public health. **(10 Marks)**
4. **Technical and Financial Viability:** The technical robustness and financial capacity to support the initiative and facility usage charges to be paid to the institute both in the form of fixed charges and royalty component as a percentage gross sales for the products from the cGMP facility. **(40 Marks)**

The firm scoring the highest marks shall be shortlisted for award of contract which may or may not be on exclusive basis depending upon the proposed capacity utilization by the firm.

7. Submission Deadline

All EOIs must be submitted by within the timeline as advertisement, to the office of Senior Controller of Administration, CSIR-IIIM, Jammu.

8. Terms and conditions:

Inclusion:

1. **Site Visit:** Bidders may visit the site before the pre-bid conference.
2. **Optional Services:** Pay-and-use services available include QA/QC laboratory, animal studies, PK-PD studies, pharmacological studies (e.g., oncology), technology/product transfers, and other services available at CSIR-IIIM, Jammu.
3. **Activities Proposed by the Bidder:** The partner company will manufacture its products under proper licensing. Any production capacity expansion, civil structural changes, or other modifications require prior written approval from CSIR-IIIM, Jammu.
4. **Agreement Tenure:** The initial agreement will be for five years, with a possible extension for an additional five years, not exceeding a total of ten years.
5. **Annual Increment:** A 10% annual increment will apply to the monthly charges/rental of the cGMP facility and allied utilities.
6. **Utilities & Maintenance:** The partner company will bear the costs of recurring expenses/incidental services (Manpower, electricity bill at flat rate, civil work, water bill, DG set power back up services and miscellaneous other expenses) and non-recurring maintenance expenses as required (expenditure on civil works repairs, epoxy flooring, electrical work, maintenance of equipments, road maintenance etc.) related to the cGMP plant and its utilities for the duration of the contract.

Exclusions: This EOI is issued for exploratory purposes only and does not constitute a binding commitment. CSIR-IIIM reserves the right to accept or reject any submissions without providing reasons.

1. **Indemnification:** The partner company must indemnify CSIR-IIIM against any harm, liability, or casualty.
2. **Force Majeure Clause:** CSIR-IIIM, Jammu shall not liable for any failure to perform its obligations under this Agreement if such failure results from acts beyond its reasonable control, including but not limited to acts of God, war, terrorism, fire, flood, earthquake, pandemic, governmental action, labor strikes, or other events that are unforeseeable, unavoidable, and outside the control of the affected party ("Force Majeure").
3. **Arbitration:** In the event of nay dispute or differences arising out of or in any way touching or concerning this agreement whatsoever the same will shall be referred to Delhi International Arbitration Centre (DIAC) set up under Arbitration and Conciliation (Amendment) Act, 2015 whose decision thereon shall be final and binding on the parties thereto.

STANDARD FORM

Annexure-I

Bidder Information Form

(a) [The Bidder shall fill in this form in accordance with the instructions indicated below. No alterations to this format shall be permitted and no substitutions shall be accepted. This should be done on the letter head of the firm].

Date: *[insert date (as day, month and year) of Bid Submission]*

Tender/EOI No.: *[insert number from Invitation for bids]*

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01.	**Bidder's Legal Name** *[insert bidder's legal name]*
02.	**In case of Joint Venture, legal name of each party:** *[insert legal name of each party in JV]*
03.	**Bidder's actual or intended Country of Registration:** *[insert actual or intended country of registration]*
04.	**Bidder's Year of Registration:** *[insert bidder's year of registration]*
05.	**Bidder's Legal Address in Country of Registration:** *[insert bidder's legal addressin country of registration]*
06.	**Bidder's authorized representative information** **Name:** *[insert authorized representative's name]* **Address:** *[insert authorized representative's address]* **Telephone/Fax numbers:** *[insert authorized representative's telephone/fax numbers]* **Email Address:** *[insert authorized representative's email address]*
07.	Attached are copies of original documents of: [check the box(es) of the attached original documents] Articles of Incorporation or Registration of firm named in 1, above.

Signature of Bidder _____

Name_____

Business Address _____

Check List: Duly filled check list to be submitted along with the Technical Bid.

Sr. No.	Requirement of Tender	Compliance	Document Submitted
1.	Bidder Information Form (Annexure I)	Yes/No	Yes/N.A.
2.	Copy of Registration of firm under Indian companies Act	Yes/No	Yes/N.A.
3.	Copy of GST registration and PAN card	Yes/No	Yes/N.A.
4.	Copy of Average annual turnover of Rs. 50 Crore, duly certified by charted accountant for at least last three financial years i.e. 2021-22;2022-23;2023-24	Yes/No	Yes/N.A.
5.	Copy of Annual Income Tax Return for at least last three financial years i.e. 2021-22; 2022-23; 2023-24 and copy of Balance sheets of 2021-22; 2022-23; 2023-24.	Yes/No	Yes/N.A.
6.	Copy of firm's statement citing minimum (3) three year of experience in the field of Healthcare sector/s such as Pharmaceuticals Manufacturing (Pharma Herbal/API Products & Services) OR Pharmaceutical Marketing & Distribution OR Hospital & Research Center/ Hospital services/Medical Education etc.	Yes/No	Yes/N.A.
7.	Copy of certificate agreeing to all the terms of EOI thereof.	Yes/No	Yes/N.A.
8.	Detailed Proposal Report	Yes/No	Yes/N.A.
9.	Company Profile	Yes/No	Yes/N.A.
10.	Statement of Intent	Yes/No	Yes/N.A.

*N.A. = Not applicable

Sd/-
Senior Controller of Administration