Expression of Interest

Quality Management System (QMS)

For

Immunogenicity laboratories and animal challenge study facilities

Under
Mission Ind-CEPI

Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic Preparedness Innovation (CEPI)

Department of Biotechnology
Ministry of Science & Technology
Government of India

Implementing Agency
Biotechnology Industry Research Assistance Council (BIRAC)
(A Government of India Enterprises)

1. **Program overview: Ind-CEPI**

Program Ind-CEPI has been conceived by the collaborative effort of Department of Biotechnology (DBT), Govt. of India, and CEPI (Coalition for Epidemic Preparedness Innovations), Norway. The objective of the mission is epidemic preparedness through rapid vaccine development and support the Indian vaccine development ecosystem aligned with the global initiative of CEPI. The Mission aims to strengthen the development of vaccines for the diseases of epidemic potential in India as well as build coordinated preparedness in the Indian public health system and vaccine industry to address existing and emergent infectious threats in India.

2. **Funding agency:**

Department of Biotechnology (DBT)

3. **Implementing agency:**

Biotechnology Industry Research Assistance Council (BIRAC).

4. **Background:**

As part of the rapid development and deployment of effective vaccines against COVID-19, Department of Biotechnology, Government of India has launched Mission COVID Suraksha, which is being currently implemented by Biotechnology Industry Research Assistance Council (BIRAC). As one of the goals of the mission, COVID Suraksha : REOI-2 has been launched to strengthen and support immunogenicity laboratories and animal challenge study facilities distributed throughout the country. To cater to the needs of global community the results generated in the facilities should be reliable and accurate. It can be ensured by the implementation of Quality Management System (QMS) and accreditation by competent authorities. A QMS in a laboratory/ animal challenge study facility plans, controls, and improves the elements that impact the achievement of the desired quality results. It acts as a tool to keep the laboratory procedures and every variable involved under control. For an immunogenicity laboratory accuracy, reliability, and timeliness of the analytical results reported define its quality. Similarly, in an animal challenge study facility quality is defined by the performance of the reliable animal study and reporting of accurate results.

To support the national need for rapid COVID-19 vaccine development, Mission Ind-CEPI under its objective for capacity building and strengthening existing facilities is requesting the Expression of Interest (EOI) to build and augment quality management systems at laboratories and animal facilities. The current REOI aims to engage agencies to establish Quality Management Systems (QMS) in the immunogenicity laboratories and animal challenge study facilities supported under Mission COVID Suraksha. These facilities will be primarily academic or scientific organizations supported by the Government of India. The immunogenicity laboratories will be primarily involved in immunogenicity assessment for clinical trial testing of COVID-19 vaccine candidates by using different assays (ELISA/CLIA, virus neutralization, CMI etc.). The supported animal challenge study facilities will be involved in demonstrating efficacy of COVID-19 vaccines through challenge studies in animal models (ACE 2 transgenic mice, syrian

hamsters, non-human primates etc.). The established QMS must ensure accurate, reliable analysis and reporting of data in compliance with NABL (National Accreditation Board for Testing and Calibration Laboratories) and NGCMA (National GLP Compliance Monitoring Authority) for immunogenicity laboratories and animal challenge study facility respectively.

5. Expression of Interest:

This Expression of Interest (EOI) is to seek applications from the suitable organization(s) having the appropriate capability to develop and implement QMS in the following areas:

a) Establishment of ISO/IEC 17025: 2017 accreditation for immunogenicity laboratories.
b) Good Laboratory Practice (GLP) compliance and certification for animal challenge study facilities.

6. Application Timelines: Key Dates

EOI Publication	14.05.2021
First closure of application	04.06.2021, 5.00 pm
Second closure of application	25.06.2021, 5.00 pm

There will be a rolling review and approval process for funding. Considering finite amount of funds, we strongly encourage early submissions of Expression of Interest.

7. Application Guidelines and Process:

The application can be submitted online as per the required format. The EOI will be open for 06 weeks.

8. Overview:

In immunogenicity laboratories and animal challenge study facilities, maintaining and implementing a Quality Management System (QMS) is a crucial part of effective vaccine development to meet the global standards. To have a well-established QMS, a proper audit process and implementation of a set of guidelines are required which is achieved by ISO/IEC 17025: 2017 certification for immunogenicity laboratories by National Accreditation Board for testing and Calibration Laboratories (NABL) and Good Laboratory Practice (GLP)certification for animal challenge study facilities by National Good Laboratory Practice Compliance Monitoring Authority (NGCMA), Department of Science and Technology, Govt. of India in accordance to Organization for Economic Co-operation and Development (OECD) guidelines. Implementation ISO/IEC 17025: 2017 and GLP in the respective facilities will streamline the processes required to meet the global requisite standards. The present REOI is to invite agencies with previous experience in the implementation of QMS in immunogenicity laboratories and animal challenge study facilities. Agencies will be selected for a period of 18 months by a committee at BIRAC with a final goal to provide accreditation to immunogenicity laboratories and animal facilities strengthened under COVID Suraksha mission.

9. Objectives:

Ind-CEPI aims to engage consultancy agencies that develop and implement QMS as per accepted national guidelines, at the Mission COVID Suraksha funded immunogenicity laboratories and animal challenge study facilities at academic institutes across the country. The consultancy agencies must ensure the following based on the facility assigned.

a. Establishment of effective quality management systems towards ISO/IEC 17025: 2017 accreditation by NABL for immunogenicity laboratories.
b. Ensure GLP compliance and certification by NGCMA for animal challenge study facilities in accordance with OECD guidelines.

Based on the facility, applicable objectives must be achieved within a period of 18 months.

10. Scope:

The REOI seeks proposals from agencies for the development and implementation of QMS based on the facilities assigned. Outlined below are the scope for each facility type.

a) For immunogenicity laboratories:

i) To conduct awareness/training on concepts, guidelines, and principles of quality management. A minimum of four awareness training of six hours each for all stake holders involved in the animal challenge study.

i) Identify and prepare SOPs, quality manual (must include quality policy and objectives), and necessary process documents towards the implementation of ISO /IEC17025:2017. Preparation of documents must be ensured at the level of

- Organization
- Personnel
- Facilities & Environment
- Equipment
- Metrological traceability
- Externally provided products and services
- Inventory
- Process requirement
- Control of data and Information management
- Risk and opportunities
- Assessment
- Improvement
- Management review program
- Safety

ii) To participate and ensure all necessary processes for application towards certification by NABL. This will include the preparation of necessary documents and applications in support of the facility ensuring successful application.

iii) To ensure post application processes for accreditation and certification by NABL. It will include addressing all non-conformance that might arise during the process of application.

iv) Post NABL certification, continue to support the laboratory for maintenance of ISO/IEC 17025:2017 so that the total engagement duration is of 18 months.

b) For animal challenge study facilities:

ii) To conduct awareness/training on concepts, guidelines, and principles of GLP according to OECD guidelines. A minimum of four awareness training of six hours each for all stake holders involved in the animal challenge study.

iii) Identify and prepare necessary process documents for GLP certification by NGCMA. Preparation of document must be ensured at the level of

- Test facility organization and personnel
- Quality assurance
- Facilities
- Apparatus, Material, and Reagents
- Test Systems
- Test and Reference Items
- Standard Operating Procedures
- Performance of the Study
- Reporting of the study results
- Storage and retention of records and materials

iv) To facilitate in the application process for GLP by NGCMA.

v) To support in preparing Action Taken Report (ATR) including corrective action (CAPA) towards ensuring GLP certification.

vi) Post GLP certification, continue to support the facility for GLP compliance so that the total engagement duration is of 18 months.

11. Eligibility criteria:

1. Agencies should be registered in India.
2. As applicable to the proposal the lead consultant* should have relevant experience in implementing ISO/IEC 17025 or five years of experience in implementation of GLP.
3. Lead consultant* should have relevant experience in biological science laboratory or preclinical animal testing while implementing ISO/IEC 17025:2017 or GLP.
4. Lead consultant* should have completed a similar kind of work leading to ISO/IEC 17025 (current and previous version) certification by NABL or GLP compliance certification from NGCMA as applicable to the proposal.
5. Agencies should not be blacklisted by any government agencies in India.

* In absence of a lead consultant in the present manpower pool of the agency, EOI must provide details of an identified lead consultant during the application and

recruitment of the consultant should be complete before the first financial disbursement. Proof of recruitment should be submitted to BIRAC prior to first financial release.

12. Expectations:

a. For clinical immunogenicity laboratories, the agency must ensure ISO/IEC 17025: 2017 certification by NABL achieving the following goals:
   i) Ensuring process documents are available in the laboratory for tests being performed
   ii) Ensuring the staff members have the necessary qualification and capabilities to perform the tests
   iii) Ensuring the availability of the system for sample processing and tracking
   iv) Ensuring the accuracy and reproducibility of data generated as per global standard

b. For animal challenge study facilities, the agency must ensure GLP certification by NGCMA by achieving the following:
   i) Ensuring test facility organization and optimized use of personnel for achieving quality results.
   ii) Ensuring a quality assurance program for assuring GLP compliance
   iii) Ensuring appropriate facilities, test system, apparatus, materials, and reagents
   iv) Ensuring the establishment of standardized operating procedures
   v) Ensuring accuracy and archival of data

c. The agency is expected to do the following post assignment of any laboratory or animal facility:
   1. Sign an agreement with BIRAC upon selection.
   2. Assess the current status of the facility and outline the strategy for setting up QMS in the laboratory or the animal facility after conducting the awareness session.
   3. Provide training and awareness about ISO 17025:2017/GLP and provide feedback from participants.
   4. Submit an action plan to BIRAC after the awareness/training secession which will include mapping of work to be done. Clear objectives to be set along with timeline so that the project completes within a period of 18 months. This will be reviewed by BIRAC regularly.
   5. Support the facility in the application process to NABL/ NGCMA for certification .
   6. Submission of a report to BIRAC during the submission of an application to accreditation bodies indicating all steps are taken and documents prepared towards the application.

7. In case of non-compliance, a report must be submitted about the non-compliance points and how they have been addressed.
8. After certification, the agency must submit a final report on the maintenance of the ISO/GLP criteria at the assigned facilities.
9. The accreditation process must be completed within 18 months

13. **Applications process:**
Agencies interested in developing and implementing QMS in laboratories and animal facilities may submit their application in the prescribed online format.

14. **Financial details:** The cost proposed by the agencies should be inclusive of all costs required for the activities mentioned and any other associated costs. The budget proposed should be per facility basis (separately for ISO and GLP certification) and excluding any travel cost. Travel costing will be paid in actuals as per BIRAC norms. No additional payments will be considered after the award of the contract. The financial release will be made to the agencies based on the achievement of objectives and the timeline proposed.

15. **Expected outcome:** Accreditation of laboratories and animal facilities supported under Mission COVID Suraksha REOI-2: Enhancement of Capacity to support COVID-19 vaccine development

16. **Evaluation and decision-making criteria:** A selection committee will evaluate the proposals based on the application forms received. A weighted average scorecard will be generated and the highest scorer will be considered for financial approval. More than one agency will be selected for getting the accreditations. The selection committee may recommend a proposal by relaxing the requisite relevant experience of the lead consultant upon satisfactory assessment of competence through the presentations and discussions.

17. **Professional fee :**
Payment of professional fee will be decided as per sanction of the competent authority. The successful applicant shall enter into necessary agreements/ work orders ensuring the professional fee against the service provided.

18. **Contact Information:**
Further information can be obtained at the BIRAC website (www.birac.nic.in)

19. **Contact Persons:**
For queries about the application and submission of the completed application form:
Dr.Sreejata Chatterjee, Programme Manager, Ind-CEPI
Email: user-040@birac.nic.in
Dr. Md. Iftikar Hussain, Sr. Program Officer, Ind-CEPI
Email: user-042@birac.nic.in