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, immunogenicity laboratories and animal challenge study facilities will be strengthened for rapid development of vaccines. To support this national need, Ind-CEPI under its objective for capacity building and strengthening existing facilities is requesting the Expression of Interest (EOI) to build and augment quality systems at these laboratories and animal facilities. The current REOI aims to engage consultancy agencies to establish Quality Management Systems (QMS) in laboratories and animal challenge study facilities supported under Mission COVID Suraksha. A QMS in a laboratory/ animal challenge study facility plans, controls, and improves the elements that impact the achievement of the desired quality results. To maintain the quality, QMS is 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 bythe performance of the reliable animal study and reporting of accurate results. 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) havingthe appropriate capability to develop and implementQMS 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	26.01.2021
Closing of Application	16.02.2021, 5.00 pm

7. Application Guidelines and Process:

The application can be submitted online as per the required format. The EOI will be open for 03 weeks.

8. Overview:

In immunogenicity laboratories and animal challenge study facilities, maintaining and implementing a Quality Management System (QMS) is a crucial part ofeffective vaccine development to meet the global standards. To have a well-established QMS, a proper audit process and implementation of a set of guidelines arerequired which is achieved by ISO/IEC 17025: 2017 certification for immunogenicity laboratories by National Accreditation Board for testing and Celebration Laboratories (NABL) and Good Laboratory Practice (GLP)certification for animal challenge study facilities by National Good Laboratory Practice Compliance Monitoring Authority (NGCMA) in accordance to Organisation 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 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 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 ISO/IEC 17025: 2017 accreditation by NABL for immunogenicity laboratories.
b. GLP compliance and certification by NGCMAfor 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 seek proposals from agencies for the development and implementation of QMS based on the facilities assigned. The scope of the REOI for 18 months include the following areas:

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 at the managerial and technical level to be conducted.

ii) Identify and prepare SOPs, quality manual (must include quality policy and objectives), and necessary process documents towards the implementation of ISO /IEC17025:2017 within a period of 4 months. 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

iii) To participate and ensure all necessary processes for application towards certification by NABL within a period of 6 months. This will include the preparation of necessary documents and applications on behalf of the facility ensuring successful application.

iv) To ensure post application processes for accreditation and certification by NABL within 12-14 months. It will include addressing all non-compliances that might arise during the process of application.

v) Post NABL certification, continue to supportthe laboratory so that the total engagement duration id of 18 months.

b) For animal challenge study facilities:

i) 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 study staff involved inthe animal challenge study.

ii) Identify and prepare necessary process documents for GLP certification by NGCMAwithin a period of 4 months. 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

iii) To participate in the application process for GLP certification and completion within 6 months.

iv) To ensure corrective action and preventive action (CAPA) towards ensuring GLP certification within 12-14 months.

v) Post GLP certification, continue to support the facility so that the total engagement duration id of 18 months.

11. Eligibility criteria:

1. Agencies should be registered in India.
2. Agencies should have five years of experience in developing, implementing and auditing QMS.
3. Agencies should have five years of experience in the implementation of ISO criteria in a laboratory and/or GLP in animal facilities.
4. Agencies should have completed a similar kind of work in Central Govt. /State Govt./PSUs/Govt. bodies/ companies in India in the last five years.
5. Agencies should not be blacklisted by any government agencies in India.
6. Preference may be given to agencies operating in the same city where assigned laboratories or animal facilities will be located.

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 NGCMAby 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 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.
5. Application to accrediting bodies for certification on behalf of the facility
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 14 months.

13. Applications process:

Agencies interested in the development and implementation of QMS in laboratories and animal facilities may submit their application in the prescribed online format. The final applications should be submitted as per timelines mentioned in section 6.

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 milestones.

15. Expected outcome: Accreditation of laboratories and animal facilities.

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.

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:

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