ISO 13485:2016 Training

Request for Expression of Interest

under
Industry- Academia Collaborative Mission for Accelerating Discovery Research to Early Development of Bio-pharmaceuticals

Innovate in India (i3) Empowering Biotech Entrepreneurs & Accelerating Inclusive Innovation.

Funded by

Department of Biotechnology, Ministry of Science & Technology, Government of India

Co-funded through World Bank Loan Assistance

(Innovate in India for Inclusiveness Project)

through
Implementing Agency
Biotechnology Industry Research Assistance Council (BIRAC)

(A Government of India Enterprises)

Program Overview – National Biopharma Mission:

Industry-Academia Collaborative Mission for Accelerating Discovery Research To Early Development For Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation", also referred to as National Biopharma Mission (NBM).

Funding agency:

Department of Biotechnology (DBT) (Program co-funded by World Bank loan).

Implementing agency:

Biotechnology Industry Research Assistance Council (BIRAC).

Background:

Towards strengthening the emerging biotechnology enterprise in India, Department of Biotechnology (DBT) Ministry of Science & Technology has initiated the Mission Program entitled "Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals - Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation" ("Program"). Biotechnology Industry Research Assistance Council (BIRAC) setup by DBT is the Implementing Agency of i3 Program (Program co-funded by World Bank loan).

The vision of the program is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals including vaccines, biologics, medical devices and diagnostics to a level that will be globally competitive over the next decade.

Request for Expression of Interest:

This Request for Expression of Interest (EoI) is to seek applications from suitable organizations that have appropriate capability and certification to conduct trainings for the following areas:

- ISO 13485:2016 (awareness and certification trainings as mentioned below)

Application Timelines: Key Dates

EOI Publication	22nd February, 2021
Closing of Application	8th March, 2021 (5:00 PM IST)

Application Guidelines and Process:

The application can be submitted online as per the required format. The REOI will be open for 02 weeks from the date of publication.

Overview:

In the medical device sector, maintaining and implementing a quality management system (QMS) is a crucial part for nurturing innovative product development and regulatory compliance, worldwide. To have a well-established QMS, a proper audit process and implementation is also required which is achieved by ISO 13485:2016 for medical device companies. Like other ISO standards, ISO 13485:2016 is designed to address the latest QMS practices, including changes in

regulatory requirements and technology. In addition to QMS, ISO 13485:2016 has a greater emphasis on risk management, risk-based decision making, medical device documentation and reporting; rules and guidelines for any company that designs or manufactures medical devices.

ISO 13485:2016 can be used by organizations which are involved in any stage of the device development such as design of the device, production, distribution, storage, installation or servicing of a medical device. ISO 13485:2016 can also be used by external suppliers that distribute or provide the medical product, including quality management system-related services and by certification bodies for the purpose of auditing processes.

Objective- Need for QMS training:

As per the Medical Devices (Amendment) Rules, 2020, a certificate of compliance with ISO-13485 is mandatory for registration of Newly Notified Medical Devices. Therefore, manufacturer or importer of a registered medical device – whether start-ups or a large company will have to ensure that the requirements of ISO 13485:2016 be met at all times. Subsequently, medical device manufacturers have to comply with QMS as per Schedule 5 of the Medical Devices Rules, 2017 which is broadly based on ISO 13485. Therefore, capacity building programmes in ISO 13485:2016 are extremely relevant for all med-tech start-ups/ companies aiming towards product commercialization in India and abroad.

The National Biopharma Mission (NBM) and BIRAC are actively involved in nurturing innovative product development ecosystem in medical device sector. NBM plans to organize ISO 13485:2016 training programmes for the capacity building of medical device start-ups and companies. The planned training should be a high value and high impact training programme of an advanced level and shall be aimed at providing guidance and practical experience, promote skill development, optimizing auditing skills, planning, executing, reporting, monitoring the effectiveness and conformity to regulatory guidelines, in order to achieve successful QMS implementation in medical device sector.

Scope:

In view of their importance, NBM plans to organize these trainings for professionals of SMEs/ start-ups who are involved in medical device and diagnostics sector within India. The following types of trainings may be conducted:

ISO training	Training/ Workshop	No. of participants
ISO 13485:2016	Awareness Webinars (2 hour each)	1000 (minimum 4 webinars)
ISO 13485:2016	Implementation Training (24 hours trainings)	750
ISO 13485:2016	Internal Auditor Training (16 hours trainings)	250

These trainings are proposed to be organized by a certified training agency which fulfil the eligibility criteria.

Terms of reference:

The selected training agency will take up all the responsibilities including, but not limited to, the following:

1. Provide and execute complete plan on how to conduct the training.
2. Publication of advertisement in national newspapers/ publications in print media and related outreach to invite applications. Minimum 6 publications in newspapers to be done for various trainings.
3. Screening the applications for selecting the participants based on weighted scoring.
4. Conduct training for selected participants via online mode.
5. All the hardware / software arrangements to conduct the training course.
6. Assessment of the trainees after the course in the form of an examination
7. Certificates to be distributed to the participants.
8. Gather feedback on the course from trainees.
9. Maintain electronic traceability system for online platform (if any).
10. Completion of all trainings within 24 months from the award of contract.

Note: The trainings will be conducted by the agency on behalf of NBM and it should be clarified at all possible places. All the activities related to the training must be done in consultation with NBM representative.

Mode of trainings:
Only online trainings to be conducted.
For ISO 13485:2016 awareness, 2 hour webinars should be conducted (minimum 4 webinars) to reach the minimum target number of 1000 participants.
For ISO 13485:2016 implementation and internal auditor trainings, a batch of 20-25 participants should be taken with minimum 2 trainers who have consulting/ implementing experience in ISO 13485.

Eligibility:
Applications are requested from organization certified and competent to impart the course as mentioned above.

1. The application can be submitted solely by Indian/ International - Company/ Non-profit organizations/ Government entities/ Society/Trusts/ Foundation/ Associations/ Institutes/ R&D Organizations which is a legal entity.
2. Joint/ collaborative applications will not be accepted.
3. Application by individuals will not be accepted.
4. The establishment period as on date of closing of application should be at least five (5) years.
5. The applicant **should not** be a Pakistani entity.

Criteria Particulars for the Proponent entities:

- Indian companies – An Indian Company is defined as one which is registered under the Indian Companies Act, 2013 and minimum 51% of the shares of the Company should be held by Indian Citizens holding Indian passport [Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders].
- International companies – Incorporated entity established under the specific statute of the respective Country/State.
- National & International Non-profit organizations/ Government entities/ Institutes/ R&D Organizations – This will include Academic Research Institutes, Universities, Research Foundation, Medical Colleges and Institutes – both public and private who are valid legal

entities such as Trust, Society or Corporations established under central or state statute of their respective countries.

Technical Eligibility for the scope:

1. Accreditation of the agency for Medical Devices Quality Management System (MDQMS) certification by National Accreditation Board for Certification Bodies (NABCB) or Certification/ accreditation of the course by International Register of Certificated Auditors (IRCA)/ Exemplar or equivalent bodies of India/the respective countries.
2. There should be 2 trainers for 2-day and 3-day courses.
3. Experience and expertise of trainers in both auditing and implementation of ISO 13485 (minimum 5-year work experience related to ISO 13485; either minimum 5 certification audits as Lead auditor, or conduct of minimum 5 trainings as lead trainer is essential for each trainer).
4. The organization should be certified to conduct accredited courses of ALL trainings mentioned above in the scope.
5. Strategy and Financial formats shall state INR (Indian Rupee) as the currency for the consideration.

Applications process:

Agencies interested in organizing the trainings on behalf of NBM may submit their applications online on the BIRAC website (https://birac.nic.in). The final applications should reach us before 5:00 PM IST on the last day of the application. Only those applications will be considered for further evaluation which are submitted online.

Financial Details:

The cost proposed in the application form should be inclusive of all costs (applicable taxes, reimbursable, sub-contracting, outsourcing, advisory etc.) required for the activities mentioned in the Terms of Reference and any other associated costs. No additional payments will be considered during evaluation process and/or after award of contract.

Separate costs should be provided for components of Awareness webinars and for ISO 13485 Implementation and Internal Auditor trainings.

Expected outcome: Certified participants from the different training programs.

Evaluation and Decision-Making Criteria:

A selection committee will evaluate the proposals based on the application forms received. Weighted average score card will be generated and the highest scorer will be considered for financial approval.

Post approval evaluation:

The selected agency will also be evaluated based on the feedback received from the participants during a mid-term review.

Requisites for Funding:
Decision to fund will be as per sanction of the competent authority. Successful applicant shall enter into necessary funding agreements.

Payment will be done in 3 instalments -

- 25% of total payment after award of contract as advance.
- 50% of the total payment after course completion for 60% of target participants.
- 25% of the total payment after course completion for 100% of target participants.

After initial payment, next payment will be subject to the mid-term review.

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

Contact Persons:
For queries about the application form:

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