ISO 13485:2016 Training

Request for Expression of Interest

Under
NATIONAL BIOPHARMA MISSION
(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 certification trainings (**Implementation training** and **Internal Audit related** awareness) as mentioned below

Application Timelines: Key Dates

EOI Publication	11th December, 2024
Closing of Application	31th December, 2024 (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 03 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 V 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:

Following training modules should be included along with ISO 14971- Risk Management of medical devices, and Usability Engineering to medical devices (IEC 62366). This training must also include the Schedule IV and V of the IMDR which is important for medical devices sector.

Training Modules:

Sr. No.	ISO training	Training/ Workshop	Expected hours (Total 38hours)	No. of participants
1	ISO 13485:2016	**Overview of medical devices (5hours) Awareness training** - Important terminology and definitions - Classification of medical Devices - Validation and verification with reference to medical devices – Overview of ISO 17029 - ISO 14971- Risk Management of medical devices, and Usability Engineering to medical devices (IEC 62366)	- **(Total 8hours)** - 1hr - 2hrs - 2hrs - 3hrs	Total 100 Candidates (20-25 candidates per batch)
2	ISO 13485:2016	**Clause 7.3: Medical device design controls and why they're important (Guest Lecture)**	- **2hrs**	Total 100 Candidates (20-25 candidates per batch)
3	ISO 13485:2016	**Standards: Salient features of the following standards:** - IEC 60601-1 Safety - IEC 60601-1-2 EMC - ISO 14971-Risk - IEC 62366 Usability - IEC 60601-1-6 Usability for Electromedical equipment (30mins based on scope of candidates attending) - Biocompatibility ISO 10993 - ISO 13485 overview - Clinical trials: brief outlook of the process, permissions, compliances - **ISO 13485:2016 Implementation and internal auditor trainings**	- **(Total 16hours)** - 1hr - 30min - 1hr - 1hr - 30min - 1hr - 1hr - 2hrs - 8hrs	Total 100 Candidates (20-25 candidates per batch)
4	ISO 13485:2016	**Regulations across the globe (5hrs)**	- **(Total 5hours)**	Total 100 Candidates

		- India- CDSCO. Overview and salient features of IMDR2017 - applications process - EU and CE, marking EUMDR - FDA and US requirements	- 2hrs - 2hrs - 1hr	(20-25 candidates per batch)
5	ISO 13485:2016	**Project Assignment*** **Part-A: Preparing a design docket as required by IMDR schedule IV and V** **Part-B: Device master file as per IMDR**	- **(Total 7hours)**	Total 100 Candidates (20-25 candidates per batch)

(*This would be an assignment to assess comprehension of candidates on the all areas covered in the course. Based on the number of candidates, 6 to 8 on the spot groups will be formed. Each group will choose the medical device of their own choice for the project. Half of the groups will engage in preparing the design docket and the remaining half will work on the device master file. The selected agency will hold a seminar with 30 minutes for each group to present and evaluate their performance. If possible, the agency shall invite external experts to participate in the evaluation; otherwise, BIRAC may be able to nominate external reviewers.)

Mode of trainings:

Only in-person (offline) training to be conducted.

Terms of reference:

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

1. Design complete plan on how to conduct the training (training design and conductance).
2. Training related publication and outreach to invite applications from the intenders.
3. Screening the applications for selecting the participants based on weighted scoring (Interview may be discussed with the BIRAC team).
4. Appropriate standard accommodation should be provided to each selected candidate during the training period.
5. Availability of all the hardware / software arrangements to conduct the training course.
6. Conduct hands-on training for selected participants
7. Assessment of the trainees after the course in the form of an examination
8. Certificates to be distributed to the participants.
9. Gather feedback on the course from trainees (in the beginning, in between, and at the end of the training).
10. Maintain electronic traceability system (if any).
11. Completion of all trainings within 3-4 months from the official start date, on signing of the

Grant-in-aid Letter of Agreement (GLA).

Important Note:

1. The trainings will be conducted by the agency on behalf of NBM and it should be mentioned at all possible places. All the activities related to the training must be done in consultation with NBM representative.
2. This training is proposed to be organized by a certified training agency which fulfil the eligibility criteria as per the Annexure – I, and Annexure - II.
3. BIRAC may also nominate trainees but enrolment in training will be subject to the fulfilment of selection criteria.

Applications process:

Agencies interested in organizing the trainings on behalf of NBM may submit their applications online only, through the submission link on BIRAC website (https://birac.nic.in). The online applications should reach to us by and before 5:00 PM IST on the last day of the application. Only successfully submitted online applications will be considered for further evaluation. No other modes of submission will be entertained.

Acknowledgment of Submission:

Upon successful submission, applicants will receive an automatic acknowledgment via email. This acknowledgment will serve as confirmation that the application has been received.

Eligibility:

The applicant must furnish the details for general and technical eligibility criteria as per the templates provided as an annexure - I and annexure - II respectively.

The relevant supporting documents for eligibility check should also be uploaded and submitted along with the proposal.

Financial Details:

The details of the budget to plan, organize, and conduct the training should be furnished as per the training budget format provided as an annexure - III. 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 the grant.

After eligibility check, if called for technical and financial presentation, the applicant must also present each module-wise separate costing for all the components (Awareness of Medical Devices Overview and for ISO 13485 Implementation & Internal Audit) of the training.

Tentative Budget: Maximum up to INR. 55,00,000.00 for all 100 candidates (4-5 batches)

Expected outcome: Certified individuals from the ISO13485:2016 training programs.

Evaluation and Decision-Making Criteria:

A selection committee will evaluate the proposals based on the application form, general and technical eligibility criteria (Annexure - I & II), budget details (Annexure – III), and declaration (Annexure IV) received from each applicant. Only qualified applicants as per the eligibility check by the experts, will be called through official communication for technical presentation for further review and screening (travel allowance will not be provided). A final shortlisted applicant as per the expert's recommendations (from skill development committee of the BIRAC) will enter into the process of Grant-in-aid Letter of Agreement (GLA) execution. BIRAC's funding support as a grant-in aid under NBM to the qualifying applicant for the conductance of ISO 13485 training is subject to approval of the BIRAC's competent authority.

Post approval evaluation:

- Reporting of Progress - On Successful completion of each Milestone, the agency will be required to submit a detailed Milestone Completion Report (MCR) as per the prescribed format.
- The agency is required to take feedback from all the participants. The same would need to be submitted to BIRAC at the end of each batch of the training.
- The selected agency will also be evaluated based on the feedback received from the participants during a mid-term review.
- Monitoring and review of the training implementation agency will be conducted by BIRAC's skill development committee, on completion of each milestone. The necessary recommendations on training implementation, changes required and financial disbursement will be obtained from the committee for further actions.

Requisites for Funding:

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

Financial support will be provided in 3 instalments -

- 50% of total payment after Acceptance of Undertaking under GLA and Signing of the GLA. Fulfilment of fund release requirements.
- 40% of the total payment after course completion for 60% of targeted participants.
- 10% of the total payment after course completion for 100% of targeted participants.
- After initial payment, next payment will be subject to the mid-term review and submission of CA audited utilization certificate (UC) and statement of expenditure (SoE) as per the standard template.
- The fund recipient shall be accountable for fund utilization as per the sanction.
- Re-appropriation of funds can be undertaken only after approval of BIRAC.

Communication of Results:

- Accepted proposals will be informed via email within the review timeline.
- Rejected proposals will also be notified, and they may be provided with feedback upon request.

Special Circumstances:

- Any requests for deadline extensions, or special considerations must be submitted in writing to the organizing committee for review and decision.

Conflict of Interest:

- The decision of BIRAC shall be final in case conflict of interest if arises.

Confirmation of Participation:

- Selected applicants must confirm their participation within 05 days of receiving the acceptance notification from BIRAC. If confirmation is not received, the spot may be offered to waitlisted applicants.

Record Keeping:

- All submitted applications, along with the corresponding documents, will be archived in the designated folder or system governed by BIRAC.
- BIRAC will maintain a record of accepted, waitlisted, and rejected applications.

Contact Information:

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

Contact Persons:

For queries about the application form:

Dr. Chaitanya, Programme Officer, NBM
Email: nbm-10@birac.nic.in

Dr. Madhvi Rao, Chief Manager, NBM
Email: nbm1@birac.nic.in

Mr. Suyash Srivastava, Administrative Assistant, NBM
Email: user-039@birac.nic.in

Annexure – I

ISO 13485:2016 Training

General Eligibility Criteria

The following check points will be observed as a mandatory eligibility compliance from the applicant for the conductance of ISO13485:2016 training.

Sr. No.	ISO 13485:2016 Training Agency Eligibility Criterion	Supporting Documents attached (self-attested)	Page No of Supporting Documents	Eligibility Check (Yes/No)
General terms of reference				
1.	Indian companies/ entities – An Indian Company/ entity is defined as one which is registered under the Indian Companies Act, 2013/ under relevant Act and minimum 51% of the share/ stakes of the Company/ entity 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]. OR 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			
2.	The Applicant must be registered in India with Taxation and other administrative authorities. The Applicant should also have a registered and established office in India.			
3.	The Applicant should not have pre-exited or terminated any contract with or by BIRAC in the last 05 years			

Annexure – II

ISO 13485:2016 Training
Technical Eligibility Criteria

The following technical check points will be observed as a mandatory eligibility compliance from the applicant for the conductance of ISO13485:2016 training.

Sr. No.	ISO 13485:2016 Training Agency Eligibility Criterion	Supporting Documents attached (self-attested)	Page No of Supporting Documents	Eligibility Check (Yes/No)
1.	The establishment should have experience of conductance of ISO13485:2016 training. Should have conducted a minimum of 5 trainings as lead trainer (essential for each trainer) as on date of closing of application.			
2.	The organization should have accreditation for Medical Devices Quality Management System (MDQMS) certification by National Accreditation Board for Certification Bodies (NABCB) or an organization with any accreditation covered by IAF MLA (multilateral agreement), to conduct all then trainings as mentioned in the scope and training modules in the RFP.			
3.	There should be at least 2-3 certified trainers under each module of the RFP. 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 training plan covers the following: i. Training design as per the RFP training modules ii. Training publications and outreach to invite applications from intenders			

	iii. Screening and selection of trainees iv. Conductance of the training and necessary arrangements v. Assessment of the trainees after the course in the form of an assignment as explained in the RFP vi. Gather feedback on the course from trainees (in the beginning, in between, and at the end of the training), and share the feedback report to BIRAC			

Annexure – III

Training budget format

The details for training fund utilization under different budget head is given below. Applicant may follow the similar pattern of budget bifurcation for submission of their detailed budget requirement.

Expenditure Heads	Particulars	Proposed budget (Amount in INR.)
Training Design, Material and Conductance		
a. Training design and material	The training cost other than basic infrastructure, computational accessories and stationary material)	
b. Outreach activity	For the publication of the training advertisement through social media handles and by outreach activities to multiple organizations, etc.	
c. Training conductance	Screening and recruitment of the candidate for the training. Training conductance material and consumable cost (computational accessories, stationary, certificate printing, training notes, feedback forms and reports, etc.)	
d. Honorarium	Honorarium cost to experts.	
Total (A)		
B. Logistic, Administrative and Miscellaneous Expenditure		
e. Logistic cost	Logistic cost includes lodging, boarding, and food of the trainees and experts). Travel cost (to and fro from accommodation place to training venue) for trainees and experts.	
f. Outsourcing	This includes any specific essential part of the training which need outsourcing	
g. Administrative	Administrative or contingency expenditure will be applicable only training related unexpected activities. Unjustified expenditure will not be considered while making the final release of the training grant amount.	
Total (B)		
Total A + B		

Annexure – IV

(To be printed on official letter head)

DECLARATION

1. I/We certify that the information in the above Expression of Interest in application form is true to the best of my knowledge.
2. I /We also understand that any misleading, or wrong information will disqualify this application straightaway.

Applicant's Official Stamp and Signature