

Call for Expression of Interest (Eoi)

IMDRF Training Endorsement Model Pilot

The International Medical Device Regulators Forum (IMDRF) invites Expressions of Interest (Eoi) from External Organizations interested in participating in the IMDRF Training Endorsement Model Pilot as a training provider.

Consistent with the IMDRF Strategic Principles for IMDRF Trainings (IMDRF/MC/N76 FINAL:2023), the pilot is intended to support training on IMDRF technical documents and related concepts through a model in which External Organizations provide training activities under IMDRF oversight and the associated training materials are reviewed and endorsed through IMDRF pilot processes.

The pilot is intended to support practical learning regarding potential IMDRF training and endorsement approaches and to help inform future IMDRF training activities.

Pilot overview

The initial pilot phase is expected to focus on in-person and/or hybrid training activities, planned to take place in Brasília, Brazil, in September 2027, in conjunction with the IMDRF meetings. The training may be held during the meeting week or immediately before the meetings, with the exact dates to be confirmed in due course.

The following training priority areas were agreed upon by the IMDRF MC and serve as the basis for proposals under the Training Pilot. External Organizations are invited to propose specific training topics and activities within these priority areas, taking into account their expertise and identified training needs. They may also indicate other relevant areas in which they could potentially contribute to IMDRF training, to inform the ongoing development and refinement of future Training Pilot Plans.

- Competence, Training, and Conduct Requirements for Regulatory Reviewers
IMDRF/GRRP WG/N40
- Clinical Evaluation IMDRF MDCE WG/N56
- Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
IMDRF/IVD WG/N64
- Medical Devices Post-Market Surveillance and Adverse Event Reporting
(GHTF/SG2/N54R8:2006; IMDRF/AET WG/N43 and N85)

The pilot utilizes a specific training-level approach in which individual training activities are conducted under IMDRF oversight, while associated materials may be reviewed and endorsed through IMDRF pilot processes.

Under the pilot, IMDRF does not endorse External Organizations as entities. The pilot is intended to support practical experience with training-level review, oversight, and endorsement processes.

IMDRF endorsement under this pilot does not include financial support, reimbursement, or funding for External Organizations, speakers, reviewers, participants, or any other entities involved in pilot activities.

Participation in pilot activities is voluntary and does not imply entitlement to financial support from the IMDRF, the MC, the Training Oversight Subcommittee (TOSC), or the IMDRF Secretariat.

Eligibility

External Organizations interested in participating in the pilot are encouraged to apply.

Organizations should demonstrate:

- experience in organizing and delivering training activities;
- experience related to medical device regulatory topics;
- ability to coordinate with international stakeholders;
- operational and logistical capability to support training delivery;
- willingness to coordinate with the IMDRF MC, TOSC, and Secretariat; and
- willingness to revise training materials based on IMDRF review and feedback process.

Expectations for the Selected Organization

The selected External Organization will be expected to work collaboratively with the TOSC throughout the preparation and implementation of the pilot. This includes participating in preparatory meetings with the TOSC and proposed speakers, developing and revising training materials, addressing TOSC review comments, complying with the timeline described in Annex III, delivering the training in accordance with the endorsed training materials, and contributing to pilot evaluation activities.

Application submission

Interested organizations should submit applications using the External Organization Application Form provided as Annex II.

Submission deadline: December 15, 2026

Completed applications should be submitted through the EoI submission [link](#). Please use the External Organization Application Form in Annex II and submit it by the deadline above.

Applications should be submitted in accordance with the timelines and processes outlined in this document and related annexes.

Additional information regarding evaluation criteria, application template, and indicative timelines is provided in Annexes I - III.

Review and selection processes

Applications will be reviewed by the TOSC using the evaluation criteria and rubric provided in Annex I.

Review activities may include:

- document review;
- clarification requests;
- coordination meetings/interviews; and
- recommendation to the IMDRF MC

Final selection decisions will be made by the IMDRF MC. The result of the selection would be communicated by the end of March, 2027.

Timelines

The selected External Organization should meet the proposed timeline as follows:

- submission of applications by December 15, 2026;
- submission of draft agenda and proposed speakers (or proposed organizations where speakers have not yet been confirmed) by April 15, 2027
- submission of full draft training materials six weeks before the training date
- submission of revised full draft training materials two weeks before the training
- provision of participant survey results four weeks after the training

Oversight and coordination

Training activities conducted under the pilot will be carried out under IMDRF oversight and coordination processes. Associated training materials may be subject to IMDRF review and endorsement processes.

Review and oversight activities may include consideration of:

- training agendas;
- training outlines;
- key messages;
- training materials; and
- aspects of training delivery.

Venue arrangements

The venue and related logistical arrangements for the training will be determined in coordination with the IMDRF Secretariat and the selected External Organization. While venue arrangements may be supported by the IMDRF Secretariat, External Organizations may also propose alternative venue arrangements as part of their application. The specific approach will be determined on a case-by-case basis.

Contact Information

For questions regarding this Expression of Interest (Eoi) or the application process, please contact the IMDRF Secretariat at: imdrf_2026@hsa.gov.sg

Annex I:

Application Evaluation Criteria/Rubric

Annex I provides indicative evaluation criteria and a rubric for review and assessment of applications submitted by External Organizations.

Indicative evaluation criteria

Applications submitted by External Organizations may be evaluated using the following indicative criteria.

Evaluation Area	Indicative Considerations
Organizational capacity	Experience organizing and delivering training programs; Operational and logistical capability; Availability to coordinate international activities
Regulatory / technical expertise	Familiarity with IMDRF documents and concepts; Experience related to medical device regulatory topics
Training quality	Quality and appropriateness of proposed agenda, learning objectives, speakers, and training approach
Collaboration capability	Ability to coordinate with the MC, TOSC, Secretariat, and other stakeholders; responsiveness to feedback
Timeline and operational readiness	Ability to meet timelines, provide materials on schedule, and support pilot coordination activities
Public interest / accessibility	Support for non-commercial and publicly accessible training principles consistent with IMDRF training objectives
Conflict of interest / transparency	Transparency regarding funding, sponsorship, and potential conflicts of interest
Logistical capability	Ability to support venue, virtual/hybrid participation, AV support, recording, and participant coordination
Fee structure	Clear fee structure that includes free attendance for IMDRF members; priority for fee structures that promote attendance of a wider audience

Note: Where available, supporting evidence such as participant feedback, post-training evaluations, or other relevant indicators may be considered in evaluating the quality and effectiveness of previous training activities.

Indicative review approach

Evaluation activities may include:

- independent review by TOSC members;
- clarification requests to applicants;
- discussion among TOSC members;
- optional coordination meetings/interview with applicants; and
- recommendation to the IMDRF MC

Indicative scoring rubric

Rating	Indicative Description
High	Fully demonstrate capability and alignment with IMDRF pilot objectives and operational expectations
Medium	Generally demonstrates capability and alignment, with some areas requiring clarification or further coordination
Low	Limited demonstration of capability, readiness, or alignment with IMDRF pilot objectives and operational expectations.

The rubric is intended to support consistent and transparent pilot review activities and may be refined based on pilot implementation experience.

Annex II

External Organization Application Template

Annex II is to be completed by the External Organizations applying to participate in the IMDRF Training Endorsement Model Pilot.

Organizational information

Please provide:

- organization name;
- primary contact person;
- contact information;
- organization website;
- organization type; and
- organizational background and mission.

Organizational experience

Please provide information regarding:

- experience organizing and delivering training activities;
- experience related to medical device regulatory topics;
- experience delivering training to regulatory authorities or government agencies;
- experience with international coordination activities; and
- examples of previous training programs.

Applicants may provide links or supporting materials related to previous training activities.

Note: Where available, applicants are encouraged to include:

- Number of training activities conducted (e.g., annually or over recent years);
- Approximate number and type of participants (e.g., regulators, industry, academia);
- Training topics; and
- Participant feedback, post-training evaluations, or other relevant indicators demonstrating the quality and effectiveness of previous training activities.

Proposed training activity

The initial pilot phase is expected to primarily support regulator-focused training activities.

Please provide:

- proposed training title;
- proposed objectives;
- proposed format (in-person / hybrid);

- proposed agenda and training outline;
- proposed speakers(s), or where final speakers have not yet been confirmed, potential speaker(s)/organization(s) including their qualifications, relevant expertise, and proposed roles within the proposed training activities; and
- explanation of how the proposed training supports IMDRF training objectives and priorities.

Operational and logistical capability

Please provide information regarding:

- venue or virtual platform capabilities;
- audiovisual and recording capabilities;
- participant management capability;
- translation/interpretation capability (if applicable);
- ability to support publicly accessible materials and recordings; and
- operational support arrangements.

Commitments and agreements

Applicants should confirm willingness to:

- coordinate with the MC, TOSC, and Secretariat;
- comply with implementation timelines;
- revise training materials based on IMDRF review and feedback;
- support IMDRF review and endorsement processes;
- participate in pilot evaluation activities; and
- support public availability of endorsed training materials and recordings, as applicable.

Fee structure

Applicants should confirm ability to provide training free of charge to IMDRF members (MC members, Official Observers, Affiliate Members, RHIs). Any fee structure for non-IMDRF members should be described in detail with confirmation of the External Organization's ability to collect and adjudicate fees.

Funding and conflict of interest information

Please provide:

- organizational funding sources;
- sponsorship information;
- any relevant conflict of interest considerations; and
- explanation of how independence and transparency will be maintained.

Additional information

Applicants may provide any additional information relevant to participation in the pilot.

Applicants may also indicate other relevant areas in which their organization could potentially contribute to IMDRF training, to inform the ongoing development and refinement of future Training Pilot Plans. These additional areas are for future planning and do not expand the four priority areas for the current pilot.

Annex III Indicative Timeline

This Annex provides an indicative timeline, key milestones, deliverables, and coordination points associated with implementation of the IMDRF Training Endorsement Model Pilot.

The timeline below is intended to support practical coordination, implementation planning, and practical delivery of pilot activities. Indicative activities, milestones, and timelines may continue to be refined during pilot implementation based on TOSC/MC discussions and operational considerations.

Timing	Activity / Deliverable
Upon publication of the Call	Issuance of Call for Expression of Interest (EoI)
December 15, 2026	Deadline of EoI application
January 2027	TOSC review and evaluation of applications Communication between TOSC and applicants for clarification
Early February, 2027	TOSC recommendation submitted to the MC
March 2027	MC selection of an External Organization
April 15, 2027	Selected External Organization submits revised draft agenda and proposed speakers to TOSC
April 15 – May 15, 2027	TOSC review of draft agenda and proposed speakers
May 15, 2027	TOSC recommendation on the draft agenda and proposed speakers submitted to the MC
June 2027	MC review/approval of agenda and speakers Publication of training information
July 2027	Preparatory Meetings with EO, TOSC and speakers External Organization submits full draft training materials to TOSC (at least six weeks prior to the training)
August 2027	Preparatory Meetings with EO, TOSC and speakers TOSC review and feedback on training materials External Organizations submits revised training materials to the TOSC (at least two weeks prior to the training) TOSC final review and endorsement of training materials
September 2027	Delivery of in-person/hybrid pilot training in conjunction with the IMDRF MC meeting in Brazil
Late 2027 – Early 2028	Pilot evaluation and collection of implementation feedback
February 15, 2028	TOSC submits pilot report to MC
March 2028	Presentation of pilot outcomes and lessons learned at the IMDRF MC Open Session

Note: Following submission of the draft agenda and proposed speakers, the TOSC and the selected External Organization should begin engagement with the proposed speakers and/or their organizations as early as practical to facilitate timely development and submission of training materials in accordance with this indicative timeline.