

IMDRF Industry Group Terms of Reference

A. Introduction

This document sets out the roles and responsibilities of the IMDRF Industry Group and provides guidance on the group's purpose, roles, responsibilities, operations, tenure and obligations, and in accordance with agreed upon terms between the International Medical Device Regulators Forum (IMDRF), DITTA (Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association) and GMTA (Global Medical Technology Alliance).

B. Role of the IMDRF Industry Group

The IMDRF Industry Group assists the IMDRF Management Committee (MC) in international harmonization efforts. The group provides strategic and well-informed advice and perspective to the IMDRF MC on matters relating to the advancement of medical device regulations and standardization. The group does not govern the decision-making process or provide oversight of the IMDRF.

The mission of the IMDRF Industry Group is to foster cooperation between regulators and industry on the international level as already undertaken on the national level. Timely collaboration is essential to support advancement towards IMDRF's mission and objectives and to facilitating access to medical technologies.

C. Membership

1. General membership of the IMDRF Industry Group

The IMDRF Industry Group is responsible for selecting its own members. These members are responsible for adequately representing to the IMDRF MC the diversity of perspectives and experiences of industry across the IMDRF Member jurisdictions (including MC members, Official Observers, Affiliate Members, and RHIs). In particular, the IMDRF Industry Group should pay special attention to ensuring the comments, feedback, and participation reflect the perspectives of its members of different sizes (e.g., small to medium sized enterprises) and manufacturers of different device types (e.g., medical device software) in the jurisdictions of all IMDRF members.

Members of the IMDRF Industry Group shall have sufficient resources and expertise to fulfil the responsibilities of membership. If possible, a representative of the trade association from the same jurisdiction as the IMDRF chair shall be nominated to the IMDRF Industry Group (one from each DITTA and GMTA).



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2. Chairmanship of the IMDRF Industry Group

The IMDRF Industry Group shall have a rotating co-Chairmanship between DITTA and GMTA, with an annual tenure. The co-Chairs are to be agreed upon by DITTA and GMTA and coincide (if possible) with the trade association of the IMDRF host country.

The co-Chairs shall serve as the primary contacts for the IMDRF Secretariat for all coordination matters, including the workshop. Alternatively, the co-Chairs may choose to provide a different contact point for the IMDRF Secretariat.

3. Publicly available information regarding the IMDRF Industry Group

The membership of the IMDRF Industry Group will be publicly available. Upon agreement with the IMDRF Industry Group, the IMDRF will post on its website meeting records (see section E.1.b.) from meetings between the IMDRF MC and the IMDRF Industry Group.

D. Operation of the IMDRF Industry Group

1. Internal meetings

The IMDRF Industry Group meets internally twice annually and when needed on an ad-hoc basis. Meetings are chaired by the group's co-Chair.

2. Meetings with the IMDRF MC

- a. Open Session. The IMDRF Industry Group is allotted up to six seats in the IMDRF MC Open Session. The six individuals attending the Open Session on behalf of the IMDRF Industry Group are responsible for adequately representing the diversity of perspectives and experiences of its members of different sizes (e.g., small to medium sized enterprises) and members of different device types (e.g., medical device software) in the jurisdictions of all IMDRF members (including MC members, Official Observers, Affiliate Members, and RHIs). The names of these individuals should be provided to the IMDRF Secretariat at least four weeks in advance of the meeting.
- b. Bilateral Meetings Between the IMDRF MC and the IMDRF Industry Group. The IMDRF MC meets with the IMDRF Industry Group twice per year during the week of face-to-face IMDRF meetings. Prior to bilateral meetings, the IMDRF MC and the IMDRF Industry Group will both, separately, coordinate messages of their members such that the discussions in the bilateral meeting are representative of all relevant perspectives. More than six individuals from the IMDRF Industry Group may attend the bilateral meeting. The individuals attending the bilateral meeting on behalf of the IMDRF Industry Group are responsible for adequately representing the diversity of perspectives and experiences of members of different sizes (e.g., small to medium sized enterprises) and members of different device



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types (e.g., medical device software) in the jurisdictions of all IMDRF members (including MC members, Official Observers, Affiliate Members, and RHIs). The names of individuals attending the bilateral meeting should be provided to the IMDRF Secretariat at least four weeks in advance of the meeting.

E. Responsibilities of the IMDRF Industry Group

The following list of tasks is inexhaustive and may be amended in agreement between the IMDRF MC, DITTA, and GMTA.

1. IMDRF Industry Group Meetings with the IMDRF MC

a. Agenda setting

- The IMDRF Industry Group is responsible for providing to the IMDRF Secretariat a draft agenda prior to any meetings with the IMDRF MC. The draft agenda should be provided in sufficient time to include it on the agenda of an MC meeting (either teleconference or Closed Session) prior to the MC meeting with the IMDRF Industry Group. The timeline below provides dates for bilateral meetings to occur during the week of IMDRF face-to-face meetings.
 - Dec 15: IMDRF Industry Group provides IMDRF Secretariat with draft agenda for bilateral meeting with IMDRF MC at March face-to-face IMDRF meetings.
 - January MC Teleconference: IMDRF MC discusses draft agenda during January teleconference.
 - Feb 15: IMDRF Secretariat provides feedback on draft agenda to IMDRF Industry Group.
 - March IMDRF Meetings: IMDRF Industry Group meets with IMDRF MC during week of face-to-face meetings.
 - May 15: IMDRF Industry Group provides IMDRF Secretariat with draft agenda for bilateral meeting with IMDRF MC at September face-to-face IMDRF meetings.
 - June MC Teleconference: IMDRF MC discusses draft agenda during June teleconference.
 - July 15: IMDRF Secretariat provides feedback on draft agenda to IMDRF Industry Group.
 - September IMDRF Meetings: IMDRF Industry Group meets with IMDRF MC during week of face-to-face meetings.



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- Agendas topics may include:
 - Discussion and decision regarding upcoming workshop topics and speakers;
 - Identification of emerging regulatory topics for which guidance from IMDRF would be beneficial;
 - Observations across jurisdictions of implementation challenges and successes with current IMDRF guidance;
 - Opportunities for training to IMDRF guidance; and
 - Summary of industry participation in IMDRF WGs.
- b. Meeting records
 - The meeting will include sufficient time (e.g., 30 minutes) for real-time drafting of a meeting record. This meeting record will be posted on the IMDRF website (see section C.3.).
- 2. The IMDRF Industry Group takes a leadership role in the planning and execution of joint IMDRF- industry workshops. This includes the following tasks and due dates:
 - a. IMDRF Industry Group to include at least two draft workshop agendas for the MC's consideration. These draft agendas should be included with the draft agenda proposed for the IMDRF Industry Group meeting with the IMDRF MC.
 - b. Potential workshop topics will be discussed and decided upon during IMDRF Industry Group meetings with the IMDRF MC.
 - c. The IMDRF Industry Group will provide the names of all industry speakers/moderators at least four weeks prior to the workshop.
 - d. The IMDRF Industry Group will schedule and execute preparatory sessions for speakers and moderators at least two weeks prior to the workshop.
- 3. Provide industry intelligence regarding emerging trends in medical device and in vitro regulation to aid IMDRF MC discussions and decision-making via:
 - a. Providing draft new work item proposals for the IMDRF MC to consider.
 - b. Coordinating industry perspectives on questions from the IMDRF MC (e.g., understanding and presenting findings to summarize perspectives across the industry on emerging regulatory topics (e.g.,



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- c. Supporting development of training materials (e.g., identify specific documents for which training would benefit different IMDRF stakeholders, provide speakers and logistical and financial support for training as discussed with the IMDRF training oversight subcommittee, provide translation services to increase accessibility).
- d. Providing feedback on draft documents and other artifacts developed specifically for industry stakeholders.
- e. Identifying opportunities across jurisdictions to harmonize regulatory guidance.
- f. Supporting industry participation in appropriate IMDRF working groups.

--- End of Terms of Reference ---