IMDRF International Medical Device Regulators Forum

Final Document

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Strategic Principles for IMDRF trainings

AUTHORING GROUP

IMDRF Management Committee

Preface

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1. Introduction

It is the goal of IMDRF to 'strategically accelerate international medical device regulatory convergence and to promote an efficient and effective regulatory model for medical devices worldwide'. It is considered that the development of well-designed, carefully targeted and freely and easily accessible training products on the work of the IMDRF working groups will contribute significantly to this objective.

This document aims to deliver on a high-level principles document on IMDRF trainings which intends to support the achievement of Priority 3 in the IMDRF 2021-2025 Strategic Plan : 'IMDRF will seek opportunities to develop stronger relationships with organizations that help advance our mission, such as standards development organizations. IMDRF will work towards promoting regulatory convergence **by developing consistent training programs** to facilitate harmonised regulatory approaches and consistent implementation among various jurisdictions'.

2. Aims of IMDRF trainings

a) Promote convergence and good regulatory practices, including displaying leadership internationally on both guidance development but also engagement in a publicly available and easily accessible format;

b) Ensuring consistent interpretation and understanding of IMDRF guidance documents by all actors, including stakeholders thereby reducing the probability of regulatory divergence;

c) Providing opportunities to engage with IMDRF technical Working Groups who have developed/authored the guidance ('e.g., ask the authors sessions');

d) Collaborating with other entities conducting trainings based on IMDRF guidance to ensure continued alignment with guidance principles,

e) Support capacity building of new IMDRF members, including affiliate members, non-IMDRF members and industry more broadly

3. Target audience of IMDRF trainings

a) Supporting stakeholders, including industry and other key actors (health care professionals, hospitals etc) in better understanding IMDRF guidance;

b) Special focus should be attributed to SMEs, characteristic of the medical device sector which have reduced possibilities for access to regulatory expertise and trainings;

c) Supporting new IMDRF regulators and non-IMDRF regulators in understanding and implementing IMDRF guidance documents;

d) Supporting the onboarding of new IMDRF working group members on foundational documents of the working group;

e) Supporting the onboarding of new staff in IMDRF regulatory authorities; ensuring appropriate knowledge transfer within IMDRF regulators jurisdictions while onboarding new staff.

4.Training development methods

a) Own resources - actively seek interest from MC members and encourage working groups to conduct online PowerPoint based trainings, workshops and or webinars identified in areas of interest (for example: AET, CYB, GRRP, PMD);

b) Collaboration with RHIs;

c) Collaboration with other interested parties (subject to terms);

d) Longer-term consideration for financial resource bundling similar to other international organisations such as ICH.

5. Identification of training needs

a) Own initiative (refer to point 4a);

b) Include an early needs identification requirement in the NWIP/E template;

c) Include a training needs section in the transmittal record to be filled in by the working group when submitting a final document for MC agreement;

d) Introduce a new consideration in the annual procedure for reviewing existing and old (GHTF) documents subject to potential revision;

e) Review of IMDRF website stats (most accessed and downloaded guidance documents)

f) Queries received by the Secretariat

g) Notification by RHIs on the development of a training module on IMDRF documents.