IMDRF
International Medical Device Regulators Forum

EU2023
EUROPEAN UNION Chair

European Commission

European Union

Progress Overview of IMDRF Work Items

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

13:00 – 13:15

Adverse Event Terminology (USA / EU)

Andrea Hanson

Market Analysis Lead, Health Products Regulatory Authority

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

Nancy Pressly, Working Group Co-Chair, US Food and Drug Administration (FDA)

Andrea Hanson, Working Group Co-Chair, Health Products Regulatory Authority (HPRA)

28th March 2023

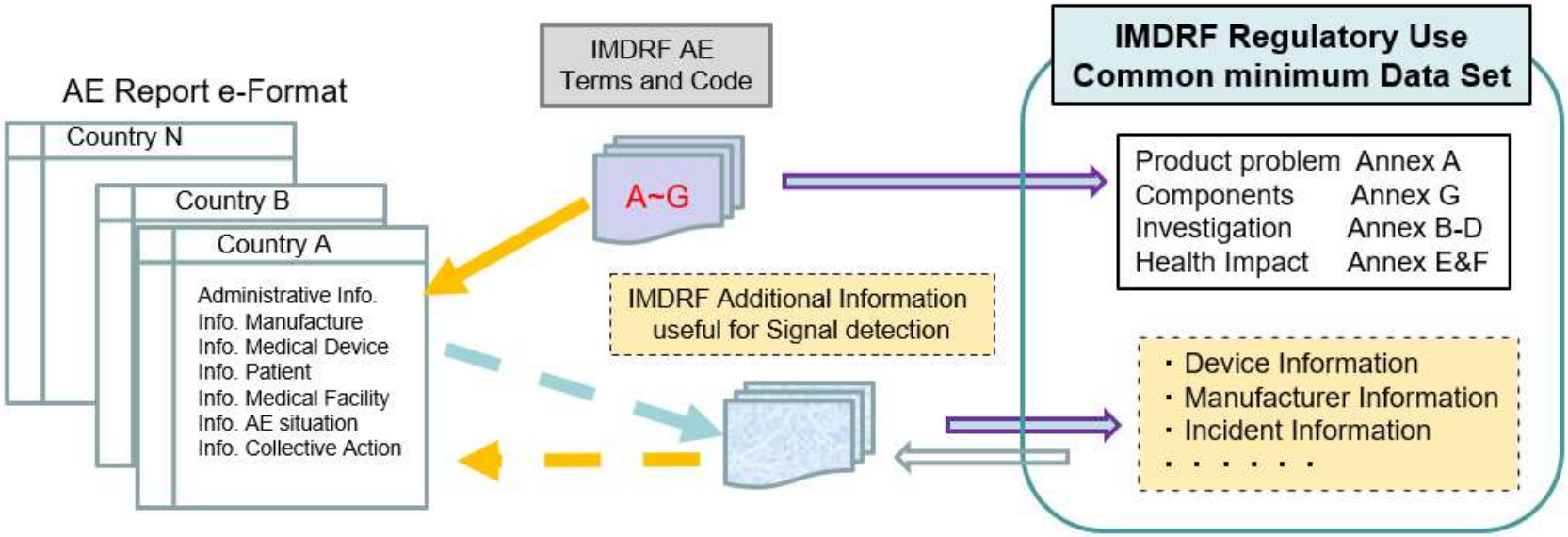
1. CURRENT ACTIVITIES

Work in Progress

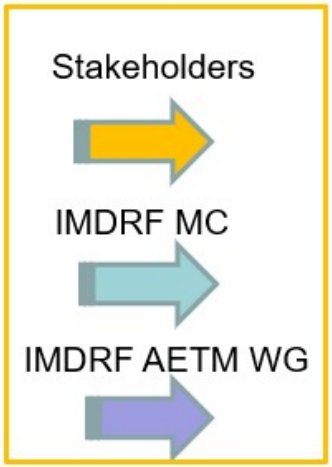
Expanding the Harmonization of Adverse Event Terminology

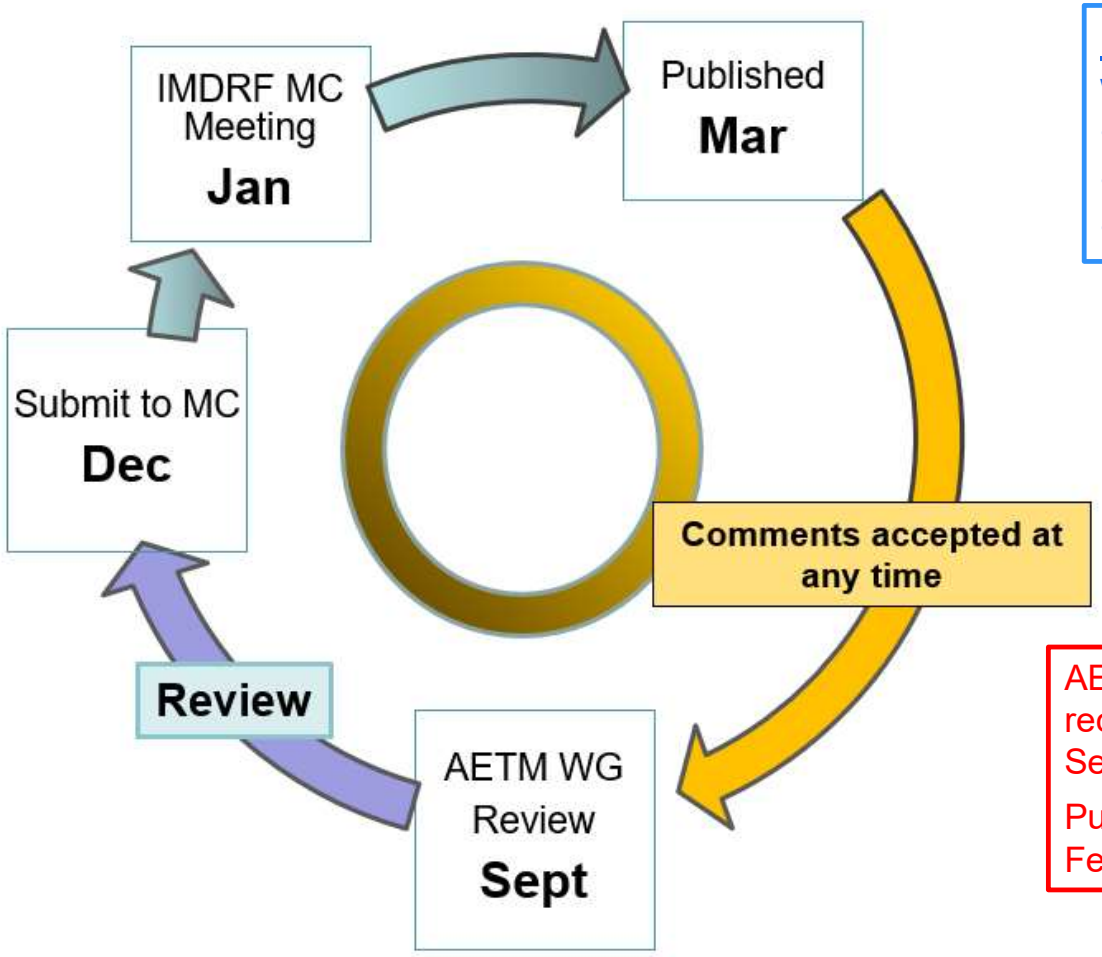
Issues being addressed:

- Common minimum data requirements for reporting, including defined data fields, data requirements, and data structure.
- Common format for data exchange between jurisdictions.



2. TERMINOLOGY MAINTENANCE





149 change requests were reviewed
- 48 accepted
- 20 modified
- 81 rejected

AETM WG reviews comments received by the 1st of September

Publication of updates – February 2023

Resources

IMDRF Terminology

IMDRF AE WG Webpage (Includes links to the terminology web browser)

IMDRF AE Terminology (Current Version)

IMDRF Terminology Maintenance

IMDRF Terminology Maintenance Webpage

Change Request Form

Related Documents

IMDRF AE Terminology Guideline Main Body (N43 Document)

IMDRF Terminology Maintenance (N44 Document)

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Thank you/Questions

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

13:15 – 13:30

Good Regulatory Review Practices (USA / Singapore)

Erin Cutts

Senior international policy analyst, U.S. Food and Drug Administration

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Good Regulatory Review Practices (GRRP) Working Group

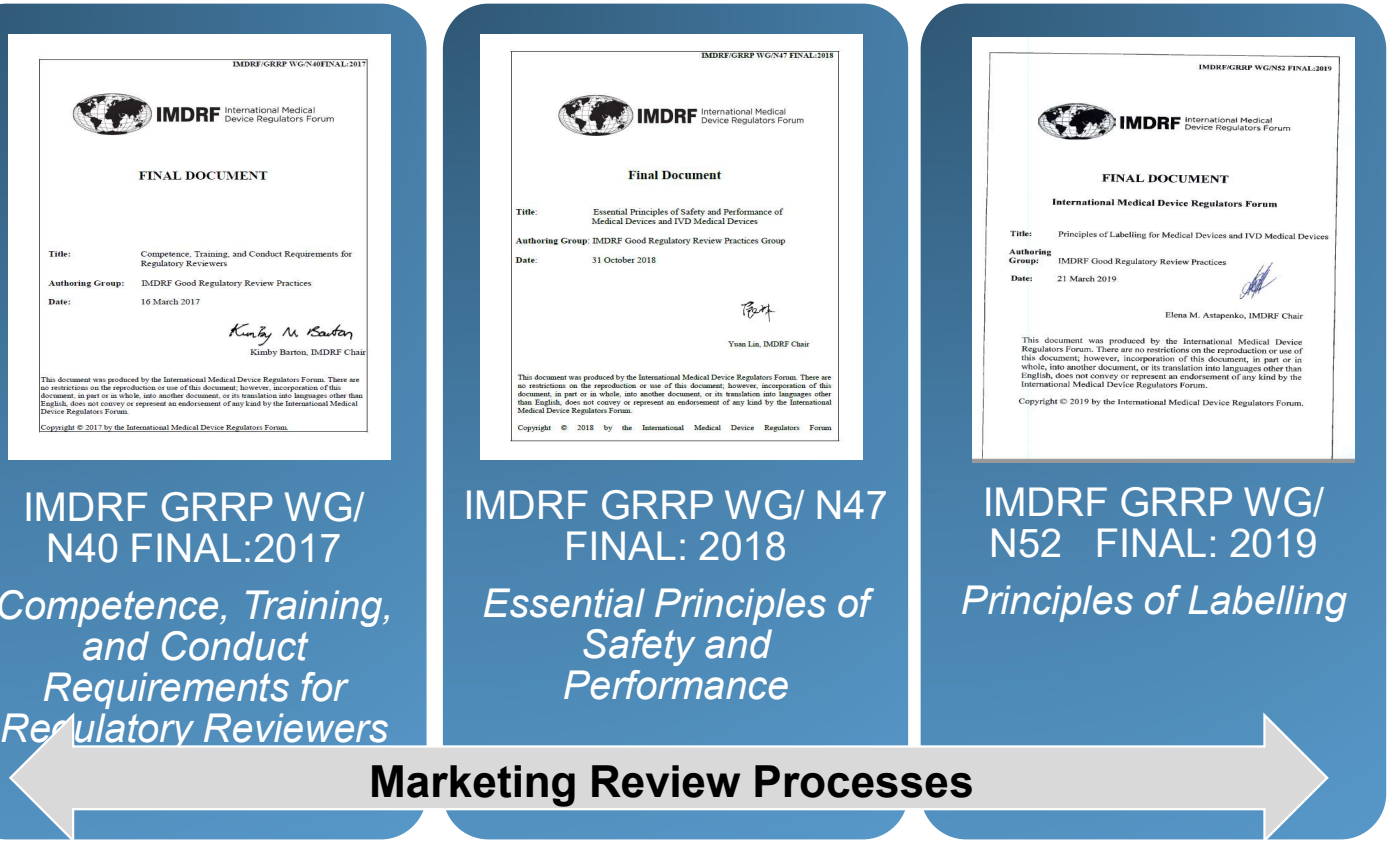
Erin Cutts, Senior International policy analyst , US Food and Drug Administration (FDA)

28th March 2023

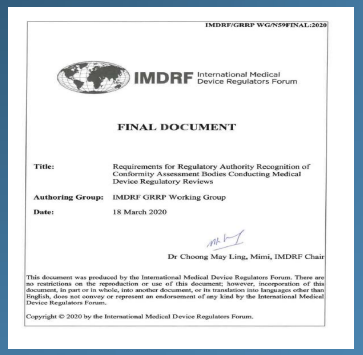
IMDRF GRRP Working Group Goals

- Develop documents focused on harmonizing marketing review requirements globally.
- Documents focus on:
  - Technical requirements for conducting marketing reviews
  - Competency requirements for marketing reviewers
  - Requirements for organizations performing marketing reviews

GRRP Documents



GRRP Documents


IMDRF/GRRP WG/N59FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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IMDRF GRRP WG/ N59 FINAL:2020

Requirements for Regulatory Authority Recognition of CABs


IMDRF/GRRP WG/N61FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: 25 September 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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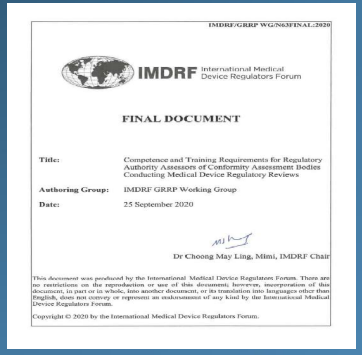
IMDRF GRRP WG/ N61 FINAL:2020

Assessment Methods for Recognition of CABs


IMDRF/GRRP WG/N63FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: 25 September 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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IMDRF GRRP WG/ N63 FINAL:2020

Competence and Training Requirements for Assessors of CABs


IMDRF/GRRP WG/N66FINAL:2021

IMDRF International Medical Device Regulators Forum

Final Document

Title: Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF Good Regulatory Review Practices Working Group

Date: 24 June 2021

Oh-Sang Kwon, IMDRF Chair

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IMDRF GRRP WG/N66 FINAL:2021

Assessment and Decision Process for the Recognition of CABs Conducting Medical Device Regulatory Reviews

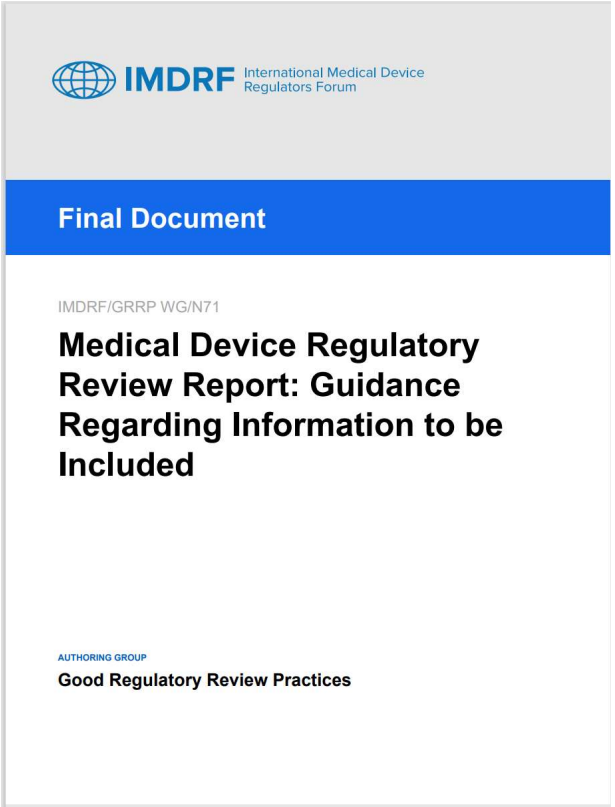
Recognition of Conformity Assessment Bodies (CABs)

Benefits of GRRP WG Documents

- Promote consistency, predictability and transparency in regulatory marketing review programs through agreed-upon sets of criteria and processes
- Provide confidence that marketing regulatory reviews conducted by CABs are rigorous enough to meet the requirements of Regulatory Authorities
- Provide opportunities for convergence of marketing review requirements
- Benefit all regulators, even those just starting to develop a regulatory medical device marketing review system

Most Recent Work Item: N71 – Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

- Published in final on Feb 3, 2023
- Provides guidance regarding creation of a medical device regulatory review report
- A regulatory review report:
  - is a written record of the CAB's determination of the extent of fulfillment of specified requirements;
  - captures, in a consistent manner, the evidence of a manufacturer's conformity with the criteria for the regulatory review; and
  - will facilitate the exchange of information between RAs.
- Working group participation included CAB representatives as observers



What's Next?

- The GRRP WG is currently considering future work and appreciates any suggestions and requests.

IMDRF International Medical Device Regulators Forum

Thank you!
Questions?

Email erin.cutts@fda.hhs.gov

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

13:30 – 13:45

Medical Device Cybersecurity (USA / Canada)

Daniel Yoon

Acting Manager, International Programs

Health Canada

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Medical Device Cybersecurity Update

US FDA & Health Canada Co-chairs

March 2023

Overview

New Work Item Extension

How stakeholders should implement and operationalize:

- Software Bill of Materials (SBOM)
- Legacy conceptual framework

New Work Item Extension

Goal: To increase international alignment and improved safety and security by:

- **Addressing implementation of an SBOM**
  - Topics include: generation, distribution, management, and use of an SBOM

- **Operationalizing the legacy device conceptual framework** articulated in the N60 document in a related, but separate document
  - Topics include: additional definitions, legacy device best practices, TPLC framework, communications, risk and vulnerability management, risk transfer, and considerations for once device no longer supported

Progress and Milestones

- February 3, 2021: New Work Kick-off Meeting
- April 2021: Final Document Outline
- April-October 2021: WG Meetings every two weeks
- November 2021: 3-day WG Meeting
- **February 2022: Submission of draft Legacy Document to IMDRF MC**
- April 2022: Public Consultation of Legacy Document
- **May 2022: Submission of draft SBOM Document to IMDRF MC**
- July 2022: Public Consultation of SBOM Document
- November 2022: 3-day WG Meeting
- January 2023: Final documents submitted to IMDRF MC
- **March/April 2023: Publish Final Legacy and SBOM Documents***

* Pending IMDRF MC Approval

IMDRF International Medical Device Regulators Forum

Thank you/Questions

Marc Lamoureux
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Suzanne Schwartz/Aftin Ross
Suzanne.Schwartz@fda.hhs.gov/Aftin.Ross@fda.hhs.gov

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

13:45 – 14:00

Personalized Medical Devices (Australia)

Tracey Duffy

First Assistant Secretary, Medical Devices and Product Quality Division, Therapeutic Goods Administration (TGA)

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Personalized Medical Devices (PMD) Working Group

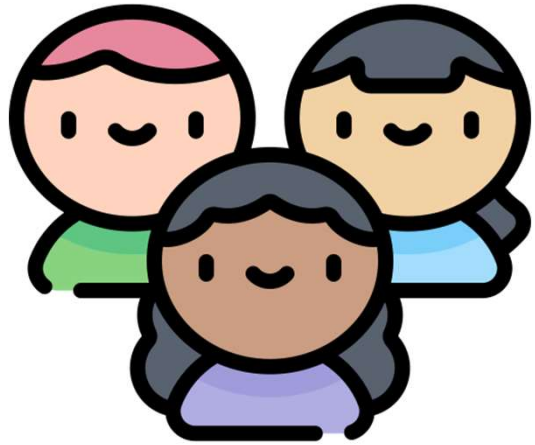
PMD Working Group Chair: Therapeutic Goods Administration, Australia

IMDRF Stakeholder Forum – 28 March 2023

Tasks given to the PMD Working Group

1. Revise PMD Regulatory Pathways (N58)
Public consultation closed 28 November 2022

2. Develop PMD Production Verification and Validation (N74)
Public consultation closed 28 December 2022



PMD Regulatory Pathways (N58)

N58, first published in 2020, is an active technical document.

In April 2022, MC approved the proposal to revise N58 to achieve the following objectives:

1. Revise the **definition** of Medical Device Production System (MDPS) to no longer limit the concept to PMDs;
2. Revise the MDPS framework to better represent **real world applications**, thereby facilitating the adoption and implementation of MDPSs by stakeholders; and
3. Expand the scope of Appendix 2 to incorporate a broad range of medical devices, **not limited to PMDs**.

Timelines & progress on the revision of N58

March 2022	• WG presents a proposal to MC to revise the existing N58
April 2022	• MC approves the proposal and tasks WG with the work
July 2022	• Working Draft N58 discussed at the WG meeting
August 2022	• Deep dive sessions to prepare the final Working Draft N58
August 2022	• Final Working Draft N58 submitted to IMDRF Secretariat for consideration at September 2022 MC meeting

Timelines & progress on the revision of N58

September 2022
- MC approved advancement from Working Draft to Proposed Document, and 60 day public consultation starting 29 September 2022

November 2022
- Public consultation closed 28 November 2022

February 2023
- Deep dive sessions to discuss and address feedback from public consultation

February 2023
- Revised version of N58 submitted to IMDRF Secretariat for MC's consideration

Public consultation – N58 PMD Regulatory Pathways

Start date: Thursday, 29 September 2022 | Closing date: Monday, 28 November 2022

- Eleven submissions received – 61 comments
- Submissions received from individuals, peak bodies representing allied health and dental sectors, and trade associations representing industry
- The WG held deep dive sessions in February 2023 to consider the feedback received in the submissions
- An updated version of the document has been submitted to the MC for consideration

Observations from N58 public consultation

- Stakeholders broadly supported the revisions; requested further clarification on delineation of roles and responsibilities of HCF and MDPS manufacturers
- Some feedback was not within the scope of revisions:
  - changing the PMD definitions
  - seeking to have IVD medical devices included in the scope
- Stakeholders sought further clarification on how PMDs will be regulated in their jurisdiction

PMD Production Verification and Validation (N74)

New Work Item Extension (NWIE) approved by MC in September 2020 to develop technical guidance covering:

- Part I: Verification and validation aspects of **Specified Design Envelope** (salient feature of patient-matched medical device definition)
- Part II: Verification and validation **aspects** of MDPS

Timelines & progress on the development of N74

March 2020	• NWIE PMD Production Validation proposal submitted to MC
September 2020	• NWIE proposal approved by MC, Australia nominated as PMD WG Chair
December 2020	• Introductory WG meeting
March 2021	• 2nd WG meeting to discuss Version 1.0 of the Working Draft
Until July 2022	• 8th meeting of the WG to discuss Version 8.0 of the Working Draft
August 2022	• Deep-dive sessions to prepare final version of Working Draft

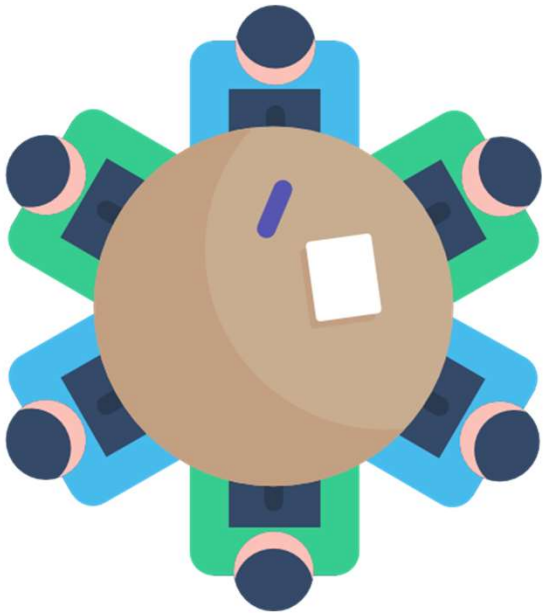
Timelines & progress on the development of N74

August 2022	• Final Working Draft N74 submitted to IMDRF Secretariat for consideration at September 2022 MC meeting
September 2022	• MC approved advancement from Working Draft to Proposed Document, and 90 days public consultation starting 29 September 2022
December 2023	• Public consultation closed on 28 December 2022
February 2023	• Deep dive sessions held to discuss and address feedback from public consultation
February 2023	• Revised version of N74 submitted to IMDRF Secretariat for MC's consideration

Public consultation – N74 PMD Production V&V

Start date: Thursday, 29 September 2022 | Closing date: Wednesday, 28 December 2022

- Four submissions received – 49 comments
- The WG held deep dive sessions in February 2023 to consider the feedback received in the submissions
- An updated version of the document has been submitted to the MC for consideration



Observations from N74 public consultation

- Limited feedback on N74, likely because the concepts presented are relatively novel and stakeholders do not have enough experience yet
- Specific feedback and broad agreement on Specified Design Envelope V&V recommendations
- Further clarification sought on the delineation of roles and responsibilities of the HCF and MDPS manufacturers at various stages of its life-cycle

Summary

- WG has met virtually 17 times since December 2020, most recently on Thursday, 2 March 2023
- WG held five deep dive sessions in February 2023 to discuss the feedback from public consultation on N58 and N74
- Outcomes from deep dive sessions in February 2023 - updated versions of N58 and N74 (Proposed Documents)
- N58 and N74 Proposed Documents have been submitted to the IMDRF Secretariat for consideration by MC at March 2023 meeting

Personalised Medical Devices Working Group (WG) members

Jurisdictions

- Argentina
- Australia
- Brazil
- Canada
- China
- Europe
- Japan
- Saudi Arabia
- Singapore
- South Korea
- UK
- USA

IMDRF International Medical Device Regulators Forum

Thank you/Questions

PMD Working Group Chair: Therapeutic Goods Administration, Australia
Email: personaliseddevices@health.gov.au

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

14:00 – 14:15

Quality Management Systems (USA / EU)

Melissa Torres

Associate Director, U.S. Food and Drug Administration

European Commission | European Union

IMDRF International Medical Device Regulators Forum

QUALITY MANAGEMENT SYSTEM (QMS) WORKING GROUP UPDATE

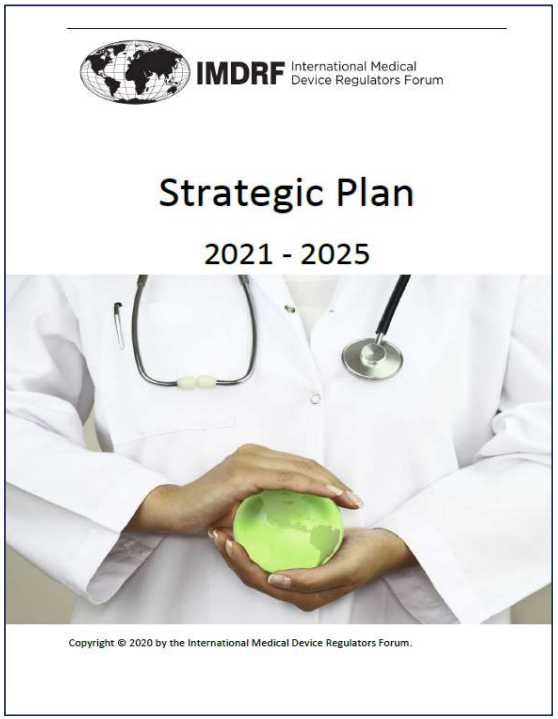
Co-Chairs:
Mairead Finucane – EC
Melissa Torres – US FDA

Background

- Quality management systems and risk management activities are integral principles to ensuring the design and manufacture of safe and effective medical devices
- While pre-market requirements can address known and foreseeable risks, an effective post-market surveillance system is necessary to manage evolving and new risks effectively
  - An effective post-market surveillance system is critical to continuously monitor feedback and implement improvements in a controlled manner under the manufacturer's quality management system to make the medical device better in its future versions or iterations
- It is important to have up to date guidance on QMS and risk management requirements outlined in ISO 13485 and ISO 14971 in order to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices.

Rationale

- Existing GHTF QS SG3 documents are outdated (2004-2010)
- QMS and risk management principles have evolved since the creation of the original GHTF documents
- Requirements within the various jurisdictions have also evolved
- GHTF documents are based on previous versions of ISO 13485 and ISO 14971 and should be updated to be in alignment with current versions of the standards
- Work is in alignment with several key objectives of the IMDRF strategic plan



Goals

Revise existing GHTF Study Group 3 Quality Systems documents:

- **GHTF/SG3/N17:2008 Guidance on the Control of Products and Services Obtained from Suppliers**
- GHTF/SG3/N18:2010 Guidance on Corrective and Preventive Action
- GHTF/SG3 N15R8: 2005 Risk Management Principles
- GHTF/SG3/N99-10:2004 Process Validation Guidance

Current Status

- New Work Item Proposal approved in September 2022
- Received agreement amongst leadership of IMDRF, GHWP, and ISO to do this work jointly amongst the 3 organizations
- Working group is currently being established
  - Call for participants/representatives from IMDRF/GHWP regulatory authorities, ISO TC 210 WG1, and industry
  - IMDRF website updates
  - Expect work to begin in the next couple of weeks

IMDRF International Medical Device Regulators Forum

Thank you!
Questions?

Email melissa.torres@fda.hhs.gov
Mairead.FINUCANE@ec.europa.eu

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EUROPEAN UNION
Chair

Regulated Product Submission (Canada / USA)

Daniel Yoon

Acting Manager, International Programs

Health Canada

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Regulated Product Submission

Co-chairs:

Patrick Axtell, US Food and Drug Administration

Daniel Yoon, Health Canada

March 28, 2023

Background

- RPS Table of Contents (ToC) is intended to provide a harmonized format for submitting medical device market authorization applications
  - Latest version was published in 2019
- RPS extension was approved in 2021 to update the ToC documents to be current
- The goal is to translate the updated ToC documents into a new type of dynamic template for building submissions

eSTAR

- eSTAR is a dynamic pdf template that guides applicants through the process of preparing medical device submissions
- Currently used by the US FDA for 510(k) and De Novo submissions.
- eSTAR will ensure all the required documents are included in the submission and placed in the appropriate structure before it is sent to the regulator
  - Ensures consistency and reduces processing delays
- Health Canada and the US FDA launched a joint pilot in January 2023 with 9 participants

N9 and N13 updates

- Minor refinements
  - Made content current for all jurisdictions
  - Minor improvements in harmonization in several subchapters
  - Removed reference to and use of Classification Matrices
  - Updated with MDR and IVDR content and references
  - Moved Essential Principles, Standards information, and Risk Management to Chapter 2 from Chapter 3
  - Simplified Regions column (will now list conforming regions or “IMDRF” for all)
- Larger changes
  - Addition of MFDS (Korea) and MHRA (UK), though regional content additions were limited
  - Addition of Post-Market Study Plans and Real-World Data subchapters
  - Consolidated Chapters 6A and 6B into a single Chapter 6 (no redundancy)
  - Substantial additions/changes to EU, TGA, NMPA, ANVISA regional content

Consultation and next steps

- N9 and N13 updates were approved by the Management Committee in January for public consultation
- Consultation is open until April 15, 2023
- WG will analyze comments and revise the ToCs accordingly after consultation closes
- WG will also begin transferring ToC updates to eSTAR template
  - Currently programmed with FDA and HC submission requirements
- Proposed final documents will be submitted for MC consideration

Membership

Jurisdiction/Affiliation	Representative
Australia	Meryl Clarke Tania Ahmed Simone McGinley Shraddha Swami Leon Weekes
Brazil	Augusto Bencke Geyer Anderson de Almeida Pereira Priscilla Consigliero de Rezende Martins
Canada	Johnny Chou Allison Oldfield Daniel Yoon (co-chair)
China	Shiqing Zhang Yue Min
European Union	Maria Chiara Orlandi (EC) Mario Gabrielli-Cossellu (EC) Rainer Edelhäuser (Germany)
Japan	Madoka Murakami (MHLW) Yuzuru Okazaki (PMDA) So Hifumi (PMDA) Hideharu Komiya (PMDA)
Singapore	Agnes Goh Koh Chee Gake
South Korea	Young-mee Kwon Yunju Lee Yi Le Ahn (Rebecca)
United Kingdom	Jillan Hussein
United States	Patrick Axtell (co-chair) Kenneth Cavanaugh
World Health Organization	Helena Ardura-Garcia
Notified Bodies	Dawn Thibodeau Sharmila Gardner

IMDRF International Medical Device Regulators Forum

Thank you/Questions

Email patrick.axtell@fda.hhs.gov
daniel.yoon@hc-sc.gc.ca

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

14:30 – 14:45

Software as a Medical Device (USA / Canada)

Daniel Yoon

Acting Manager, International Programs

Health Canada

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Software as a Medical Device (SaMD) Update

US FDA & Health Canada Co-chairs

March 2023

Overview

New Work Item Proposal

- The SaMD Working Group published 4 technical documents from 2013-2017

- The rapid pace of technological advancement in SaMD has tested these documents and refinements are needed to improve consistency, predictability, and transparency of pre- and post- market regulatory programs

- Refining these documents would support innovation and timely access to safe and effective SaMD globally while promoting global convergence of review requirements in areas of advanced and innovative technologies.

New Work Item Proposal

Goal: To refine the previously published SaMD documents to improve international alignment and ensure ongoing consistency, predictability, and transparency by:

- **Considering improvements to the existing documents by publishing new document(s) related to:**
  - The granularity of the risk categorization matrix (N12)
  - Enhancing focus on better characterizing the device to inform downstream risk considerations
  - The location of where the software may be running (N10)
  - Other improvements as identified by working group members
- **Considering additional opportunities for international alignment related to:**
  - Alignment and coordination with other IMDRF WGs and technical documents (e.g. AI, Cybersecurity)

Progress and Planned Milestones

- June-July 2022: Identification of WG members and co-chair coordination meeting
- August 2022: Survey to WG members re: proposals for changes to existing documents
- September 2022: WG kick-off meeting, meeting every two weeks
- April 2023: 3 x half-day virtual WG meeting
- **August 2023: Planned submission of draft document to IMDRF MC**
- October 2023: Public consultation of document(s)*
- January 2024: 3/4-day WG meeting
- March 2024: Final document(s) submitted to IMDRF MC
- **May 2024: Publish final technical document(s)***

IMDRF International Medical Device Regulators Forum

Thank you/Questions

Marc Lamoureux
marc.lamoureux@hc-sc.gc.ca

Brendan O'Leary
Brendan.Oleary@fda.hhs.gov

IMDRF
International Medical Device Regulators Forum

EU2023
EUROPEAN UNION Chair

14:45 – 15:00

Good Machine Learning Practice (USA / UK)

Melissa Torres

Associate Director, U.S. Food and Drug Administration

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Artificial Intelligence (AI)/Machine Learning (ML) Enabled Medical Devices Working Group Update

Co-Chairs:
Matthew Diamond – US FDA
Russell Pearson – UK MHRA

Background

Good Machine Learning Practice (GMLP) brings together high-level, fundamental principles important for the development, use and monitoring of Machine Learning (ML)-enabled medical devices.

ML-enabled products have unique considerations that can be addressed, at least in part, with GMLP implemented across the product life cycle.

Rapid technological advancements in AI/ML, combined with manufacturers from sectors beyond medical devices, makes development of GMLP an important priority to lower product and development risks and to protect against regulatory divergence.

Rationale

- There is a close interplay between ML-enabled medical devices and other software based medical devices.
  - GMLP must be developed to be compatible with best practice SaMD guidance and built upon existing core aspects of medical device regulations.
    - Core aspects include quality management systems, risk management and clinical evaluation to ensure the GMLP complements the state of the art and regulatory compliance.
- Work is aligned with the IMDRF Strategic Plan to develop a harmonized approach to the management of AI medical devices.
- Generating consensus across the product lifecycle via creation of a GMLP document will also assist with the IMDRF objectives to strengthen post-market activities and a total product lifecycle regulatory approach to medical devices.

Goal

- To develop a new document on the topic of Good Machine Learning Practice (GMLP) that will provide internationally harmonized principles to help promote the development of safe and effective ML-enabled medical devices.
  - Generate consensus on the key considerations for how AI/ML products can meet regulatory, risk management, quality management and clinical evaluation in order to promote consistency across jurisdictions.
  - Build upon the US FDA/Health Canada/UK MHRA joint document on GMLP Guiding Principles.

March 2023

Good Machine Learning Practice Principles

U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

These guiding principles may be used to:

- Adopt good practices that have been proven in other sectors;
- Tailor practices from other sectors so they are applicable to medical technology and the health care sector; and
- Create new practices specific for medical technology and the health care sector.

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise are Leveraged Throughout the Total Product Life Cycle	**Good Software Engineering and Security Practices are Implemented**
Clinical Study Participants and Data Sets are Representative of the Intended Population	**Training Data Sets are Independent of Test Sets**
Selected Reference Datasets are Based Upon Best Available Methods	**Model Design is Tailored to the Available Data and Reflects the Intended Use of the Device**
Focus is Placed on the Performance of the Human-AI Team	**Testing Demonstrates Device Performance during Clinically Relevant Conditions**
Users are Provided Clear, Essential Information	**Deployed Models are Monitored for Performance and Re-training Risks are Managed**

Current Status

- New Work Item Proposal approved in January 2022
- Working group is currently being established
  - Call for participants/representatives from IMDRF regulatory authorities, RHIs, and industry
  - IMDRF website updates
  - Expect work to begin in the next couple of weeks

IMDRF International Medical Device Regulators Forum

Thank you!
Questions?

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