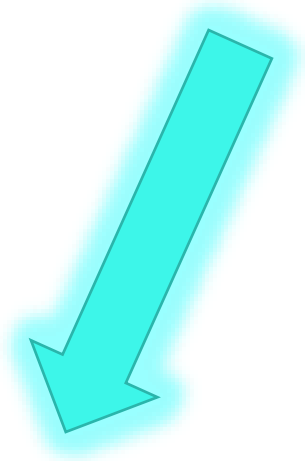
IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

Nancy Pressly/ Evan Jacobs – Food and Drug Administration, United States of America

Andrea Hanson – Health Products Regulatory Authority, Ireland.



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IMDRF 24th Session – Berlin, Germany

About US

- The Adverse Event Terminology and Coding working group was established in 2015
- The group is composed of members from 11 regions.
- The group has two Co-Chairs (FDA & HPRA) and a AEWG Maintenance Chair (MHRA).
- The group convenes every 3 weeks via teleconference. A face-to-face meeting will be held in October 2023.

About Us

The aim of the working group is to:

- Improve, harmonize and where necessary expand the terminology and systems being used to code information relating to medical device adverse events, and
- Establish and maintain IMDRF adverse event terminology composed of the following three parts: terms for medical device malfunction, terms for patient/user outcome and terms for part/component of medical device.

Strategic Plan - IMDRF Key Objectives 2021-2025

1. Managing regulatory challenges for medical devices and innovative technologies by providing **timely and appropriate guidance**
2. **Strengthening post-market surveillance** for medical devices and implementing regulatory life cycle processes

- **Priority 2: Post-Market** - Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients.
- Topic: **Adverse Event Terminology Harmonize adverse event terminology** to expand terminology and systems being used to code information relating to medical device adverse events

Publications

IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes IMDRF/AE WG/N43FINAL: 2020 (Edition 4).

Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem

Annex B: IMDRF terminologies for categorized Adverse Event Reporting (AER) – Type of Investigation

Annex C: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Findings

Annex D: IMDRF terminologies for categorized Adverse Event Reporting (AER) – Investigation Conclusion

Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Clinical Signs and Symptoms or Conditions

Annex F: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Health Impact

Annex G: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Component

Maintenance of IMDRF AE Terminologies IMDRF/AE WG/N44FINAL:2020 (Edition3)

Ongoing work

1. Leverage post-market monitoring and surveillance

   a) The development of a Common Data Set for Adverse Event Data Exchange between IMDRF Regulators, through the:

      a) Development of the exchange mechanisms.
      b) Development of an “exchange request form”.
      c) Development of a guidance document to explain the system.
      d) The implementation of a pilot study.

   b) The continued development and improvement of the Adverse Event Terminology and coding system to ensure that it is accurate, agile and moving with innovation, through the management of queries and the **annual maintenance cycle**.

Ongoing work

2. Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance

   a) The development of a training presentation / video to reinforce the key principles of the system (N43 document).

   b) The development of a guidance document to support the exchange of the Common Data Set.

   c) The development of a **new** guidance document and a video to further support the practical use of the Adverse Event Terminology and coding system.

Opportunities and Challenges

- Regulatory convergence with increased use of the Adverse Event Terminology and coding system.
- Increased harmonisation with use of common terminology.
- Opportunity for increased oversight and signal detection.
- Easier exchange of information.

- More guidance is needed to support the practical use of the codes.
- Confidentiality arrangement and EU General Data Protection Regulation (GDPR) need to be factored into the use and the exchange of the Common Data Set.
- Further development of analytical algorithms is required.

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

Nancy A. Pressly, Food and Drug Administration (FDA), United States of America, Nancy.Pressly@fda.hhs.gov
Andrea Hanson, Health Products Regulatory Authority (HPRA), Ireland, European Union, Andrea.Hanson@hpra.ie

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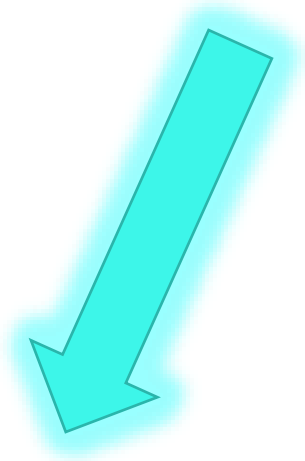
Artificial Intelligence/Machine Learning-Enabled (AI/ML) Working Group

Matthew Diamond (FDA) and Russell Pearson (MHRA)



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About US

Established in summer 2023. The AI/ML Working Group (WG) seeks to prioritize consensus in the AI/ML sector, where rapid technological advancements and an influx of manufacturers from sectors beyond medical devices is seen. Regulatory consensus for AI/ML has a close interplay with Software as a Medical Device (SaMD) for many jurisdictions, it's therefore also a priority to maintain alignment with broader software guidance.

The working group convenes monthly starting from September 13th 2023

Working group Membership

We have participants from;

African **M**edical **D**evices **F**orum (AMDF), Argentina, Australia, Brazil, Canada, European Union, Israel, Japan, **P**an **A**merican **H**armonization **O**rganisation (PAHO),Singapore, South Africa, South Korea, Switzerland, United Kingdom, United Stated of America, Global **D**iagnostic **I**maging, Healthcare IT and Radiation **T**herapy **T**rade **A**ssociation (DITTA), **G**lobal **H**ealth **W**orking **P**arty (GHWP) and **G**lobal **M**edial **T**echnology **A**lliance (GMTA).

Alignment with the IMDRF Strategic Plan

Our working groups initial task is develop a new document on Good Machine Learning Practice (GMLP) principles that looks to generate safer AI/ML-enabled medical devices and global alignment across the total product lifecycle. This aligns primarily with the IMDRF's pre-market strategic objective.

Publications

There have been no publications from this new WG to date.

Our current work item is focused on producing Good Machine Learning Practice (GMLP) Principles.

GMLP brings together high-level, fundamental principles important for the development of ML-enabled medical devices (MLMD). These MLMDs have unique considerations that can be addressed, at least in part, with GMLP implemented across the product life cycle. The rapid technological advancements in the AI/ML sector, combined with an influx of manufacturers from sectors beyond medical devices (e.g., pharmaceuticals, software engineering and data science) makes rapid consensus building on the topic of GMLP an important priority to lower product and development risks and to protect against regulatory divergence.

Upcoming work

The working will meet for the first time on 13th September and is currently undergoing a review of 10 GMLP principles previously published by the UK MHRA, US FDA and Health Canada as a starting point for generating the IMDRF GMLP principles.

Opportunities and Challenges

A challenge for the AI working group is to generate consensus rapidly in order to generate relevant guidance documents.

More specific challenges and opportunities will be uncovered as the work progresses.

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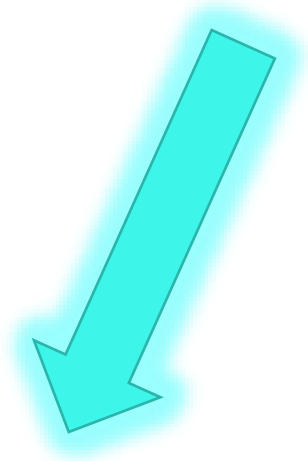
Medical Device Cybersecurity Update

US FDA & Health Canada Co-chairs



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September 2023

Overview

New Work Item Extension **3**

Expansion and Implementation of Legacy 4

Expansion and Implementation of Software Bill of Materials (SBOM) 4

Progress and Planned Milestones **5**

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
- **April 2023: Published Final Legacy and SBOM Documents**

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Thank you/Questions

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IMDRF Good Regulatory Review Practices (GRRP) Working Group Update

Dr. Lakshmidevi Balakrishnan, Health Sciences Authority (HSA), Singapore

Dr. Kenneth Cavanaugh, Food and Drug Administration (FDA), United States of America

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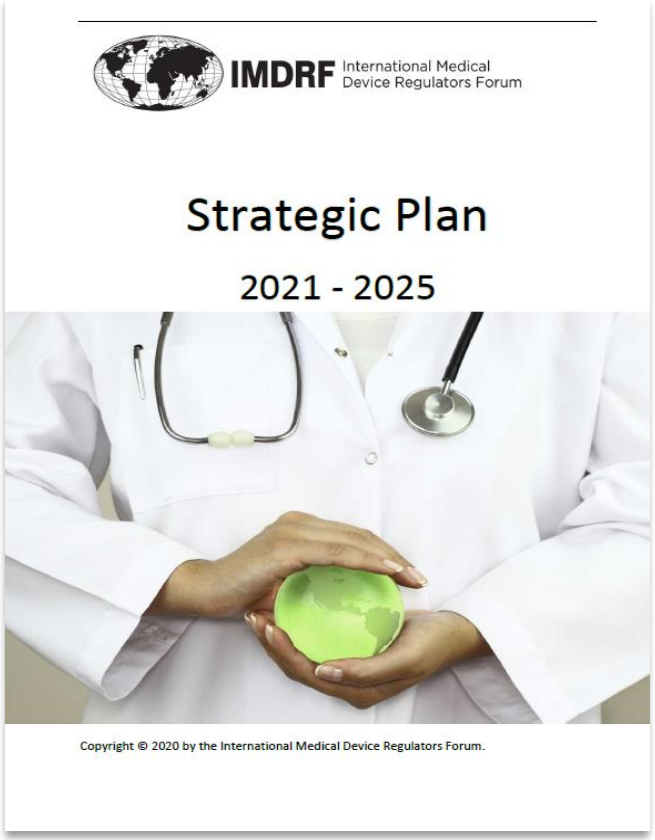
IMDRF GRRP Working Group Goals

- 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

IMDRF/GRRP WG/N40FINAL:2017

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Competence, Training, and Conduct Requirements for Regulatory Reviewers

Authoring Group: IMDRF Good Regulatory Review Practices

Date: 16 March 2017

Kimby Barton, IMDRF Chair

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IMDRF GRRP WG/ N40 FINAL:2017

Competence, Training, and Conduct Requirements for Regulatory Reviewers

IMDRF/GRRP WG/N47 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices Group

Date: 31 October 2018

Yuan Lin, IMDRF Chair

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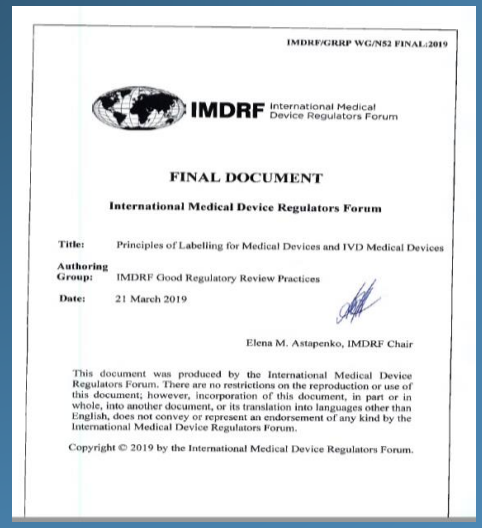
IMDRF GRRP WG/ N47 FINAL: 2018

Essential Principles of Safety and Performance



IMDRF/GRRP WG/N52 FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Principles of Labelling for Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

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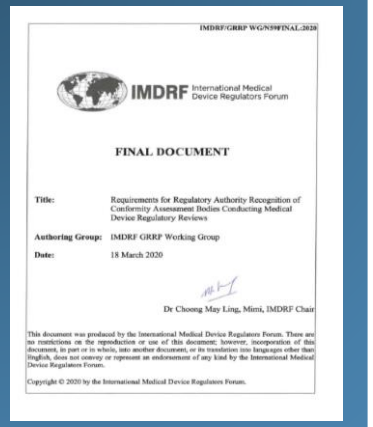
IMDRF GRRP WG/ N52 FINAL: 2019

Principles of Labelling

Marketing Review Processes

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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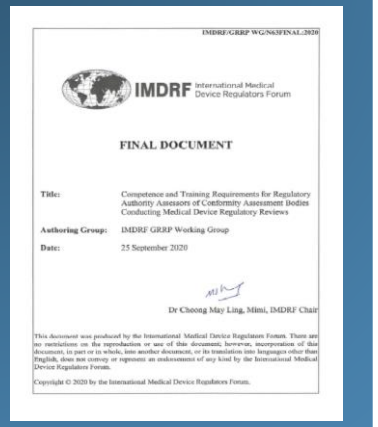
IMDRF GRRP WG/ N61 FINAL:2020

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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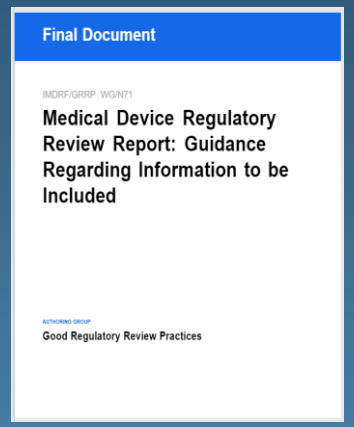
IMDRF GRRP WG/N66 FINAL:2021

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


Final Document

IMDRF/GRRP WG/N71

Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

AUTHORING GROUP

Good Regulatory Review Practices

IMDRF GRRP WG/N71 FINAL:2023

Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

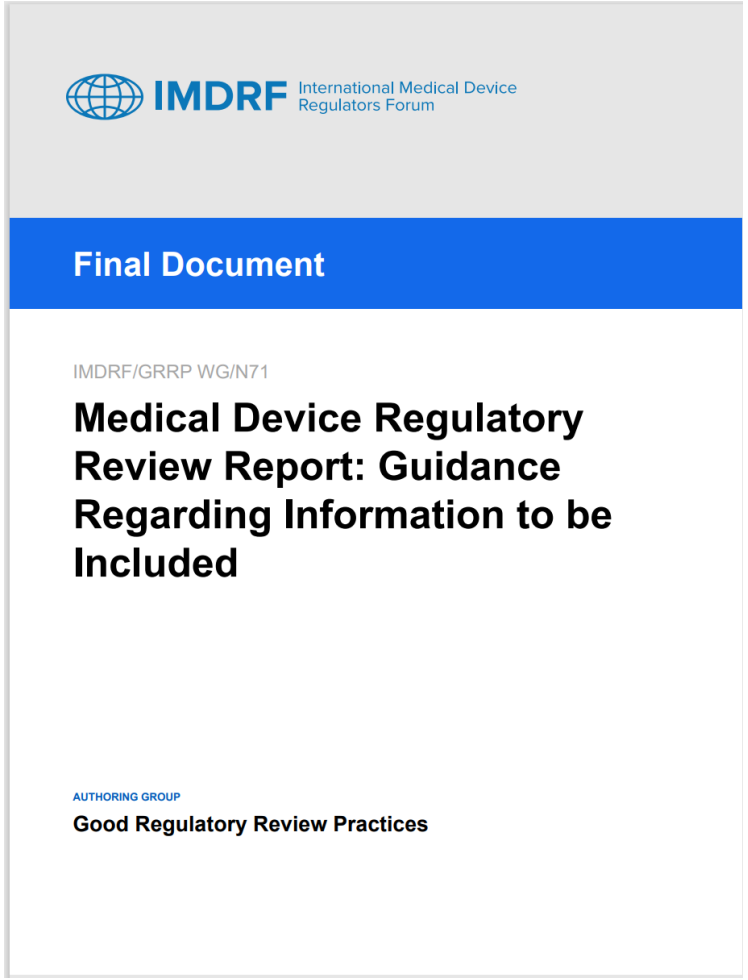
Recognition of Conformity Assessment Bodies (CABs)

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



New Work Item

- A NWIP was approved in June 2023 to update previous GRRP documents for consistency with policy and terminology in most recently published GRRP document (IMDRF/GRRP WG/N71).
  - Changes needed in order to be consistent with and inclusive of the current approaches of several RAs
  - The GRRP WG reviewed existing GRRP documents and identified four that should be revised to ensure appropriate and consistent terminology throughout the all GRRP documents
  - The proposed changes to terminology demonstrate convergence among RAs toward a common language and concepts

Goals:
To achieve consistent terminology to fulfill Priority 1 of the 2021-2025 IMDRF Strategic Plan: to develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices

Documents to be Updated

- The GRRP WG reviewed existing GRRP documents and identified four that should be revised to ensure appropriate and consistent terminology throughout the all GRRP documents : N66, N61, N63, and N59
  - These changes require more than simple search and replace since careful consideration should be paid to which term is selected and how it is used based on the specific context

- References section of other GRRP documents will also be reviewed for updates
  - To ensuring date and language in references section is up to date

Next Steps

- WG to review proposed edits and meet to discuss proposed edits from Sep- Dec 2023
- WG to submit documents for draft consultation to MC for consideration in Mar 2024
- Public consult of draft document in May 2024
- WG to deliberate comments and finalize changes by Oct 2024
- WG to submit final document for MC review in Dec 2024

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Thank you!
Questions?

Email erin.cutts@fda.hhs.gov

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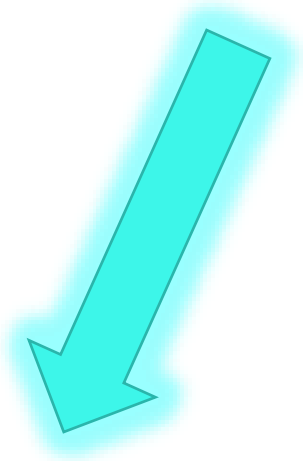
Personalized Medical Devices(PMD) Working Group

WG Chair: Tracey Duffy, Therapeutic Goods Administration (Australia)



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PMD Working Group

Objectives:

- *To develop technical guidance documents and harmonized recommendations for regulating PMDs across various jurisdictions*
- *To engage with stakeholders in the development, adoption, and implementation of the recommendations*

- Current Working Group established in December 2020
- Eighteen virtual meetings since December 2020; most recently on 10 August 2023
- Objectives align with IMDRF Strategic Plan 2021-2025 (Priority area: Pre-market)

PMD Working Group members

Jurisdiction	Representative
Argentina	Marcela Rizzo Adriana David
Australia	Tracey Duffy (WG Chair) Rebecca Bateson Uphar Chamoli
Brazil	Adriano Soares da Silva Joao Henrique Campos de Souza Maria Angela da Paz
Canada	Andrea Katynski
China	Yue Min Shuo Pan
Europe	Nada Alkhayat (European Commission) Matthias Neumann (Germany) Mariana Madureira (Portugal) Stefan De Vos (Belgium)

Jurisdiction	Representative
Japan	Mariko Ando Ryosuke Morita Takashi Ooba Yudai Nakazuru
Saudi Arabia	Abdullatif S. Al Watban
Singapore	Shuling Peng
South Korea	Si Hyung Yoo Yunju Lee
UK	Penny Wilson
USA	Matthew A. Di Prima Erin Keith

Publications

- Definitions for Personalized Medical Devices (IMDRF/PMD WG/ N49)

  Published November 2018

- Personalized Medical Devices – Regulatory Pathways (IMDRF/PMD WG/ N58)

  First published April 2020; Revised version being prepared for publication

- Personalized Medical Devices – Production V&V (IMDRF/PMD WG/ N74)

  Published April 2023

PMD Production Verification & Validation (N74)

- Document published 11 April 2023

- Builds on the definitions and concepts in N49 *Definitions of Personalized Medical Devices* and N58 *Personalized Medical Devices – Regulatory Pathways*

- Technical guidance on verification and validation aspects of
  - specified design envelope (patient-matched medical devices)
  - medical device production systems

PMD Regulatory Pathways (N58) - Revisions

- Scope of N58 revisions include:
  - revising the MDPS definition and framework to better represent real world applications, and facilitate its adoption
  - expanding the scope of Appendix 2 to incorporate a broad range of devices, not limited to PMDs

- Feedback from public consultation (Sept – Nov 2022) considered in developing the revised N58

- Revisions approved for publication by the MC, pending minor changes and WG consensus

Opportunities and Challenges

- Sharing and use of relevant information and scientific expertise amongst stakeholders
- Recommendations provide a basis for consistent and transparent requirements across jurisdictions
- Definitions for different categories of PMDs (IMDRF N49) adopted in most member jurisdictions
- WG's current focus on finalizing minor changes to the N58 (revised) document and its publication

Opportunities and Challenges

- Developing timely and fit-for-purpose recommendations to address risks introduced by new and emerging technologies in PMDs
- Consistent interpretation and understanding of the recommendations by all stakeholders
- WG intends to:
  - promote IMDRF PMD documents and educate stakeholders
  - develop training/guidance materials for stakeholders in line with N76 recommendations
  - monitor implementation and collect feedback
- Inviting stakeholders to provide suggestions on developing effective training and guidance materials to ensure consistent interpretation of the documents

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Thank you / Questions

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

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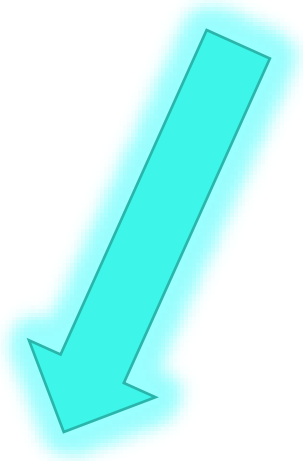
Regulated Product Submission Working Group

Patrick Axtell, US Food and Drug Administration

Daniel Yoon, Health Canada



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IMDRF 24th Session – Berlin, Germany

About Us

- Initially formed in 2012 at the inaugural IMDRF meeting in Singapore
- RPS Table of Contents (ToC) is intended to provide a harmonized format for submitting medical device market authorization applications
- Work item extension was approved in 2021 to update the ToC documents to be current and translate the updated ToC into eSTAR, 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
- Used by the US FDA for 510(k), De Novo, and Pre-Sub submissions
  - eSTAR required for 510(k)s starting on October 1, 2023
- RPS Table of Contents (ToC) built in to provide a harmonized format for submitting medical device regulatory authorization applications
- eSTAR ensures required documents are included and submission is complete before it is sent to the regulator
  - Provides automation, standardizes structure, reduces processing delays
- Health Canada and the US FDA launched a joint pilot in January 2023 with 9 participants

Membership

Jurisdiction/Affiliation	Representative
Australia	Fiona McCormack Simone McGinley 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	Yuzuru Okazaki So Hifumi Hideharu Komiya Yusuke Tamura
Singapore	Agnes Goh Koh Chee Gake
South Korea	Young-mee Kwon Yunju Lee Yi Le Ahn (Rebecca)
United Kingdom	Eve Hutchinson Rebecca Riches-Duit
United States	Patrick Axtell (co-chair) Kenneth Cavanaugh Lili Duan
World Health Organization	Mark Lanigan
Notified Bodies	Dawn Thibodeau Sharmila Gardner Martin Witte Purvi Patel

Publications

- N9 and N13 are the working group's core documents
  - N9: non-IVD version of ToC
  - N13: IVD version of ToC

- Other documents related to the development of the ToC were published, including
  - N27: Assembly and Technical Guide
  - N19: Common Data Elements for Medical Device Identification

Ongoing work

- Consultation on the updated versions of N9 and N13 took place February – May 2023
  - Over 200 comments were received from 8 stakeholders
  - Requests for improved clarity, terminology changes, minor text changes and additions, layout/organizational changes
- Working group is going through comments
- Afterwards, updated ToCs will be transferred to eSTAR template
  - Currently programmed with FDA and HC submission requirements
  - Adding requirements for other jurisdictions will be explored
- Proposed final documents will be submitted for MC consideration

Opportunities and Challenges

- Some comments highlighted the need for N9 and N13 to align with the documents published by other working groups, such as cybersecurity's N60
  - May require discussions with chairs of applicable working groups
- Learnings from joint HC/FDA eSTAR pilot could help with expanding eSTAR to include other jurisdictions
- Keeping current harmonization (preventing divergence)
- Ensuring eSTAR and N9/N13 documents remain consistent
  - eSTAR is required to have current policies in place
  - N9 and N13 will be updated with policy changes as soon as possible

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Provide your feedback on this Working Group!

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Thank you/Questions

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

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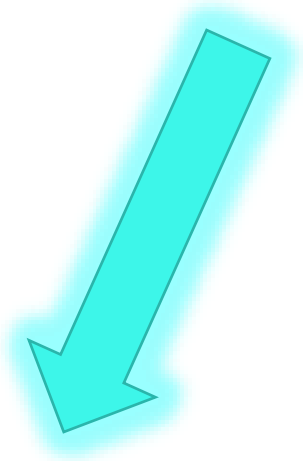
Quality Management System (QMS) Working Group Update

Co-Chairs:

Máiréad Finucane / Maria Del Carmen Sanz – EC

Melissa Torres – US FDA



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IMDRF 24th Session – Berlin, Germany

About US

- Quality management systems and risk management activities are integral principles to ensuring the design and manufacture of safe and effective medical devices
- 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

Therefore, the aim of the working group is 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.

Working Group Establishment

- 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 organisations
- Working group nominations have been approved by IMDRF Management Committee at last meeting. Participants/representatives from:
  - IMDRF/GHWP regulatory authorities
  - ISO TC 210 WG1
  - Industry, and
  - Notified bodies

Existing Publications

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

Opportunities and Challenges

- Transfer of old GHTF documents into IMDRF templates
- Prioritisation of work items
- Proposal to begin with the update supplier controls (GHTF/SG3/N17:2008 Guidance on the Control of Products and Services Obtained from Suppliers)
- First meeting of the working group to be scheduled after Management Committee meeting

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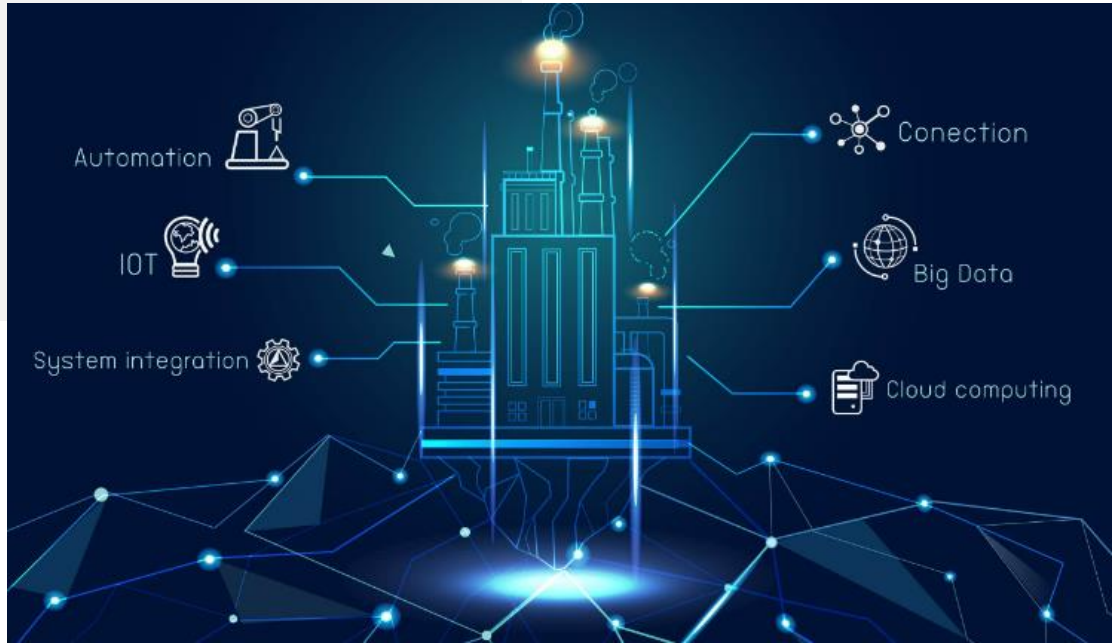

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Thank you/Questions

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Mairead.FINUCANE@ec.europa.eu
Maria-Del-Carmen.SANZ-URDIN@ec.europa.eu

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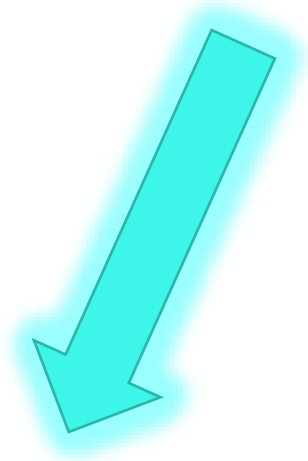
Software as a Medical Device (SaMD) Update

US FDA & Health Canada Co-chairs



Provide your feedback on this Working Group!

Follow this link and let us know:

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September 2023

About US

- The SaMD Working Group published 4 technical documents from 2013-2017
- Working group membership:
  - Argentina National Administration of Drugs, Food and Medical Devices (ANMAT): Bioing. Carolina Magnatti, Bioing. José Médico Orellano, Dr. José Atilio Méndez
  - Australia Therapeutic Goods Administration (TGA): Dr David Hau, Lesley-Anne Farmer
  - Brazilian Health Regulatory Agency (ANVISA): Mr Francisco Iran Cartaxo Barbosa, Mr Helio Bomfim de Macedo Filho, Mr Jangley Bahia Costa
  - Health Canada: Marc Lamoureux, Janet Hendry, Martina Buljan
  - European Union: Matthias Neumann, Nada Alkhayat, Rolf Oberlin Hansen, Valerie Soumet
  - Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA): Camille Vidal, Hyun-Bae Park, Koen Cobbaert, Tomohisa Fukunaga
  - Global Medical Technology Alliance (GMTA): Cassie Scherer, Diane Johnson, Kees Maquelin, Mr Toshiaki Nakazato
  - Japan: Dr Kentaro Kato, Dr Madoka Murakami, Mr Kuniki Imagawa, Yuhei Fukuta
  - Singapore Health Sciences Authority (HSA): Mr Ong Ming Hao, Ms Siew Jie Yee
  - South Korea Ministry of Food and Drug Safety (MFDS): Byung-Gwan Kim (Mr), Rosa Da-yeong Ryoo (Ms)
  - Switzerland Swissmedic: Rudolf Waelti
  - United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA): David Grainger, Russell Pearson
  - United States of America Food and Drug Administration (FDA): Sonja Fulmer, Catherine Bahr, Wil Vargas, MiRa Jacobs
- The SaMD Working Group meets bi-weekly

About Us

The SaMD Working Group's activities align directly with 2021-2025 IMDRF Strategic Priority 1: Pre-Market – specifically the SaMD Topic Area. Ongoing work aims to bring clarity to how device descriptions are provided and considerations necessary to understand SaMD risk, which are in alignment with furthering a harmonized risk category framework. Future opportunities will further this objective and the development and refinement of SaMD-related international definitions.

- 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/considerations in areas of advanced and innovative technologies.

Ongoing Work

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

- **Publishing a new document related to:**
  - Enhancing focus on better characterizing the device to inform downstream risk considerations
    - Drafted document includes discussion of how to clearly characterize medical device software to improve consistent understanding of these devices by regulators globally
    - Drafted document includes considerations for identifying and understanding medical devices software risks based upon information-based hazards

Opportunities and Challenges

- **Opportunity for future improvements to the existing documents by publishing new document(s) related to:**
  - The granularity of the risk categorization matrix (N12)
  - The location of where the software may be running (N10)
  - Other improvements as identified by working group members
- **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
- **November 2023: Planned submission of draft document to IMDRF MC**
- December 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)***

* Pending IMDRF MC Approval

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Thank you/Questions

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