IMDRF International Medical Device Regulators Forum

Update on the International Medical Device Regulators Forum (IMDRF)

Michelle Noonan
International Policy Analyst
Office of the Center Director
Center for Devices and Radiological Health
US Food and Drug Administration

IMDRF Overview

- Launched in February 2012
- Successor to the Global Harmonization Task Force (GHTF)
- Chair and secretariat rotate on annual basis, beginning with Australia (2012), EU (2013), US (2014), Japan (2015), Brazil (2016), Canada (2017), China (2018), Russia (2019), Singapore (2020), S. Korea (2021), Australia (2022), EU (2023)
  - The US will be the Chair in 2024
- Decisions are made by consensus, not voting
- 2 in person meetings per year (March and September)
  - Includes public stakeholder session which provides updates from MC members, IMDRF working groups, RHIs, industry associations, etc.
- 2 teleconferences per year (January and July)

World Health Organization

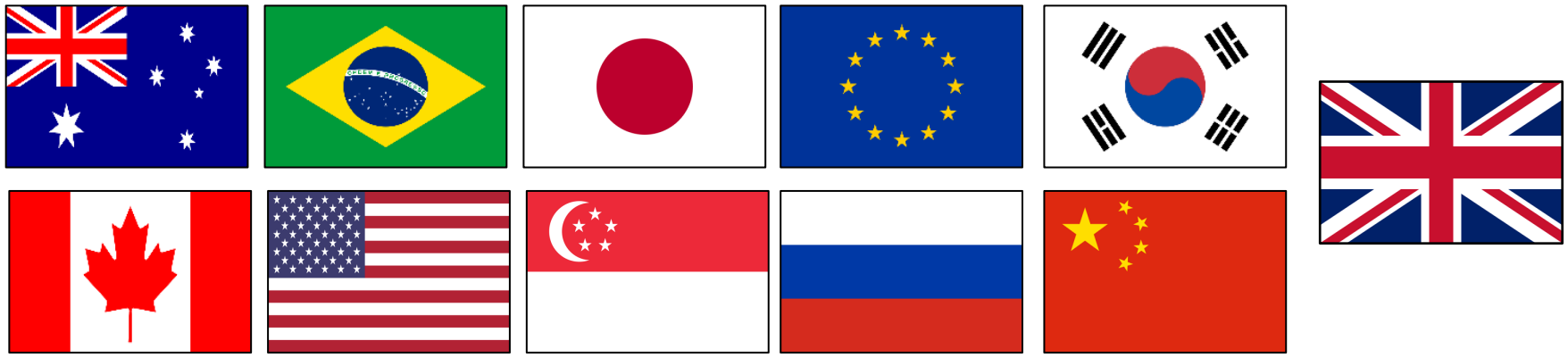
Official Observers

APEC
Asia-Pacific Economic Cooperation

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Pan American Health Organization

Regional Harmonization Initiatives



Management Committee (MC) Members

IMDRF
International Medical Device Regulators Forum

IMDRF Mission and Goals

Mission

To strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

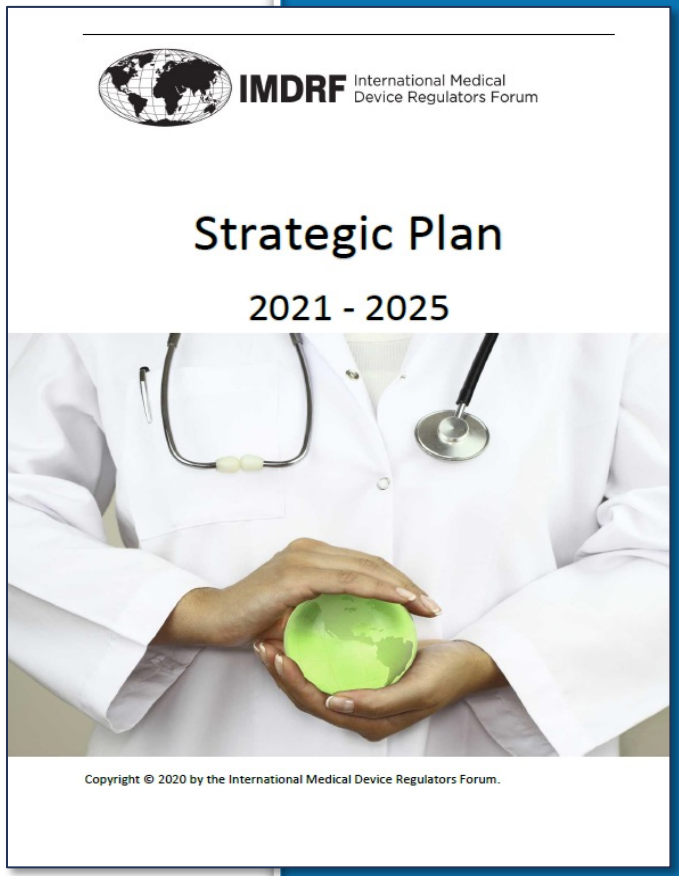
Goals

- Accelerate international medical device regulatory harmonization and convergence building on the work of the Global Harmonization Task Force.
- Address common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies.
- Accelerate innovation by clear and practical regulatory expectations.
- Focus on premarket and postmarket requirements.

IMDRF Strategic Plan 2021 – 2025 Key Objectives

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

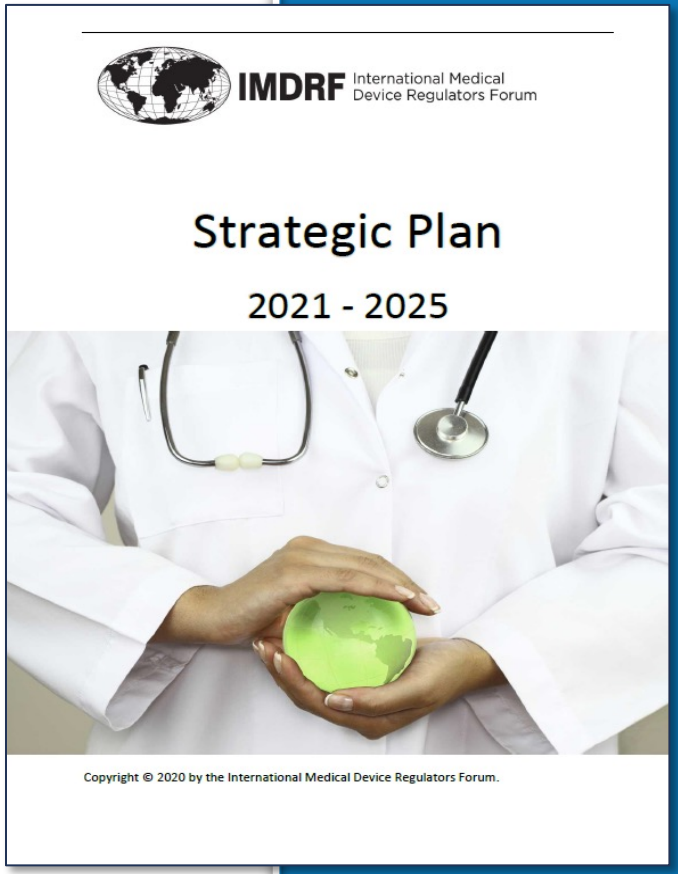
- Working with standards setting bodies to play an active role in ensuring that international standards continue to be effective tools in conforming to essential principles for safety and performance for medical devices.
- Promoting further development of useful and relevant international standards for innovative technologies in medical devices to enhance their safety and effectiveness.
- Embarking on a challenging journey towards achieving a single premarket review process for medical devices.



IMDRF Strategic Plan 2021 – 2025 Key Objectives

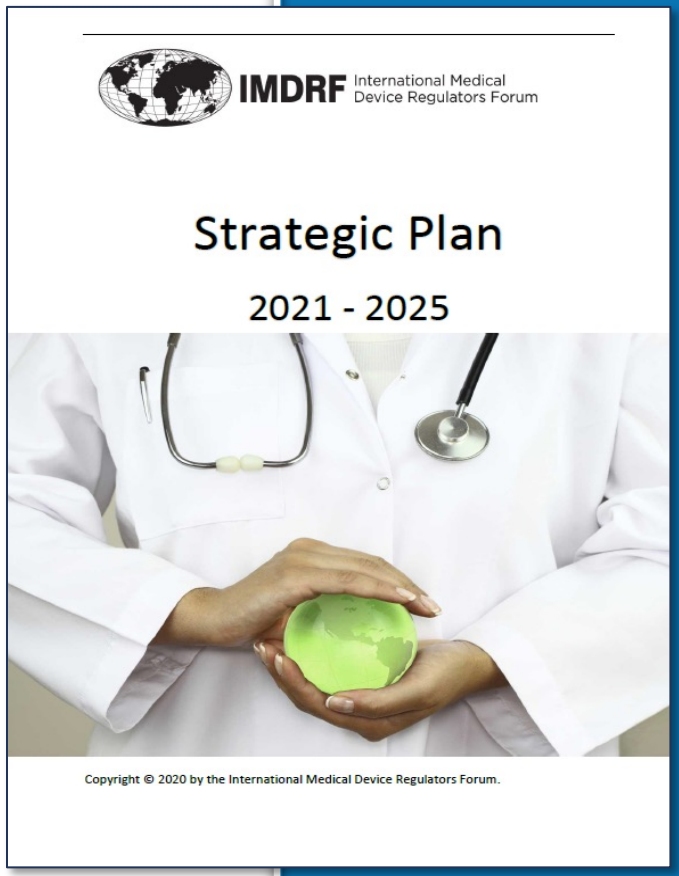
Strengthen postmarket surveillance for medical devices and implement regulatory life cycle processes.

- Standardize information collected by regulators via post-market surveillance activities, such as via utilization of the UDI System to precisely identify the implicated device and harmonized terminology for medical device reporting.
- IMDRF would seek to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices.



IMDRF Strategic Plan 2021 – 2025 Priority Areas

1. **Pre-market**
   - Develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices.
2. **Post-market**
   - Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients.
3. **Relationships with Stakeholders**
   - Continue to promote close communication about IMDRF activities and outputs with stakeholders, such as: medical devices industries, other regulators, international organizations, standards development organizations, patient and professional associations, academia, regional harmonization initiatives, etc.



IMDRF

International Medical Device Regulators Forum

Current IMDRF Working Groups

1. Good Regulatory Review Practices (GRRP) (Chairs: US and Singapore)
2. Regulated Product Submission (RPS) (Chairs: US and Canada)
3. Cybersecurity (Chairs: US and Canada)
4. Personalized Medical Devices (Chair: Australia)
5. Artificial Intelligence (Chair: S. Korea)
6. Adverse Event Terminology (Chair: US)
7. Software as a Medical Device (Chairs: US and Canada)
8. Quality Management Systems (Chair: US)

IMDRF

International Medical Device Regulators Forum

Closed IMDRF Working Groups

- Medical Device Single Audit Program (MDSAP)
- Standards
- Unique Device Identification (UDI)
- National Competent Authority Report (NCAR)
- Patient Registries
- Clinical Evaluation
- Principles of In Vitro Diagnostic Medical Device Classification

IMDRF

International Medical Device Regulators Forum

Good Regulatory Review Practices Working Group

Goal

To develop harmonized premarket review requirements.

Benefits

- Promotes consistency, predictability, transparency, and quality of regulatory programs and criteria for assessing premarket technical documentation for medical devices.
- Provides greater global convergence and harmonization of premarket requirements.
- Supports the future development of a single globally harmonized premarket review program.

Current Work Item

- Development of premarket reporting templates and work instructions to guide CABs in consistently evaluating marketing submissions and documenting their certification recommendations in marketing review reports.
  - WG is aiming to finalize the document by early next year.

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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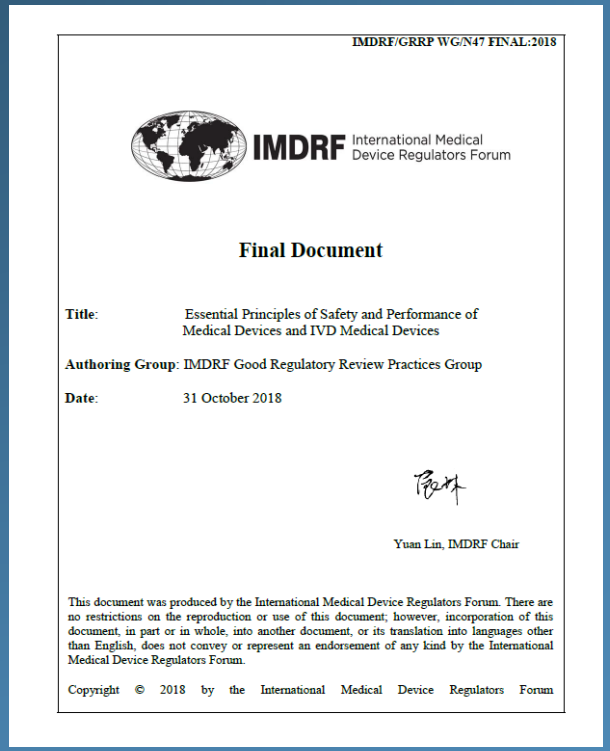
IMDRF GRRP WG/ N40 FINAL:2017

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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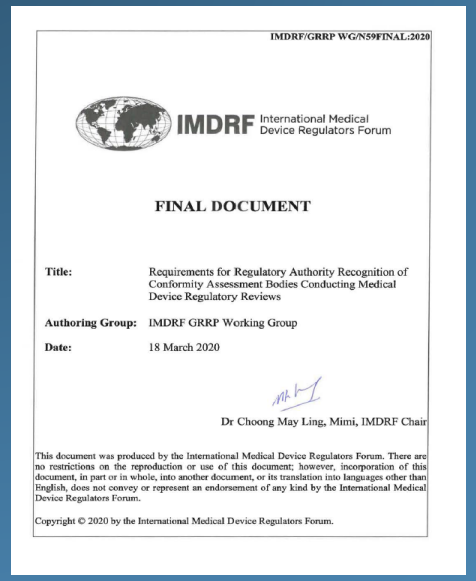
IMDRF GRRP WG/ N52 FINAL: 2019

Principles of Labelling

Pre-market Review Processes



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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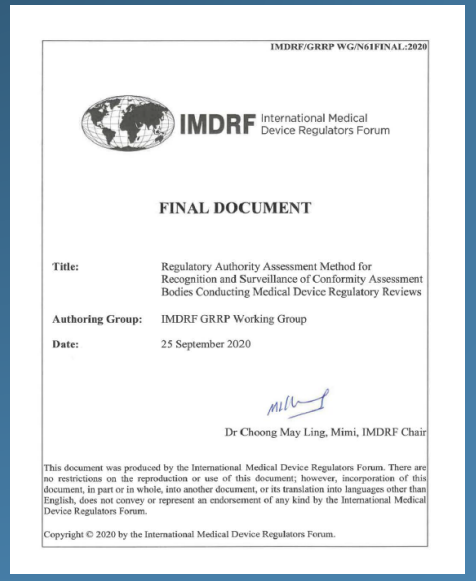
IMDRF GRRP WG/ N59 FINAL:2020

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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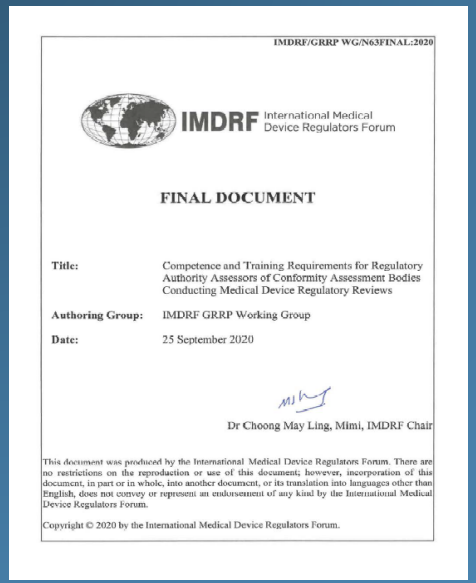
IMDRF GRRP WG/ N61 FINAL:2020

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)

IMDRF

International Medical Device Regulators Forum

Regulated Product Submission Working Group

Goal

To develop a harmonized approach to regulatory submissions.

Benefits

- Allows industry to file electronic applications with multiple regulatory authorities using the same method.
- Instead of separate vocabularies and implementation guides for each regulatory authority, one harmonized approach reduces regulatory burden while increasing predictability, transparency, and regulatory cooperation.

Current Work Item

Development of dynamic templates with specific electronic content for each regulatory authority, as well as harmonized content for all regulatory authorities using FDA's eSTAR template and IMDRF's Table of Contents as a basis.

IMDRF/RPS WG/N9(Edition 3) FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 0.7 (XXXX-XX-XX)*

STATUS: eSTAR INCOMPLETE *This eSTAR is incomplete, and will be treated as an improperly prepared eCopy and not reviewed. You will be notified by a standard eCopy Hold email.*

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? **Blue Help Text Buttons** when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions and/or feedback?
A: Questions and feedback regarding this template can be sent to eSubPilot@fda.hhs.gov.

Q: What if I have several devices in one submission?
A: When a question asks about a device, consider the question as it applies to any device within the submission.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices, and therefore should be ignored.

Q: Is eSTAR compatible with Mac computers?
A: Yes. However, Mac computers will add hidden dot files (e.g., ".Trashes") to thumb drives by default. These dot

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

0.7 (XXXX-XX-XX): Added Safety and Performance information to the Predicates and Substantial Equivalence

Application/Submission Type

Application Jurisdiction ○ US FDA ○ Health Canada ?

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International Medical Device Regulators Forum

Cybersecurity Working Group

Goal

To provide fundamental concepts and considerations on the general principles and best practices on medical device cybersecurity.

Benefits

- Provides harmonized medical device cybersecurity guidance for all responsible stakeholders, including manufacturers, healthcare providers, regulators, and users across the entire device lifecycle.
- Promotes broad information sharing policies for cybersecurity incidents, threats, and vulnerabilities.

Current Work Item

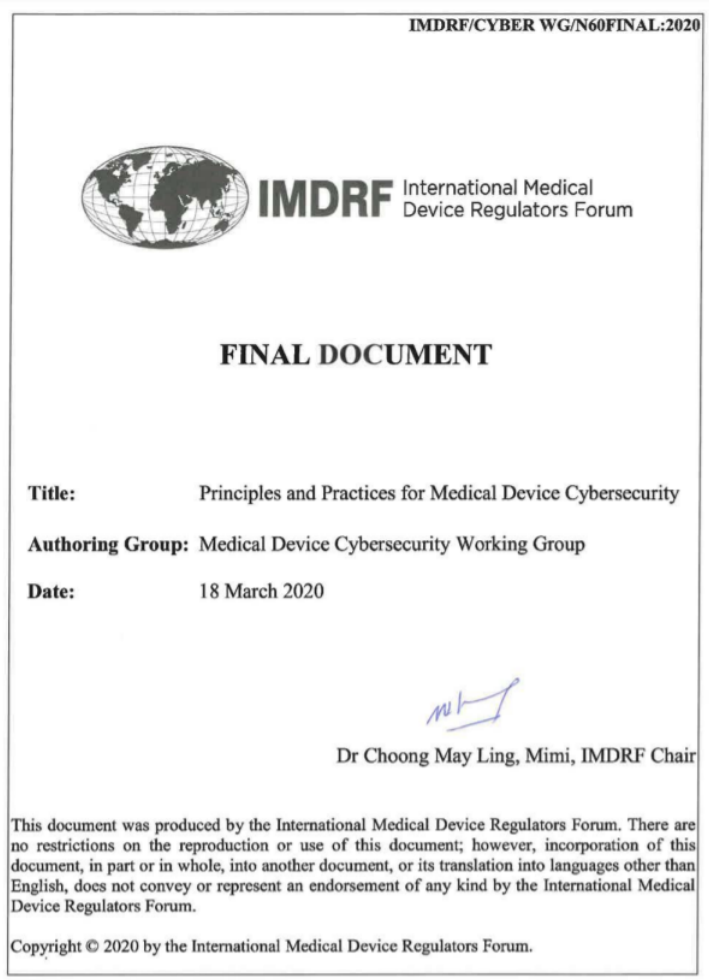
Develop 2 documents which build upon the legacy medical devices and software bill of materials concepts outlined in the document IMDRF/CYBER WG/N60 *Principles and Practices for Medical Device Cybersecurity*

- WG is aiming to finalize both documents early next year.

Cybersecurity WG Finalized Document

Principles and Practices for Medical Device Cybersecurity

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-pp-mdc-n60.pdf



IMDRF/CYBER WG/N60FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Principles and Practices for Medical Device Cybersecurity

Authoring Group: Medical Device Cybersecurity Working Group

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

IMDRF

International Medical Device Regulators Forum

Personalized Medical Devices Working Group

Goal

To develop a harmonized approach to defining medical devices that are manufactured for a particular individual.

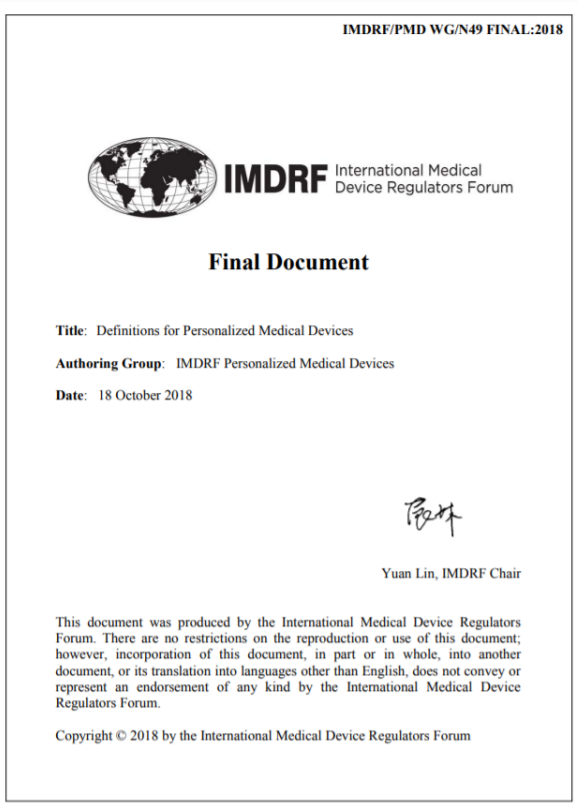
Benefits

- Addresses an emerging trend towards personalized treatments in the medical devices sector.
- Can lead to harmonization of requirements for safety, performance, and manufacturing of these products.
- Can ensure that an appropriate level of regulatory oversight is taken.
- Provides a basis for consistent and transparent requirements across multiple jurisdictions.

Current Work Item

- Build upon the 2 finalized IMDRF documents on definitions and regulatory pathways for personalized devices.
  - Production Verification and Validation – public consultation period open until 12/28/22
  - Update to the Regulatory Pathways document – Closed on 11/28/22

PMD WG Finalized Documents



IMDRF/PMD WG/N49 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Definitions for Personalized Medical Devices

Authoring Group: IMDRF Personalized Medical Devices

Date: 18 October 2018

Yuan Lin, IMDRF Chair

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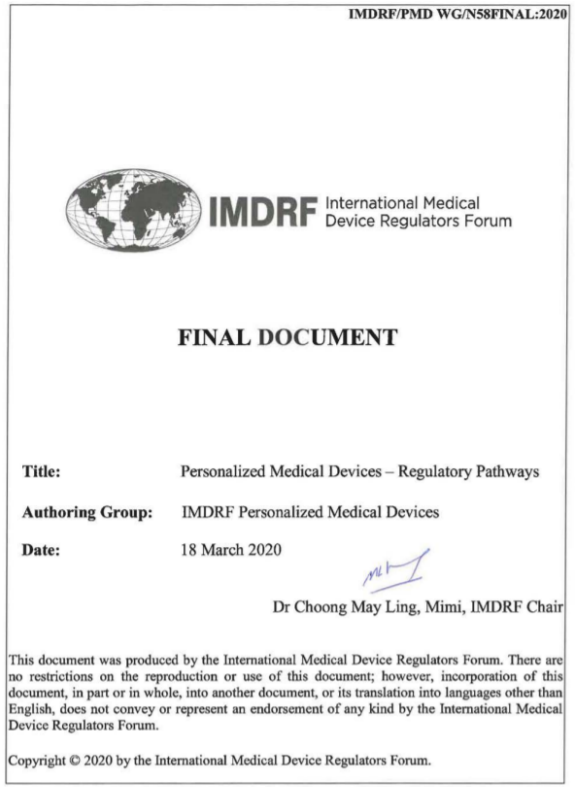
Definitions for Personalized Medical Devices

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181018-pmd-definitions-n49.pdf



IMDRF/PMD WG/N58FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Personalized Medical Devices – Regulatory Pathways

Authoring Group: IMDRF Personalized Medical Devices

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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Regulatory Pathways for Personalized Medical Devices

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-pmd-rp-n58.pdf

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Artificial Intelligence Working Group

Goal

Achieve a harmonized approach to the management of Artificial Intelligence (AI) medical devices.

Benefits

Traditional regulatory approaches are inappropriate to efficiently manage machine learning enabled medical devices and many jurisdictions have developed their own approaches to the regulation of machine learning enabled medical devices. This work is the first step that can ensure a more globally harmonized approach for handling machine learning enabled devices.

Current Work Item

- Published *Machine Learning Enabled Medical Devices: Key Terms and Definitions* published in May 2022
- Working on a new work item proposal

IMDRF

International Medical Device Regulators Forum

Adverse Event Terminology Working Group

Goal

Develop harmonized terminology to code information relating to medical device adverse events.

Benefits

- Improves the efficiency of adverse event management systems for faster response by both industry and regulatory agencies, with the use of a single harmonized adverse event terminology and coding system
- Improved accuracy of capturing and reporting of medical device related adverse events
- Reduced ambiguity
- Better usability
- More sophisticated signal detection

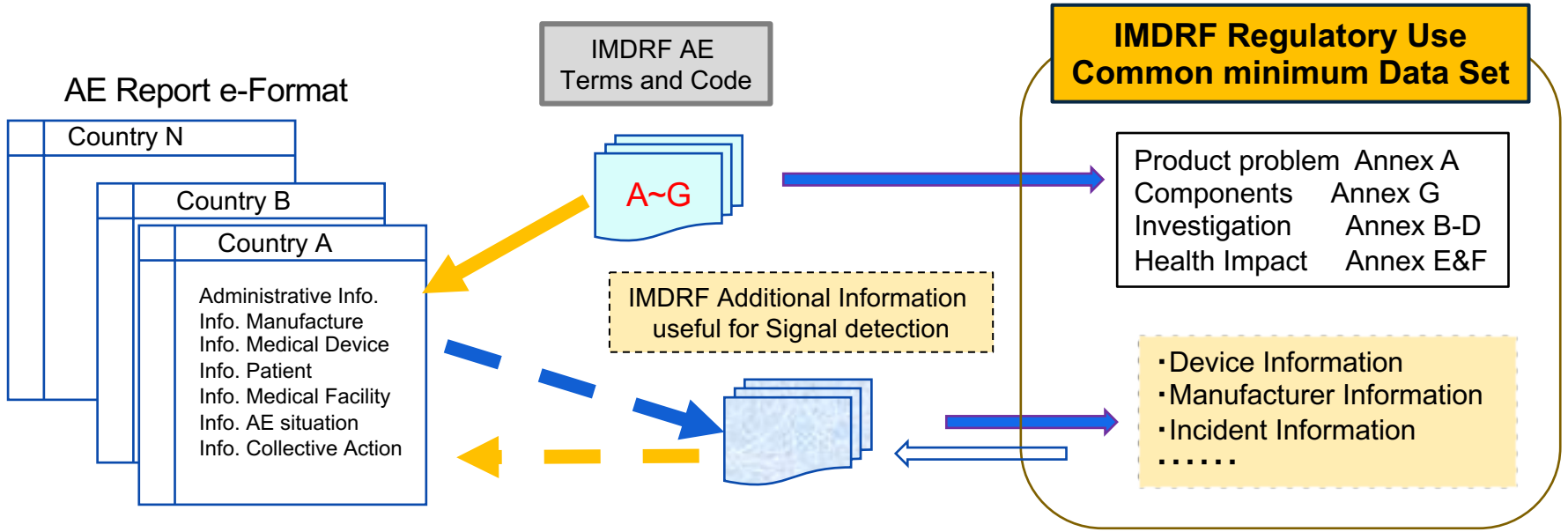
Current Work Items

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

Harmonization of Adverse Event Terminology

Purpose
Harmonize additional AE data to be able to utilize adverse event reporting for signal detection

- **Phase 1** Define additional sets of harmonized adverse event terms and codes
- **Phase 2** Develop common minimum data requirements for reporting that are standardized across jurisdictions



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Software as a Medical Device (SaMD) Working Group

Goal

To support innovation and timely access to safe and effective SaMD globally by identifying commonalities, establishing a common vocabulary, and developing approaches for appropriate regulatory controls that promote regulatory convergence.

Current Work Items

To review and update existing SaMD IMDRF documents to reflect current principles and practices.

- IMDRF/SaMD WG/N10 Key Definitions
- IMDRF/SaMD WG/N12 Risk Framework
- IMDRF/SaMD WG/N23 Quality Management Systems
- IMDRF/SaMD WG/N41 Clinical Evaluation

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Quality Management Systems (QMS) Working Group

Goal

To update existing GHTF QMS documents to align with current versions of ISO 13485 and ISO 14971 and reflect best practices.

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

IMDRF International Medical Device Regulators Forum

Thank you/Questions?

Email CDRHInternational@fda.hhs.gov