IMDRF Essential Principles and Standards

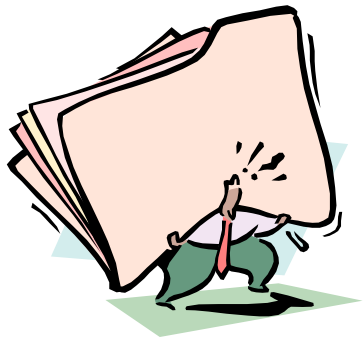
Kenneth J. Cavanaugh Jr., Ph.D.
Deputy Director, Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

March 3, 2022

Why Is Harmonization Important?

- Less standardization for medical devices compared to pharmaceuticals due to differences in:
  - Technology
  - Regulatory systems

- Global regulatory engagement, along with industry stakeholder participation, can promote:
  - Consistency
  - Efficiency
  - Predictability



IMDRF International Medical Device Regulators Forum

- Voluntary effort involving medical device regulators from around the world to harmonize various regulatory requirements across their jurisdictions
  - Non-regulators can participate as observers
- Proposed IMDRF documents incorporate public comments prior to finalization and adoption

Net result: Increased global regulatory cooperation and review process efficiency

Current IMDRF Members

- *Australia*
- *Brazil*
- *Canada*
- *China*
- *Europe*
- *Japan*
- *Russia*
- *Singapore*
- *South Korea*
- *USA*

Official Observers:

- *Argentina*
- *United Kingdom*
- *WHO*

Affiliate Members:

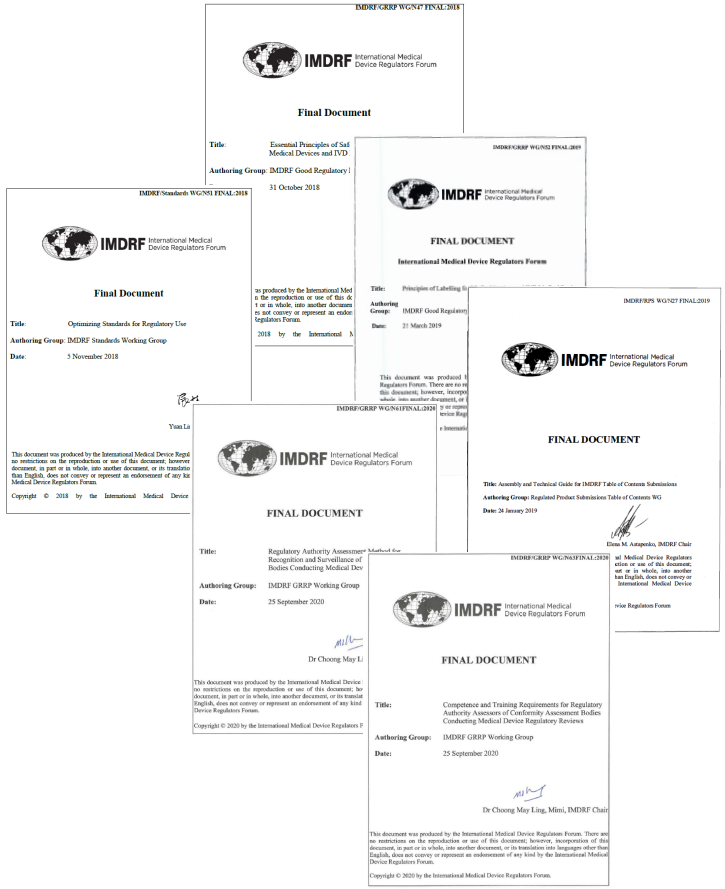
APEC

Pan American Health Organization

GHWP
Global Harmonization Working Party
Towards Medical Device Harmonization

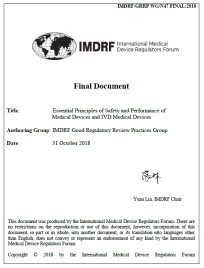
IMDRF Good Regulatory Review Practices (GRRP) Working Group

- Improve consistency and quality of medical device marketing submissions
- Increase efficiency and competency of review process



Essential Principles (EPs)

- Fundamental design and manufacturing requirements that provide assurance that a medical device or IVD is safe and performs as intended by the manufacturer
  - IMDRF/GRRP WG/N47 FINAL:2018 – *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
  - IMDRF/GRRP WG/N52 FINAL:2019 – *Principles of Labelling for Medical Devices and IVD Medical Devices*


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 Liu, IMDRF Chair

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, may only be done with the agreement of any kind by the International Medical Device Regulators Forum.

Copyright © 2018 by the International Medical Device Regulators Forum


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: 31 March 2019

Hyun M. Ampofo, IMDRF Chair

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, may only be done with the agreement of any kind by the International Medical Device Regulators Forum.

Copyright © 2019 by the International Medical Device Regulators Forum.

Safety and Performance

- General and specific risk considerations specific to medical devices, IVDs, or both
  - Includes list of relevant standards/guidance documents

- Examples:
  - Material characterization
  - Clinical evaluation
  - Conditions of use
  - Diagnostic functions
  - Software aspects
  - General labeling principles

5.6 **Protection against Electrical, Mechanical, and Thermal Risks**

5.6.1 Medical devices and IVD medical devices should be designed and manufactured in such a way as to protect users against mechanical risks connected with, for example, resistance to movement, instability, and moving parts.

Labeling

- Labeling elements and information specific to medical devices, IVDs, or both
- Includes:
  - Label
  - Instructions for use
  - Software as a medical device
  - Lay users
  - Information intended for the patient

6.1 Label

6.1.1 The label should indicate if the medical device is for use by a single individual and has been manufactured according to a written prescription or pattern (e.g., it is a personalized medical device).

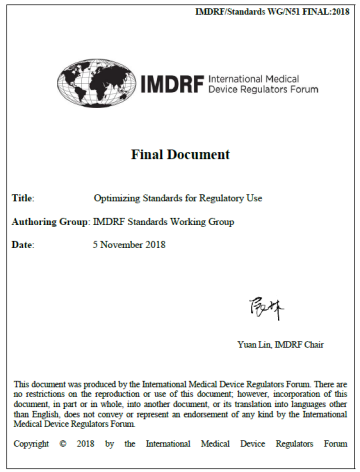
IMDRF vs ISO EPs

- IMDRF EP documents developed in parallel with corresponding ISO documents
  - ISO 16142-1:2016 and 16142-2:2017
  - ISO 20417:2021
- General agreement between IMDRF and ISO documents with some different areas of focus
  - IMDRF incorporates more regulatory considerations and jurisdictional variations
  - ISO includes more non-regulatory considerations, and some jurisdictions are better able to adopt consensus standards as regulatory requirements

Role of Performance Standards

- Consensus standards can provide harmonized approaches to meeting EPs
  - Mapping individual standards to specific EPs could be a pathway to more harmonized regulatory review

- ISO 16142-1 and IMDRF N51 discuss considerations for designing and adopting standards for regulatory purposes:
  - Scope
  - Level of detail
  - Stakeholder participation



IMDRF/Standards WG/N51 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 5 November 2018

Yuan Lin, IMDRF Chair

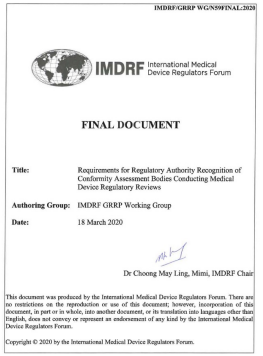
This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

Copyright © 2018 by the International Medical Device Regulators Forum

Ongoing IMDRF Efforts

- Current GRRP work focus: Establishing baseline principles for third-party marketing reviews
  - Conformity assessment body (CAB) competencies
  - CAB recognition process and requirements
  - CAB marketing review process

- Potential foundation for future medical device single review program
  - Standards expected to play an important role in ensuring consistency and rigor



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

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

Copyright © 2020 by the International Medical Device Regulators Forum.

Final Thoughts

- IMDRF guidelines and consensus standards work together to promote convergence in medical device development and review practices
- Increased standards development activity and integration with regulatory guidelines will further enhance device harmonization
- Global participation in standards development will be especially important going forward