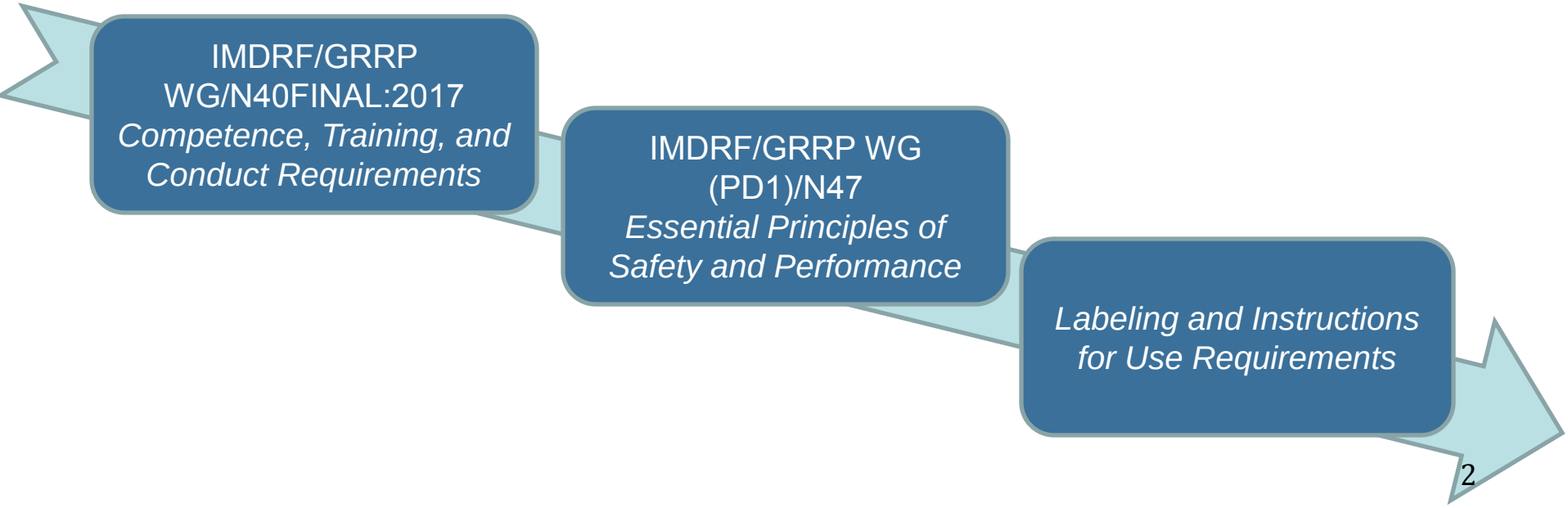
IMDRF International Medical Device Regulators Forum

GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

Working Group Chair: Melissa Torres
US Food and Drug Administration

GOALS

The Good Regulatory Review Practices working group has focused efforts on harmonizing premarket requirements in alignment with the IMDRF strategic priority to improve the effectiveness and efficiency of premarket review.



CURRENT WORK ITEMS

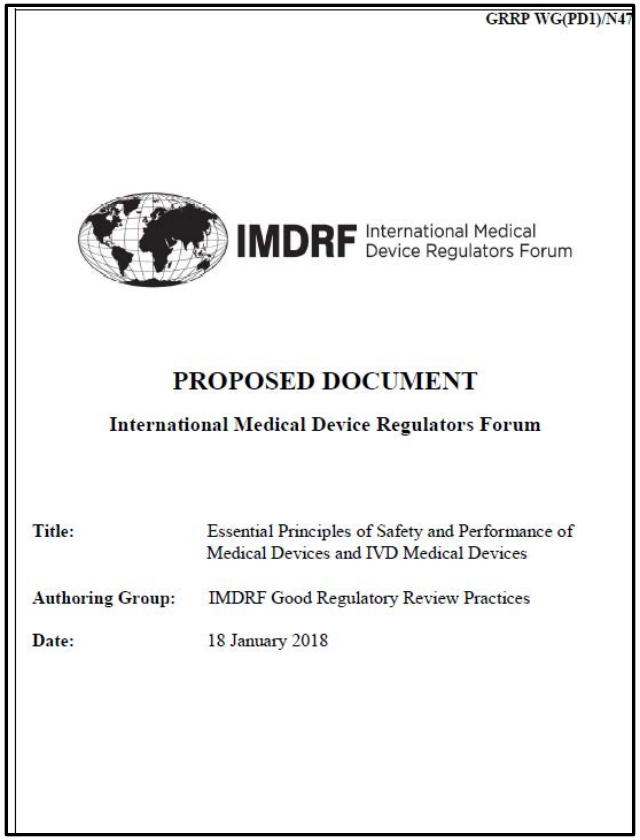
- New Work Item Proposals
  - March 2017: Approved to revise GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices* to create a new/updated IMDRF document outlining essential principles that can be used as a foundation for creating a more harmonized premarket review process.
  - September 2017: Approved to revise GHTF *Label and Instructions for Use for Medical Devices* (GHTF/SG1/N70:2011) in conjunction with the Essential Principles document to update to reflect current labeling and instructions for use requirements.

CURRENT STATUS

- IMDRF GRRP WG(PD1)/N47 *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
  - Face to face working group meeting in Silver Spring, MD in December 2017
  - Document approved during the January IMDRF MC teleconference for public consultation for a period of 90 days
- GHTF *Label and Instructions for Use for Medical Devices* (GHTF/SG1/N70:2011)
  - Draft document created
  - Working through teleconferences

Essential Principles: Key Changes

- Updated based on EU MDR, ISO 16142, and other jurisdictional requirements.
- Streamlined medical device and IVD medical device requirements.
- Updated requirements in areas such as SaMD, cybersecurity, performance characteristics of IVDs, etc.
- Removal of the majority of labeling principles and ensure coverage in label and instructions for use document.
- Addition of an Annex outlining the importance in the use of standards to assist in meeting EPs.
- Linkage of EPs to relevant guidances and standards to assist in meeting particular EPs.



GRRP WG(PD1)/N47

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title:	Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
Authoring Group:	IMDRF Good Regulatory Review Practices
Date:	18 January 2018

Essential Principles of Safety and Performance

Medical Devices and IVD Medical Devices

- General
- Clinical Evaluation
- Chemical, Physical, and Biological Properties
- Sterility, Packaging, and Microbial Contamination
- Considerations of Environment and Conditions of Use
- Protection against Electrical, Mechanical, and Thermal Risks
- Active Devices and Devices Connected to Them
- Software or SaMD
- Diagnostic or Measuring Function
- Labeling and Instructions for Use
- Protection against Radiation
- Protection against Risks posed by Devices for Use by Lay Persons
- Devices Incorporating Materials of Biological Origin
- Devices Incorporating a Substance Considered to be a Medicinal Product/Drug

Medical Devices

- Chemical, Physical, and Biological Properties
- Protection against Radiation
- Requirements for Implantable Medical Devices
- Protection against the Risks Posed to the Patient or User by Medical Devices Supplying Energy or Substances

IVD Medical Devices

- Performance Characteristics
- Chemical, Physical, and Biological Properties

Relationship with Standards and Guidances

Essential Principle	Guidances	Relevant Standards
5.1	GHTF/SG3/N18:2010 *Quality Management System –Medical Devices – Guidance on Corrective Action and Preventive Action and related QMS Processes* GHTF/SG3/N17:2008 *Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers* GHTF/SG3/N99-10:2004 *Quality Management Systems - Process Validation Guidance* GHTF/SG3/N15R8 *Implementation of Risk Management Principles and Activities within a Quality Management System* ISO 13485:2016 Handbook	ISO 13485 ISO 14971 ISO 23640 CLSI EP25
5.2	Declaration of Helsinki GHTF/SG5/N1R8:2007 *Clinical Evidence – Key Definitions and Concepts* GHTF/SG5/N2R8:2007 *Clinical Evaluation* GHTF/SG5/N3:2010 *Clinical Investigations* GHTF/SG5/N6:2012 *Clinical Evidence for IVD Medical Devices - Key Definitions and Concepts* GHTF/SG5/N7:2012 *Clinical Evidence for IVD Medical Devices - Scientific Validity Determination and Performance Evaluation.* GHTF/SG5/N8:2012 *Clinical Performance Studies for In Vitro Diagnostic Medical Devices*	ISO 14155

Label and Instructions for Use Document

- Updating based on EU MDR, IMDRF GRRP WG(PD1)/N47, ISO CD 20417, and jurisdictional requirements. For example:
  - Streamlining medical device and IVD medical device requirements
  - Updating requirements in areas such as SaMD, UDI, etc.
  - Inclusion of labeling concepts from EP document

GRRP AND STANDARDS

- IMDRF Good Regulatory Review Practices working group continues to coordinate work with:
  - IMDRF Standards working group
  - ISO TC210 WG 2 *General aspects stemming from the application of quality principles to medical devices*
    - CD 20417 *Medical Devices – Information to be provided by the manufacturer*
    - ISO 16142 (Part 1 and Part 2) *Medical Devices – Recognized essential principles of safety and performance of medical devices*
- Proposal to have a joint meeting between ISO TC210 WG 2 and IMDRF GRRP in May 2018 to work on finalizing EP and draft Label and Instructions for Use documents

TIMELINE

Teleconferences

April
- Public consultation period for EPs closes

May
- Face to face working group meeting to address EP public comments and finalize draft Label and Instructions for Use document
- Submit Label and Instructions for Use document to MC

June
- Draft Label and Instructions for Use document to be considered for a 60 day consultation period during MC teleconference

July/ August
- Submit EP and Label and Instructions for Use document to MC

Sept.
- Final EP and Label and Instructions for Use documents to be considered during MC meeting

THANK YOU