IMDRF International Medical Device Regulators Forum

GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

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US Food and Drug Administration

Good Regulatory Review Practices (GRRP) Goals

The IMDRF Good Regulatory Review Practices (GRRP) 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.

IMDRF GRRP WG/ N40 FINAL:2017
Competence, Training, and Conduct Requirements

IMDRF GRRP WG/ N47
Essential Principles of Safety and Performance

IMDRF GRRP WG/N52
Principles of Labeling

GRRP Current Work Items

1. Revising 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.

2. Revising GHTF *Label and Instructions for Use for Medical Devices* (GHTF/SG1/N70:2011) in conjunction with the Essential Principles document to reflect current labeling requirements.

GRRP WG

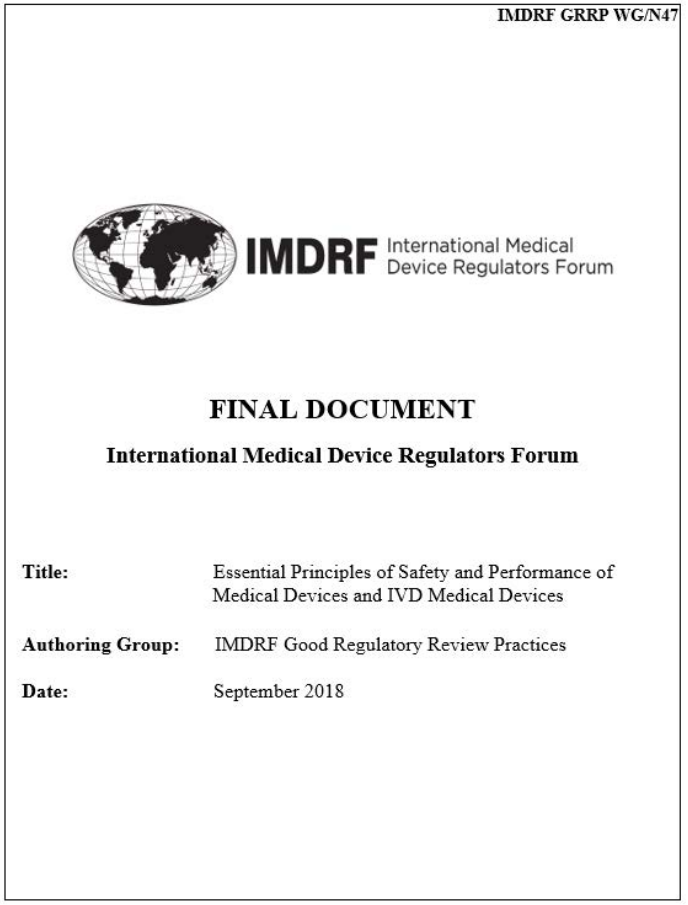
- Joint ISO TC210 WG 2 and IMDRF GRRP meeting held in May 2018 in Eindhoven, Netherlands.
  - Finalized Essential Principles document
  - Finalized draft Labeling document
- IMDRF Good Regulatory Review Practices working group coordinates with:
  - IMDRF Standards and UDI Working Groups
  - ISO TC210 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*

Essential Principles: Current Status

- IMDRF GRRP WG/N47 *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
  - Revised GHTF (GHTF/SG1/N68:2012) *Essential Principles of Safety and Performance of Medical Devices*
  - Public consultation for 90 days – closed on 4/18/18.
    - Received ~ 250 comments
  - Comments addressed and document sent to MC for consideration as final

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.



IMDRF GRRP WG/N47

IMDRF International Medical Device Regulators Forum

FINAL 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:	September 2018

Essential Principles of Safety and Performance

Medical Devices and IVD Medical Devices

- General
- Clinical Evaluation
- Chemical, Physical, and Biological Properties
- Sterilization 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

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
- Devices Incorporating a Substance Considered to be a Medicinal Product/Drug

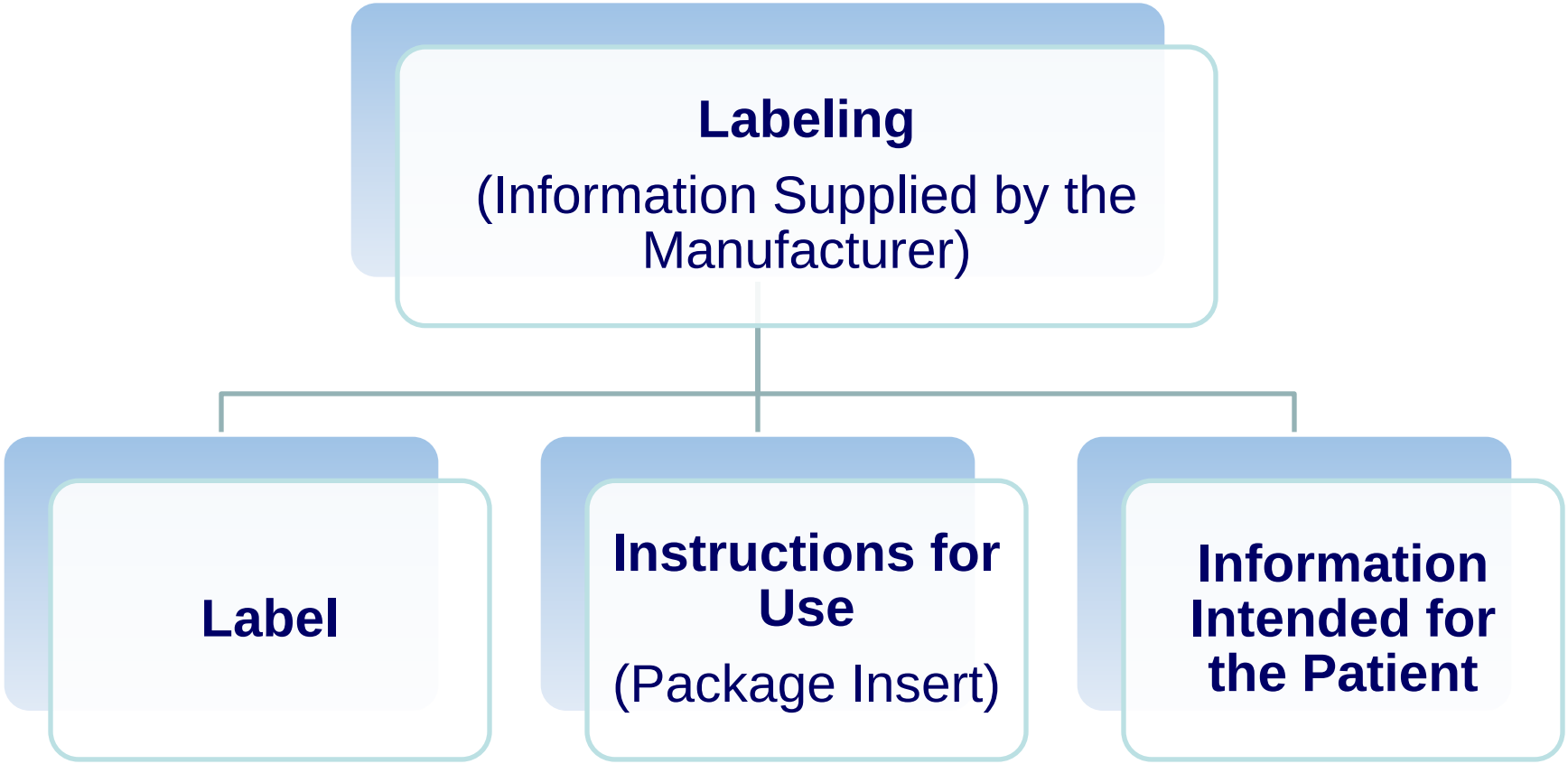
IVD Medical Devices

- Performance Characteristics
- Chemical, Physical, and Biological Properties

Essential Principles: 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 ISO 24971 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

Principles of Labeling: Overview



Principles of Labeling: Current Status

- IMDRF GRRP WG (PD1)/N52 *Principles of Labeling for Medical Devices and IVD Medical Devices*
  - Revised GHTF *Label and Instructions for Use for Medical Devices* (GHTF/SG1/N70:2011) based on EU MDR, IMDRF GRRP WG(PD1)/N47, ISO CD 20417, and jurisdictional requirements. For example:
    - Streamlined medical device and IVD medical device requirements
    - Included requirements for SaMD and UDI
    - Included labeling concepts from EP document
    - Included information intended for the patient
  - Public consultation for 60 days – closed on 9/12/18

GRRP WG: Next Steps

- Finalize *Principles of Labeling* document – March 2019
- New Work Item Proposal under consideration with MC:
  - Conformity Assessment/Recognition program to support the development of a Medical Device Single Review Program (MDSRP)
    - Will model the Medical Device Single Audit Program (MDSAP) by leveraging existing documents where possible and making modifications as necessary to accommodate MDSRP requirements

THANK YOU