GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

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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.
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
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.
# 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 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

## Medical Devices
- Chemical, Physical, and Biological Properties
- Protection against Radiation
- Requirements for Implantable Medical Devices

## IVD Medical Devices
- Performance Characteristics
- Chemical, Physical, and Biological Properties
### Essential Principles:

**Relationship with Standards and Guidances**

<table>
<thead>
<tr>
<th>Essential Principle</th>
<th>Guidances</th>
<th>Relevant Standards</th>
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PRINCIPLES OF LABELING:
OVERVIEW

Labeling
(Information Supplied by the Manufacturer)

Label

Instructions for Use
(Package Insert)

Information Intended for the Patient
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