IMDRF GOOD REGULATORY REVIEW PRACTICES (GRRP) WORKING GROUP UPDATE

Working Group Chairs:

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IMDRF GRRP Working Group Goals

- Develop documents focused on harmonizing pre-market review requirements globally. Documents focus on:
  - Technical requirements for conducting pre-market reviews
  - Competency requirements for pre-market reviewers
  - Requirements for organizations performing pre-market reviews

- Work products align with the IMDRF strategic priority to promote harmonized pre-market review requirements for medical devices.
IMDRF GRRP WG/N40 FINAL: 2017
Competence, Training, and Conduct Requirements for Regulatory Reviewers

IMDRF GRRP WG/N47 FINAL: 2018
Essential Principles of Safety and Performance

IMDRF GRRP WG/N52 FINAL: 2019
Principles of Labelling

Pre-market Review Processes
IMDRF GRRP WG/N59 FINAL:2020
Requirements for Regulatory Authority Recognition of CABs

IMDRF GRRP WG/N61 FINAL:2020
Assessment Methods for Recognition of CABs

IMDRF GRRP WG/N63 FINAL:2020
Competence and Training Requirements for Assessors of CABs

Recognition of Conformity Assessment Bodies (CABs)
IMDRF GRRP WG/N66 PD1: Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews

- Outlines the assessment process and outcomes, including the method to “grade and manage” nonconformities resulting from a recognizing Regulatory Authority’s assessment of a Conformity Assessment Body (CAB).
- Documents the decision process for recognizing a CAB or cessation of recognition.
- Public consultation through April 19, 2021:
  
  http://www.imdrf.org/consultations/cons-adpr-cab-cmdrr.asp
NEW WORK ITEM EXTENSION

The GRRP WG has developed a NWIE to further harmonize pre-market review processes:

• Submitted for the March 2021MC meeting for review.
• Focused on the development of a reporting model for medical device regulatory reviews conducted by CABs.
  – Involves the creation of templates and work instructions to guide CABs in consistently evaluating marketing submissions and documenting their certification recommendations in marketing review reports.
• Provides the opportunity for convergence across RAs with respect to how medical devices are evaluated.
**Benefits of GRRP WG Documents**

- Promotes consistency, predictability and transparency in the regulatory pre-market review programs through agreed upon sets of criteria and processes.

- Provides confidence that pre-market regulatory reviews conducted by CABs are rigorous enough to meet the requirements of Regulatory Authorities.

- Provides opportunities for convergence of pre-market review requirements.

- Benefits all regulators, even those just starting to develop a regulatory medical device premarket review system.
**NEXT STEPS**

- NWIE has been submitted to the IMDRF MC for consideration during the March 2021 IMDRF MC.
  - If approved, begin working on NWIE through teleconferences.
- Address comments received from the public consultation for IMDRF GRRP WG/N66 PD1: *Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews* and finalize document for consideration for the September 2021 IMDRF MC meeting.
THANK YOU