IMDRF International Medical Device Regulators Forum

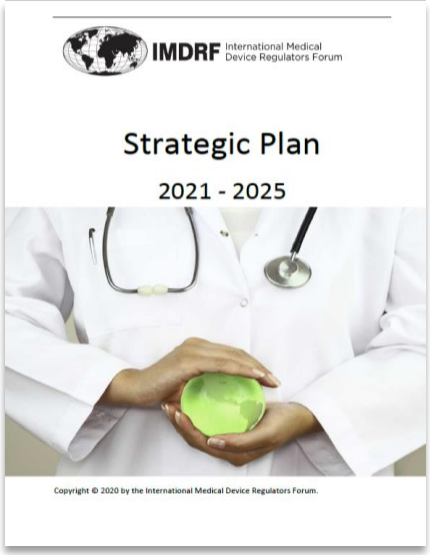
IMDRF Good Regulatory Review Practices (GRRP) Working Group Update

Working Group Co-Chairs

Singapore and US

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 International Medical Device Regulators Forum

IMDRF/GRRP WG/N40FINAL:2017

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Competence, Training, and Conduct Requirements for Regulatory Reviewers

Authoring Group: IMDRF Good Regulatory Review Practices

Date: 16 March 2017

Kimby Barton, IMDRF Chair

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IMDRF GRRP WG/ N40 FINAL:2017

Competence, Training, and Conduct Requirements for Regulatory Reviewers

IMDRF/GRRP WG/N47 FINAL:2018

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 Lin, IMDRF Chair

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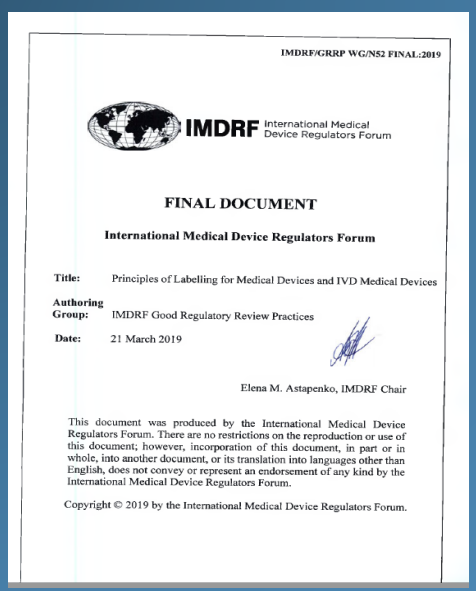
IMDRF GRRP WG/ N47 FINAL: 2018

Essential Principles of Safety and Performance



IMDRF/GRRP WG/N52 FINAL:2019

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: 21 March 2019

Elena M. Astapenko, IMDRF Chair

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IMDRF GRRP WG/ N52 FINAL: 2019

Principles of Labelling

Pre-market Review Processes

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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

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IMDRF GRRP WG/ N59 FINAL:2020

Requirements for Regulatory Authority Recognition of CABs

IMDRF/GRRP WG/N61FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: 25 September 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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IMDRF GRRP WG/ N61 FINAL:2020

Assessment Methods for Recognition of CABs

IMDRF/GRRP WG/N63FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: 25 September 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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IMDRF GRRP WG/ N63 FINAL:2020

Competence and Training Requirements for Assessors of CABs

IMDRF/GRRP WG/N66FINAL:2021

IMDRF International Medical Device Regulators Forum

Final Document

Title: Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF Good Regulatory Review Practices Working Group

Date: 24 June 2021

Oh-Sang Kwon, IMDRF Chair

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IMDRF GRRP WG/N66 Final: 2021 *Assessment and Decision Process for the Recognition of CABs Conducting Medical Device Regulatory Reviews*

Recognition of Conformity Assessment Bodies (CABs)

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.

New Work Item Extension

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

- Approved during the March 2021 MC meeting.
- Focuses on the development of a reporting model for medical device regulatory reviews conducted by CABs.
  - Involves the creation of a reporting template and work instruction to guide CABs in consistently evaluating marketing submissions and documenting their recommendations in marketing review reports.
- Provides the opportunity for convergence across RAs with respect to how medical devices are evaluated.

Current Status

- The IMDRF GRRP WG has begun working on the NWIE
  - Membership expanded to include both Regulators and representatives from CABs.
  - Initial draft reporting template developed.
  - Teleconferences held every 2 weeks.
- Goal is to submit the first draft to the MC for the March 2022 meeting for a 2-month public consultation period.

THANK YOU