IMDRF International Medical Device Regulators Forum

IMDRF GOOD REGULATORY REVIEW PRACTICES (GRRP) WORKING GROUP UPDATE

Working Group Chairs:

Lakshmidevi Balakrishnan
HSA – Singapore

Melissa Torres
US Food and Drug Administration

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.

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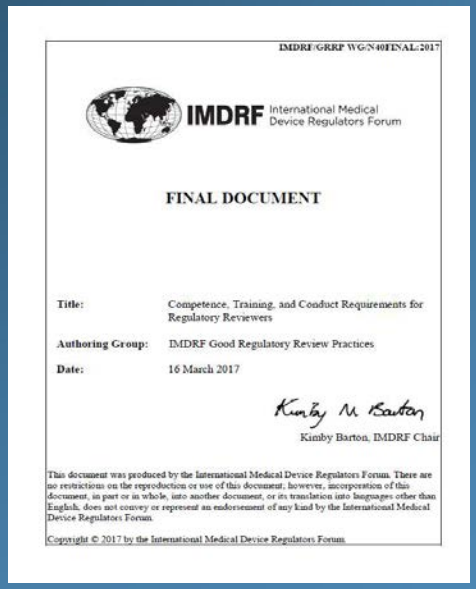

IMDRF/GRRP WG/N40FINAL:2017

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 M. Barton

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

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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

Yoon Lin, IMDRF Chair

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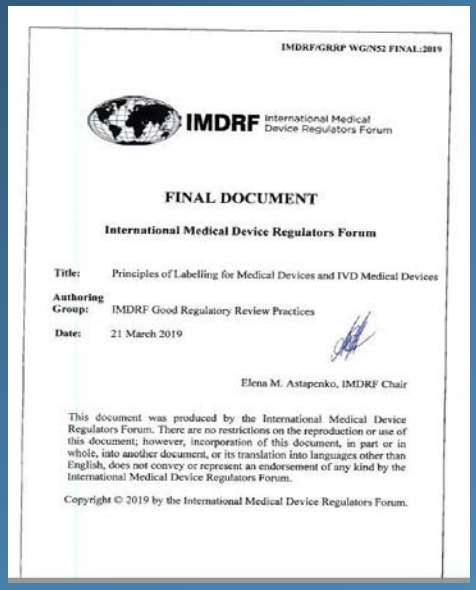
IMDRF GRRP WG/ N47 FINAL: 2018

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

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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

Recognition of Conformity Assessment Bodies (CABs)

CURRENT WORK ITEM

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.
- Models the Medical Device Single Audit Program (MDSAP) document IMDRF/MDSAP WG/N11 FINAL:2014.
- 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.

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THANK YOU