IMDRF International Medical Device Regulators Forum | 26th Session

IMDRF Good Regulatory Review Practices (GRRP) Working Group Update

Working Group Co-Chairs Singapore and US

Ms. Low Lai Peng

Deputy Director, Therapeutic Devices Branch, Medical Devices Cluster

Health Sciences Authority, Singapore

IMDRF GRRP Working Group Goals

- Develop documents focused on harmonizing marketing review requirements globally
- Documents have focused on:
  - Technical requirements for conducting marketing reviews
  - Competency requirements for marketing reviewers
  - Requirements for organizations performing marketing reviews

GRRP Documents

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

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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

Marketing Review Processes

SEATTLE WASHINGTON "The Emerald City" The City of Flowers

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IMDRF 2024 Chair

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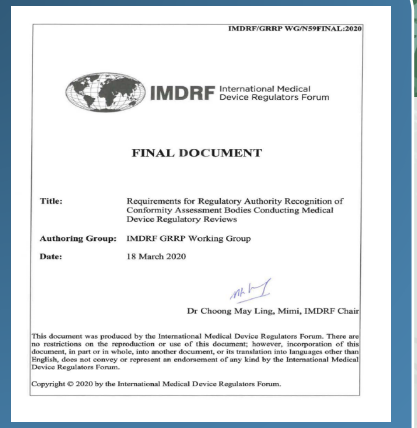
GRRP Documents


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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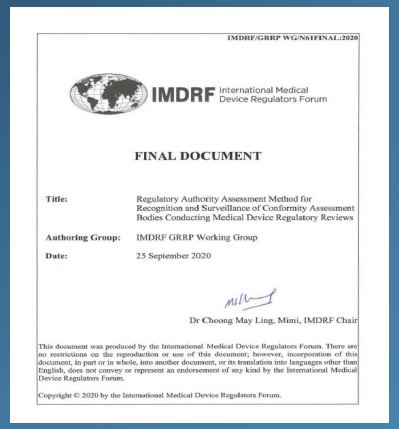
IMDRF GRRP WG/ N59 FINAL:2020

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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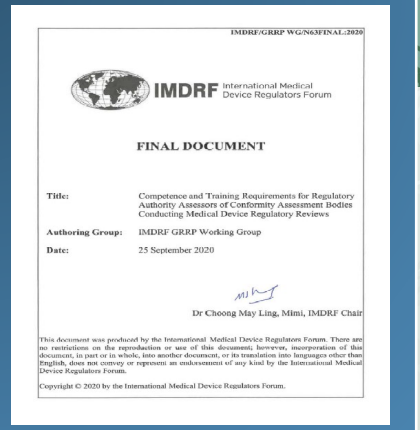
IMDRF GRRP WG/ N61 FINAL:2020

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


Final Document

Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

IMDRF GRRP WG/N71 FINAL:2023

Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

Recognition of Conformity Assessment Bodies (CABs)

Benefits of GRRP WG Documents

- Promote consistency, predictability and transparency in regulatory marketing review programs through agreed-upon sets of criteria and processes
- Provide confidence that marketing regulatory reviews conducted by CABs are rigorous enough to meet the requirements of Regulatory Authorities
- Provide opportunities for convergence of marketing review requirements
- Benefit all regulators, even those just starting to develop a regulatory medical device marketing review system

Essential Principles Training

- Input from external stakeholders identified the value of training on the IMDRF Essential Principles of Safety and Performance

- Organized EP training sessions on September 11 and 19, 2024
  - Targeting current and prospective Affiliate Members
  - Delivered by IMDRF MC Members and industry associates

Most Recent Work Item

- Published as final on 26 April 2024
- The WG conducted a comprehensive review of the existing GRRP documents and identified areas requiring revision. The updates primarily focus on:
  - Ensuring the use of appropriate and consistent terminology throughout all GRRP documents
  - Clarifying the scope and interrelationships between various documents
- All of these documents represent published IMDRF documents, with updates limited to minor revisions, primarily aimed at ensuring consistent terminology and policy alignment.

New Work Item

Playbook for Medical Device Regulatory Reliance Programs

- NWIP was approved in June 2024
- Growing global interest in regulatory reliance for medical devices
  - *As defined by the WHO, "reliance" is the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision*
- To develop a document that outlines general strategies and detailed instructions for developing and implementing regulatory reliance programs within and across regulatory jurisdictions
  - High-level considerations & strategies for reliance
  - Types of regulatory reliance models & areas of application (e.g. pre-market and post-market decision-making areas)
  - Steps for reliance implementation

Next Steps

- The IMDRF GRRP WG has begun working on the NWIP
  - To develop initial draft
  - Teleconferences held weekly

- Goal is to submit the first draft to the MC for consideration in early 2025

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THANK YOU

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