IMDRF International Medical Device Regulators Forum

IMDRF Good Regulatory Review Practices (GRRP) Working Group Update

Dr. Lakshmidevi Balakrishnan, Health Sciences Authority (HSA), Singapore

Dr. Kenneth Cavanaugh, Food and Drug Administration (FDA), United States of America

Provide your feedback on this Working Group!

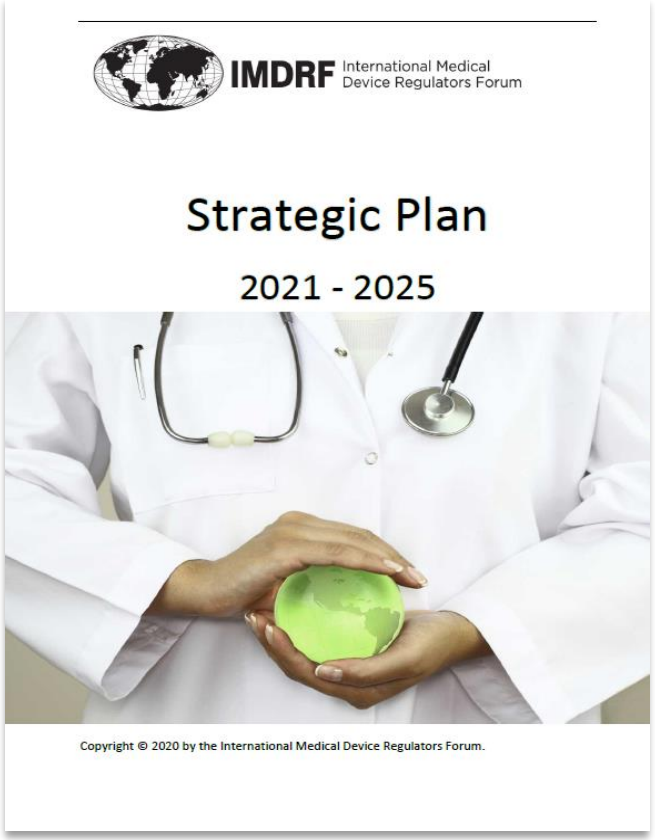
Follow this link and let us know:

https://forms.office.com/e/SHNbVjTfCv

IMDRF 24th Session – Berlin, Germany

IMDRF GRRP Working Group Goals

- Develop documents focused on harmonizing marketing review requirements globally.
- Documents focus 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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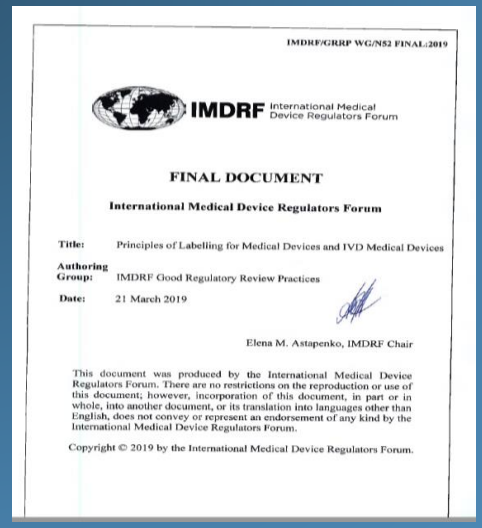
IMDRF GRRP WG/ N47 FINAL: 2018

Essential Principles of Safety and Performance



IMDRF/GRRP WG/N52 FINAL:2019

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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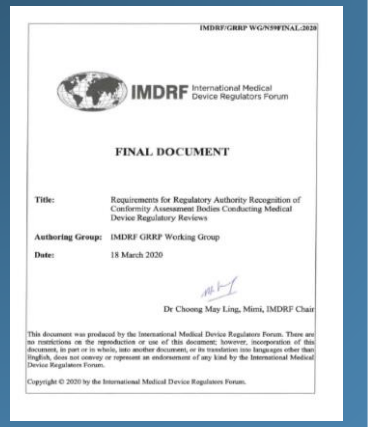
IMDRF GRRP WG/ N52 FINAL: 2019

Principles of Labelling

Marketing Review Processes

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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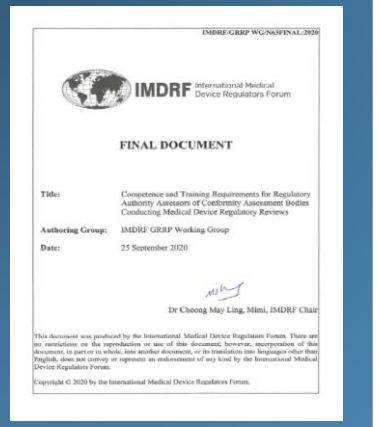
IMDRF GRRP WG/ N61 FINAL:2020

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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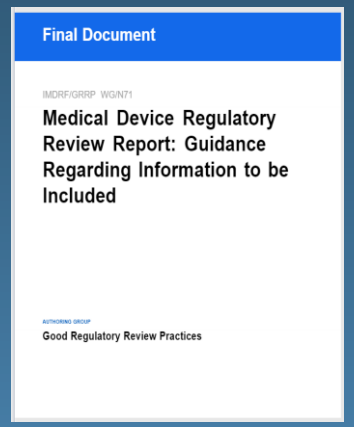
IMDRF GRRP WG/N66 FINAL:2021

Assessment and Decision Process for the Recognition of CABs Conducting Medical Device Regulatory Reviews


Final Document

IMDRF/GRRP WG/N71

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

AUTHORING GROUP

Good Regulatory Review Practices

IMDRF GRRP WG/N71 FINAL:2023

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

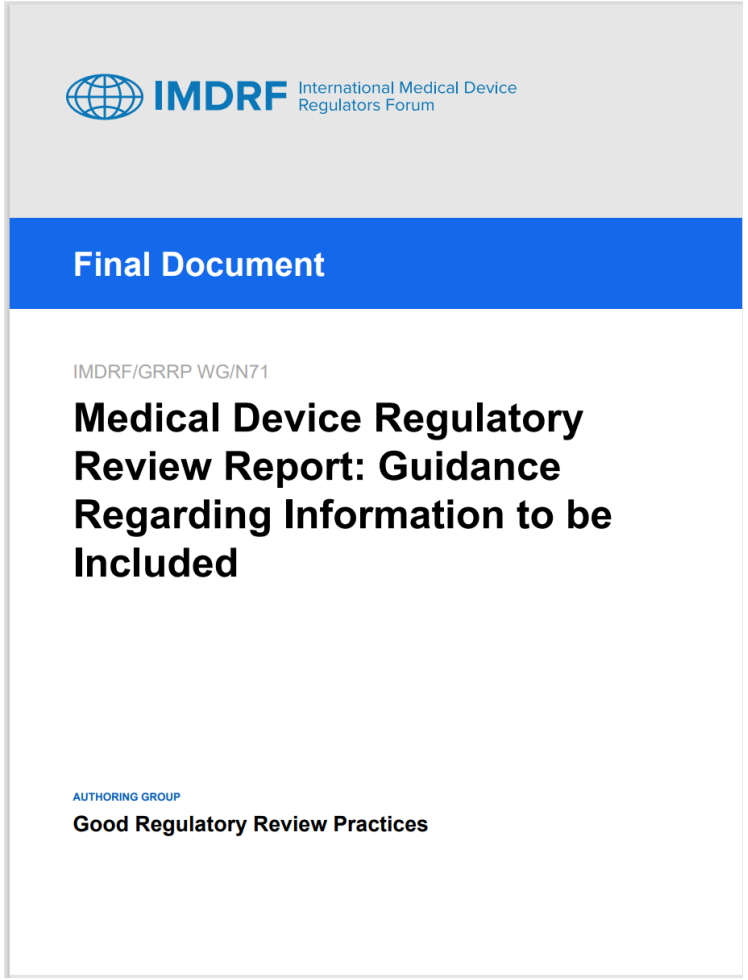
Recognition of Conformity Assessment Bodies (CABs)

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

Most Recent Work Item: N71 – Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

- Published in final on Feb 3, 2023
- Provides guidance regarding creation of a medical device regulatory review report
- A regulatory review report:
  - is a written record of the CAB's determination of the extent of fulfillment of specified requirements;
  - captures, in a consistent manner, the evidence of a manufacturer's conformity with the criteria for the regulatory review; and
  - will facilitate the exchange of information between RAs.
- Working group participation included CAB representatives as observers



New Work Item

- A NWIP was approved in June 2023 to update previous GRRP documents for consistency with policy and terminology in most recently published GRRP document (IMDRF/GRRP WG/N71).
  - Changes needed in order to be consistent with and inclusive of the current approaches of several RAs
  - The GRRP WG reviewed existing GRRP documents and identified four that should be revised to ensure appropriate and consistent terminology throughout the all GRRP documents
  - The proposed changes to terminology demonstrate convergence among RAs toward a common language and concepts

Goals:
To achieve consistent terminology to fulfill Priority 1 of the 2021-2025 IMDRF Strategic Plan: to develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices

Documents to be Updated

- The GRRP WG reviewed existing GRRP documents and identified four that should be revised to ensure appropriate and consistent terminology throughout the all GRRP documents : N66, N61, N63, and N59
  - These changes require more than simple search and replace since careful consideration should be paid to which term is selected and how it is used based on the specific context

- References section of other GRRP documents will also be reviewed for updates
  - To ensuring date and language in references section is up to date

Next Steps

- WG to review proposed edits and meet to discuss proposed edits from Sep- Dec 2023
- WG to submit documents for draft consultation to MC for consideration in Mar 2024
- Public consult of draft document in May 2024
- WG to deliberate comments and finalize changes by Oct 2024
- WG to submit final document for MC review in Dec 2024

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Provide your feedback on this Working Group!

Follow this link and let us know:

https://forms.office.com/e/SHNbVjTfCv

Thank you!
Questions?

Email erin.cutts@fda.hhs.gov