IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority, Singapore

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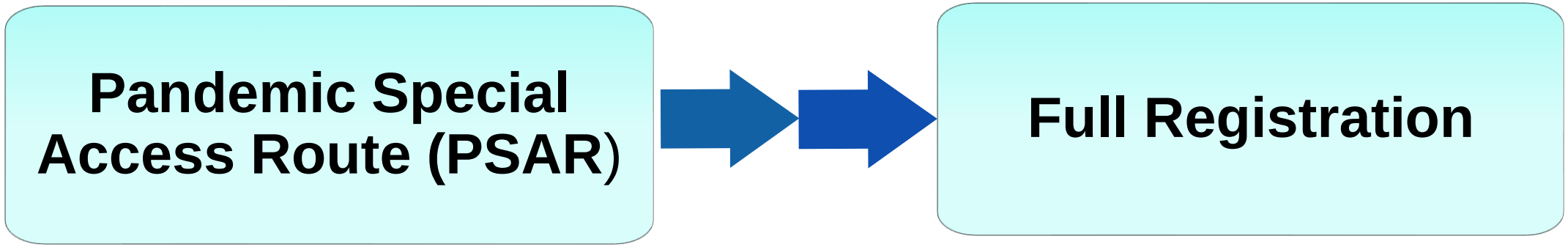
September 2023

COVID-19 Tests - Transition from Special Access to Full Registration



- All COVID-19 tests previously authorised under PSAR have been moved to full registration
- Any new COVID-19 test will go through the standard pre-market evaluation and full registration process applicable to all IVDs
  - PSAR will no longer be applicable
- Guide on the key validation requirements for **full registration** available online - Validation Requirements for Product Registration of COVID-19 Diagnostic Tests – Self-Tests**.**

Manufacturing of dental devices in dental laboratories in Singapore

- **Dental laboratories** specialise in manufacturing or customising devices used by registered dentists to assist in providing oral heath care to their patients.
  - In Singapore, these labs mainly manufacture "custom-made medical devices" that are mainly lower risk (class A and class B) dental devices such as crowns, bridges, dentures and orthodontic appliances following the prescription/written instruction from a registered dentist
  - Each unit of these dental devices is custom-made for an individual patient and does not fit others
  - The manufactured devices are supplied to the prescribing dentists, who fits the devices for their patients

- **Dental laboratories** in Singapore operate
  - Within MOH licensed facilities under the Healthcare Services Act (HCSA) such as healthcare institutions (e.g. National Dental Centre) and dental clinics; **OR**
  - As standalone set ups (i.e. private entities)

- **Standalone dental laboratories**, which operate outside hospitals and dental clinics, are not licensed by MOH
  - No regulatory oversight on these entities, their manufacturing and supply

A titrated regulatory approach for manufacturing in dental laboratories

A risk calibrated regulatory approach based on the following considerations:

i) These dental laboratories have been supporting the practice of dentistry by manufacturing custom-made dental MDs for over 40 years

ii) To date, we have not come across any serious safety incidents associated with the custom-made dental devices (specific to an individual patient) manufactured in local dental laboratories

iii) The manufacturing activity by these dental laboratories are mainly low risk:

- They manufacture lower risk MDs (risk class A and B) and mainly custom-made dental MDs.
- They manufacture the dental MDs solely based on a prescription or written instructions from a registered dentist to an individual patient and supply to these patients only through their dentists
- There is professional oversight from a registered dentist in terms of prescribing and fitting of the dental MD

A titrated regulatory approach for manufacturing in dental laboratories

- **Notification of Manufacturing**: All standalone dental laboratories manufacturing solely lower risk dental MDs (Class A and Class B) will be required to notify their local manufacturing site and their scope of activities via an online form to HSA.
  - They are required to implement and maintain a quality management system based on ISO 13485 and may be subject to random compliance audits by HSA.

  NOTE: *A standalone dental lab manufacturing higher risk MDs (Class C and D) will be subject to standard regulatory requirements i.e. a Manufacturer's licence requirement and ISO 13485 certification of their facility, with third party audit*

- **Product Notification for traceability**: Standalone dental laboratories will be required to notify the types of dental MDs (e.g. aligners, bridges) they manufacture to HSA prior to supply

- **Post-market Controls:** They will be subject to post-market reporting requirements (e.g. mandatory reporting of adverse events related to their MDs) and other duties and obligations (e.g. maintain manufacturing and distribution records, complaint records, ensure traceability of MDs manufactured)

Medical Device Special Access Route – Strengthening Regulatory Oversight

- **Special Access Route (SAR)**: Allows import and supply of unregistered medical device in order to meet unmet clinical needs or for compassionate use on patients upon request from a doctor
  - Requesting doctor must provide clinical justification to substantiate the clinical need
  - Not subject to the standard pre-market evaluation and registration process

- HSA implemented following additional measures to strengthen the oversight on SAR requests for unregistered medical devices in the interest of patient health and safety:

Additional Measures

For **Class C and D** unregistered MDs
- Request for an unregistered MD must be endorsed by the Chairman, Medical Board (CMB) of the hospital; **and**

For specific categories of **Class D** unregistered MDs
- Prior approval is required from the Director-General of Health's (DGH) Office in MOH for the use of
  - New technologies and state-of-the-art medical devices, including novel indications for existing medical devices or technologies
  - Unregistered implants (e.g., pacemakers, breast implants)

SAR Guidance Document:
hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gn-35-r4-guidance-on-special-access-routes-(2023-jan)-pub.pdf?sfvrsn=a9ad0cba_2

Guidance Documents – Key Updates

- Updated Guidance on Risk Classification of *In* vitro Diagnostic medical devices published in July 2023
  - Greater alignment to the IMDRF IVD risk classification guidance
- Updated Guidance on licensing of manufacturers, importers and wholesalers of medical devices published
  - MDSAP certificates accepted as an evidence of QMS for medical device manufacturers

❑ Guidance documents and Guidelines can be accessed online at:

https://www.hsa.gov.sg/medical-devices/guidance-documents

IMDRF Good Regulatory Review Practices (GRRP) Working Group Update

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

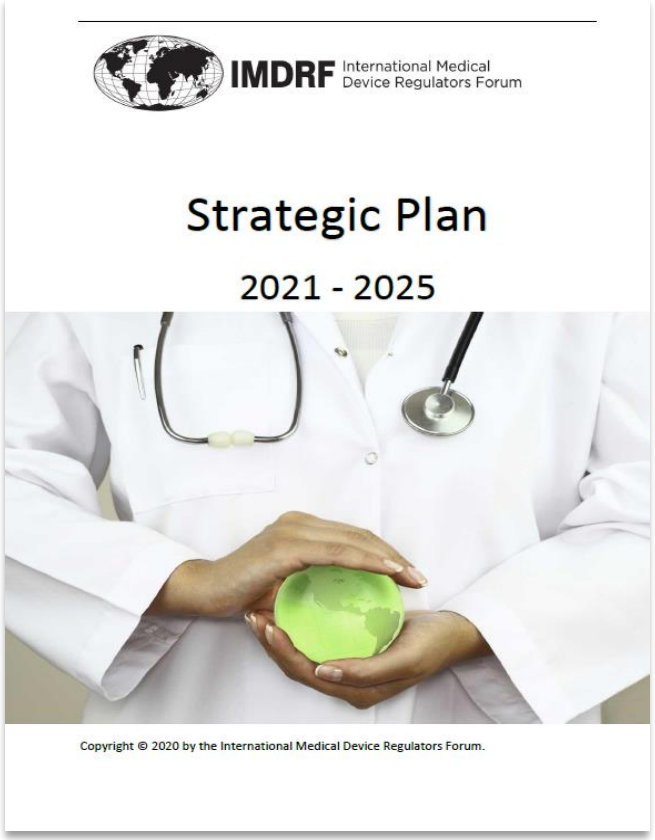
Dr. Kenneth Cavanaugh, Food and Drug Administration (FDA), United States of America

IMDRF 24th Session – Berlin, Germany

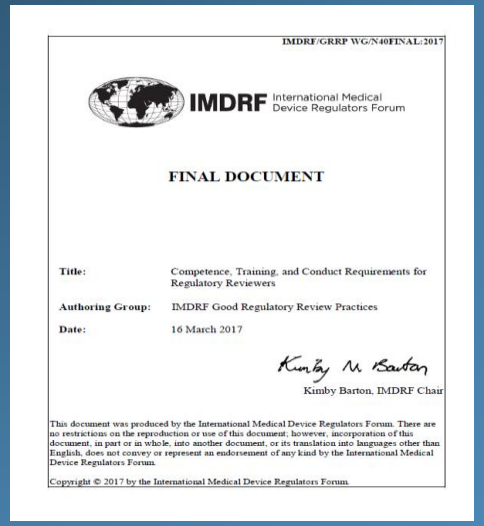
IMDRF International Medical Device Regulators Forum

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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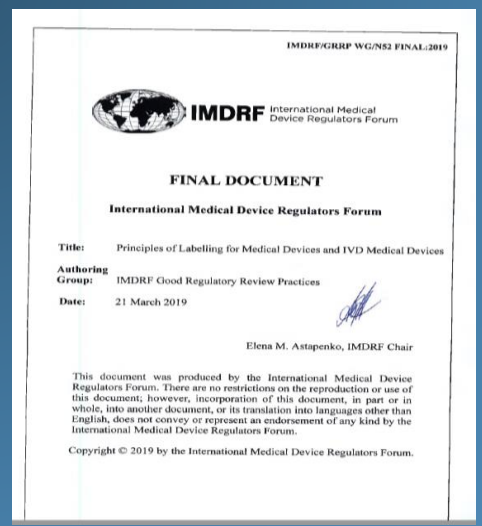
IMDRF GRRP WG/ N47 FINAL: 2018

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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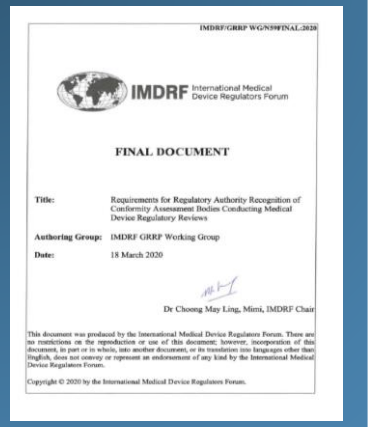
IMDRF GRRP WG/ N52 FINAL: 2019

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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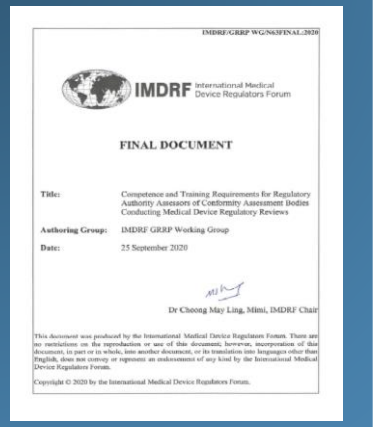
IMDRF GRRP WG/ N61 FINAL:2020

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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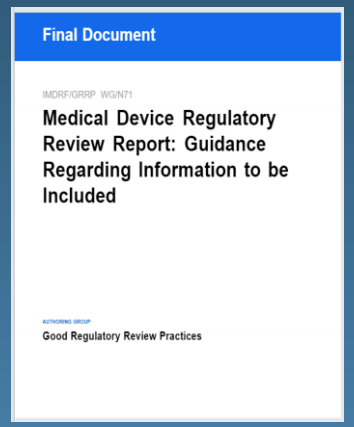
IMDRF GRRP WG/ N66 FINAL:2021

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

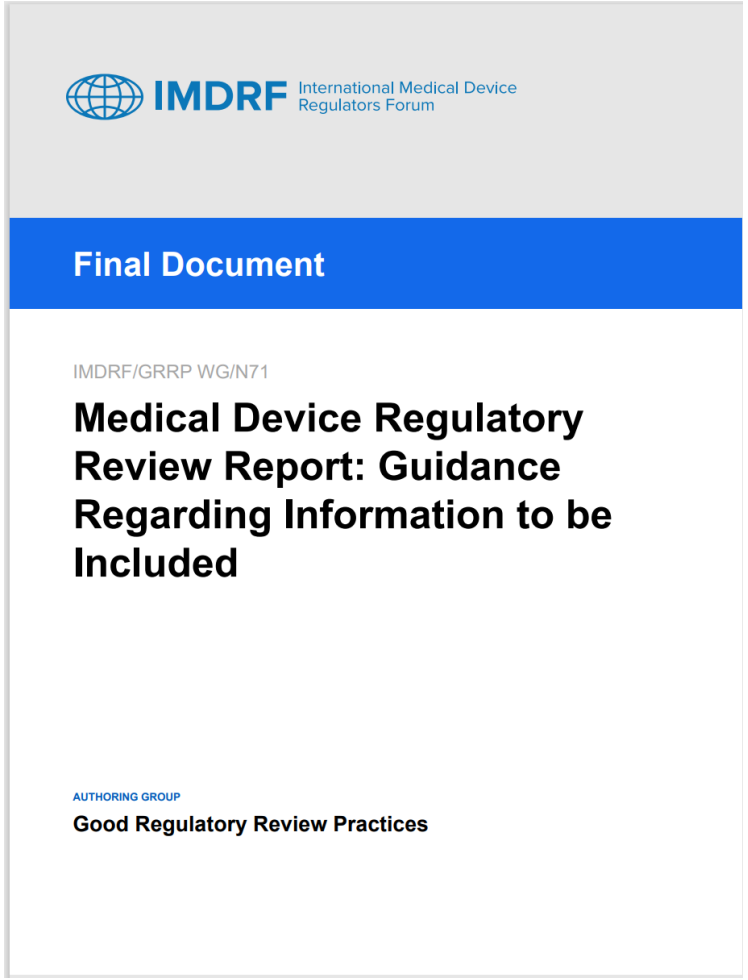
Recognition of Conformity Assessment Bodies (CABs)

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

Thank you!
Questions?

Email erin.cutts@fda.hhs.gov