

Good Regulatory Review Practices (GRRP) Working Group

Co-Chairs:

Lai Peng Low, HSA (Singapore)







About GRRP WG

Established: 2016

Goal: Develop guidance for harmonizing global marketing review practices

Membership

- IMDRF Management Committee Members
- Official Observers
- Affiliate Members
- Regional Harmonization Initiatives
- Notified Bodies





About GRRP WG

Typical meetings: Weekly teleconferences when revising documents, plus yearly face-to-face meeting when practical

GRRP WG supports the mission of IMDRF by:

- Providing timely guidance for fundamental regulatory review activities
- Engaging in training and capacity-building efforts
- Fostering global dialogue on broader regulatory review topics





Publications



Competence, Training, and Conduct Requirements for Regulatory Reviewers

Final Document Final Document IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2) **Essential Principles of Safety** and Performance of Medical **Devices and IVD Medical Devices IMDRF Good Regulatory Review Practices** IMDRF GRRP WG/N47 Essential Principles of Safety and Performance for Medical Devices and

IVDs

Regulatory Review Process

Principles of Labeling for Medical Devices and IVD Medical Devices

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IMDRF Good Regulatory Review Practices

IMDRF GRRP WG/N52

Principles of Labeling for Medical Devices and IVDs





Publications

Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

IMDRF Good Regulatory Review Practices

Final Document

IMDRF GRRP WG/ N59

Requirements for Regulatory Authority Recognition of CABs Final Document

MARFIGRAP WOARST FRAL 2024 (Edition 2)

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

MINDRE Good Regulatory Review Practices

IMDRF GRRP WG/ N61

Assessment Methods for Recognition of CABs Final Document

MDRF/GRRP WG/M63 FINAL-2024 (Edition 2)

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

IMDRF GRRP WG/N63

IMDRF Good Regulatory Review Practices

Competence and Training Requirements for Assessors of CABs Final Document

MDRFFGRAP WOMEFINAL 2024 (Edmon 2)

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

IMDRF GRRP WG/N66

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

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

Final Document

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Good Regulatory Review Practices

IMDRF GRRP WG/N71

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

Conformity Assessment Body (CAB) Recognition and Operations

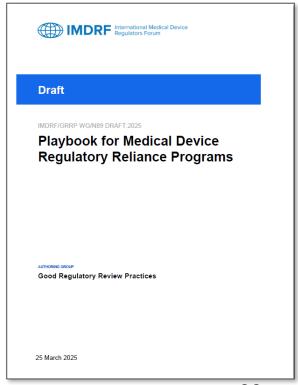




Ongoing work

Playbook for Medical Device Regulatory Reliance Programs

- Outlines general strategies and specific considerations for developing and implementing regulatory reliance programs within and across regulatory jurisdictions
- Initiated June 2024
- Draft playbook available for public consultation *April – May 2025*



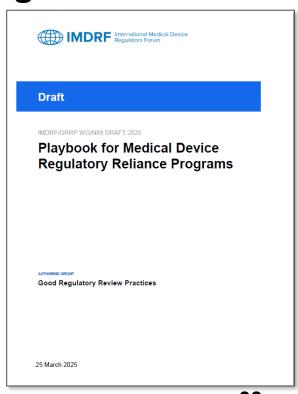




Ongoing work

Playbook for Medical Device Regulatory Reliance Programs

- 400+ comments received
- Key themes of comments:
 - Improving readability
 - Providing useful examples of reliance
 - Identifying/resolving potential barriers to reliance
- Publication of final playbook planned for early 2026







Opportunities and Challenges

- IMDRF recognizes the value in developing robust regulatory reliance programs that can benefit all stakeholders, along with the challenges associated with such programs
- Guidance from GRRP and other IMDRF WGs, along with appropriate use of international consensus standards, can serve as trusted, globally recognized building blocks for reliance
- GRRP WG welcomes feedback on real-world lessons learned from developing and implementing reliance programs, and on additional opportunities for IMDRF to contribute in this area





Thank you/Questions