



Good Regulatory Review Practices (GRRP) Working Group Update

Co-chairs: US and Singapore





About Us

Established: 2016

Goals: Aims to develop documents harmonizing global marketing review requirements

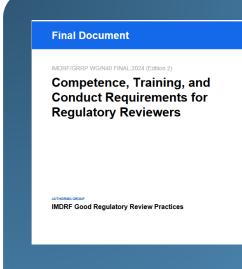
Documents have focused on:

- Technical requirements for conducting marketing reviews
- Competency requirements for marketing reviewers
- Requirements for organizations performing marketing reviews





GRRP Documents



IMDRF GRRP WG/N40

Competence, Training, and Conduct Requirements for Regulatory Reviewers

Final Document

IMDRF/GRRP WG/N47 FINAL-2024 (Edition 2)

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

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IMDRF Good Regulatory Review Practices

IMDRF GRRP WG/N47

Essential Principles of Safety and Performance for Medical Devices and IVDs Final Document

IMDRF/GRRP WG/N52 FINAL:2024 (Edition 2)

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

Regulatory Review Process



GRRP Documents



IMDRE/GRRP WG/N59 FINAL 2024 (Edition 2)

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

IMDRF Good Regulatory Review Practices

IMDRF GRRP WG/ N59

Requirements for Regulatory Authority Recognition of CABs

Final Document

Regulatory Authority Assessment Method for Recognition and Surveillance

IMDRF/GRRP WG/N61 FINAL:2024 (Edition 2)

of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

IMDRF Good Regulatory Review Practices

IMDRF GRRP WG/ N61

Assessment Methods for Recognition of CABs

Final Document

IMDRF/GRRP WG/N63 FINAL:2024 (Edition 2)

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

IMDRF Good Regulatory Review Practices

IMDRF GRRP WG/N63

Competence and Training Requirements for Assessors of CABs

Final Document

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

IMDRF Good Regulatory Review Practices

IMDRF GRRP WG/N66

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

Final Document

IMDRF/GRRP WG/N71 FINAL:2024 (Edition 2)

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

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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

- Following the NWIP approved in 2024, the group has been tasked to develop a Playbook for Medical Device Regulatory Reliance Programs
- This playbook will serve as a foundational building block for reliance programs, outlining general strategies and instructions for developing and implementing regulatory reliance programs within and across regulatory jurisdictions
- The group has been working on developing a draft document which is expected to be published for public consultation this year





Thank you