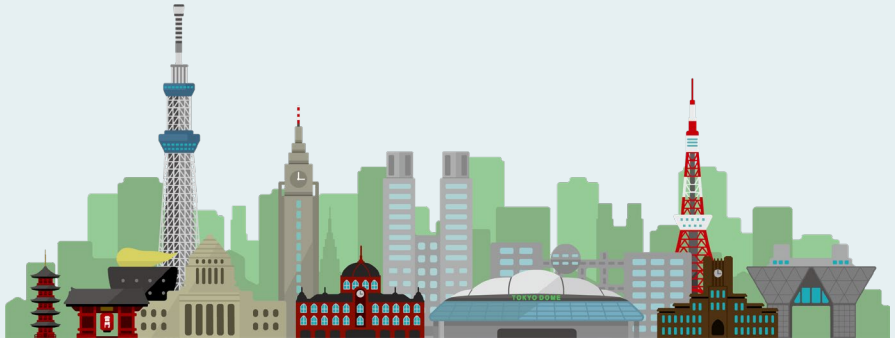
IMDRF International Medical Device Regulators Forum



Good Regulatory Review Practices (GRRP) Working Group Update

Co-chairs: US and Singapore

IMDRF International Medical Device Regulators Forum

About Us

Established: 2016

Goals: Aims to develop documents harmonizing global marketing review requirements

Documents have focused on:

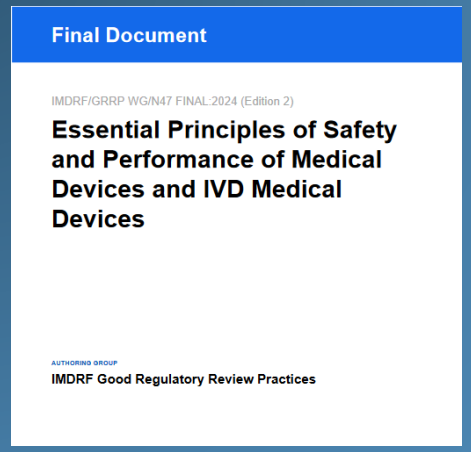
- **Technical requirements** for conducting marketing reviews
- **Competency requirements** for marketing reviewers
- **Requirements for organizations** performing marketing reviews

IMDRF International Medical Device Regulators Forum

GRRP Documents

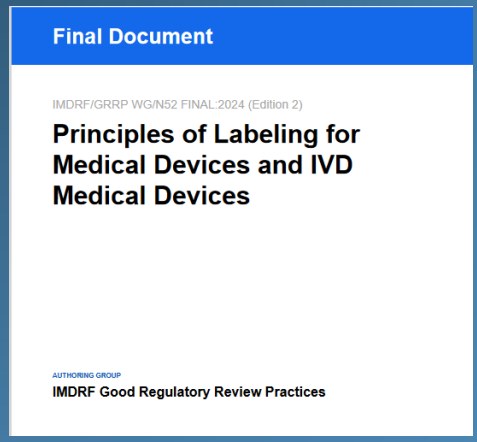
IMDRF GRRP WG/N40

Competence, Training, and Conduct Requirements for Regulatory Reviewers



IMDRF GRRP WG/N47

Essential Principles of Safety and Performance for Medical Devices and IVDs



IMDRF GRRP WG/N52

Principles of Labeling for Medical Devices and IVDs

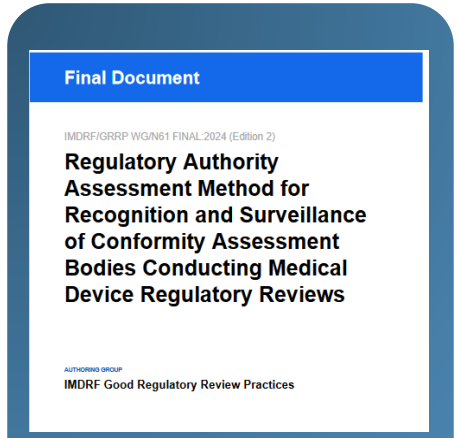
Regulatory Review Process

IMDRF International Medical Device Regulators Forum

GRRP Documents

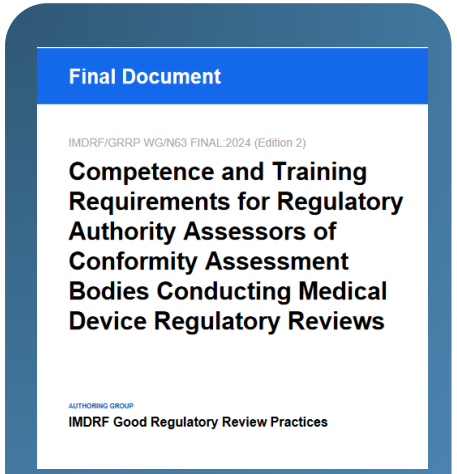
IMDRF GRRP WG/ N59

Requirements for Regulatory Authority Recognition of CABs



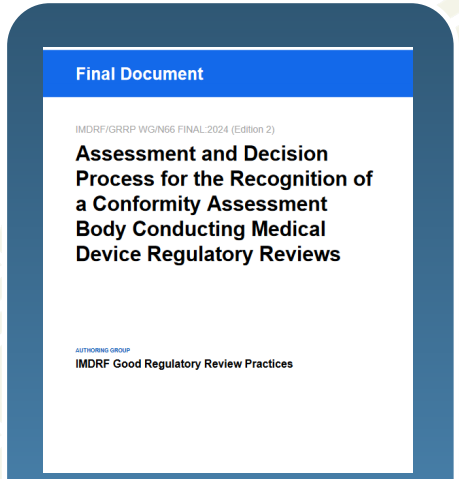
IMDRF GRRP WG/ N61

Assessment Methods for Recognition of CABs



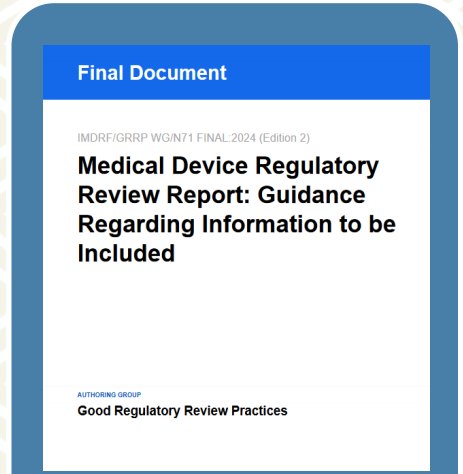
IMDRF GRRP WG/N63

Competence and Training Requirements for Assessors of CABs



IMDRF GRRP WG/N66

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



IMDRF GRRP WG/N71

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

Conformity Assessment Body (CAB) Recognition and Operations

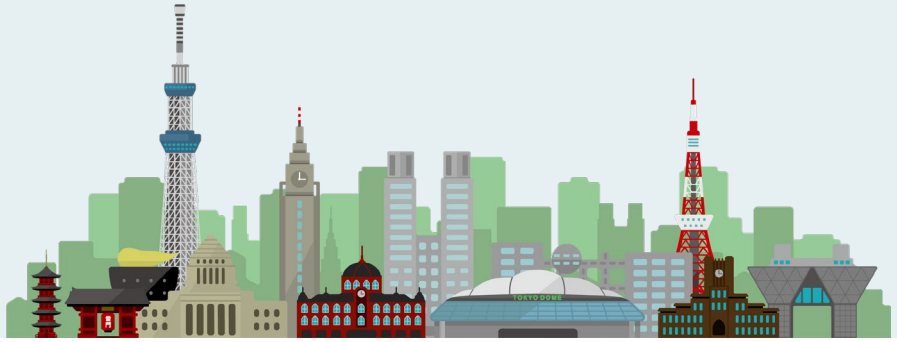
Ongoing work

- 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

IMDRF International Medical Device Regulators Forum



Thank you