

# Good Regulatory Review Practices (GRRP) Working Group

## Co-Chairs:

Lai Peng Low, HSA (Singapore)

Ken Cavanaugh, FDA (USA)





# 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

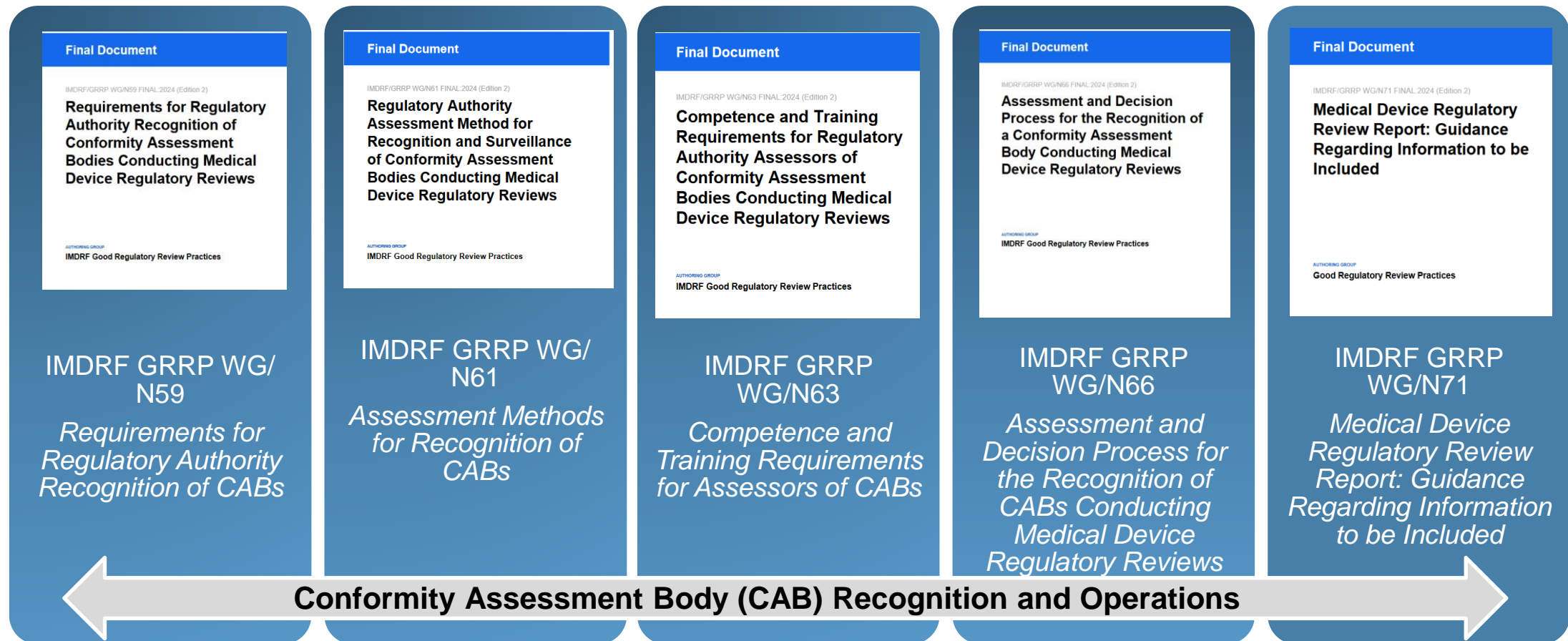


# Publications





# Publications

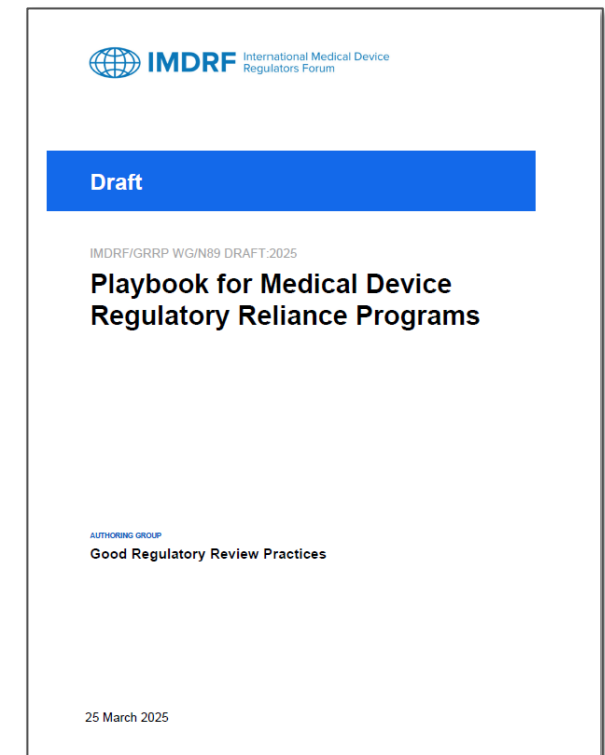




## Ongoing work

### 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*

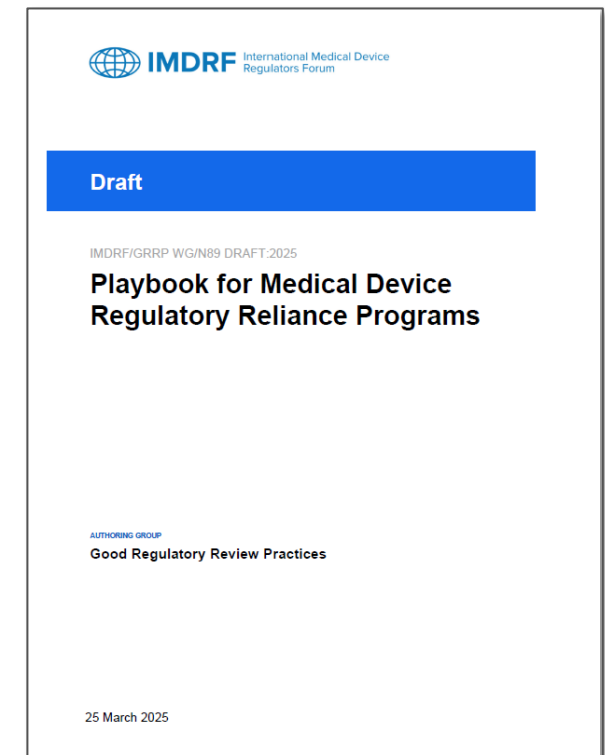




## Ongoing work

### 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