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International Medical
Device Regulators Forum

IMDRF GOOD REGULATORY REVIEW PRACTICES (GRRP) WORKING GROUP UPDATE

**Working Group Co-Chairs
Singapore and US**



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IMDRF GRRP Working Group Goals

- Develop documents focused on harmonizing pre-market review requirements globally. Documents focus on:
 - Technical requirements for conducting pre-market reviews
 - Competency requirements for pre-market reviewers
 - Requirements for organizations performing pre-market reviews
- Work products align with the IMDRF strategic priority to promote harmonized pre-market review requirements for medical devices.





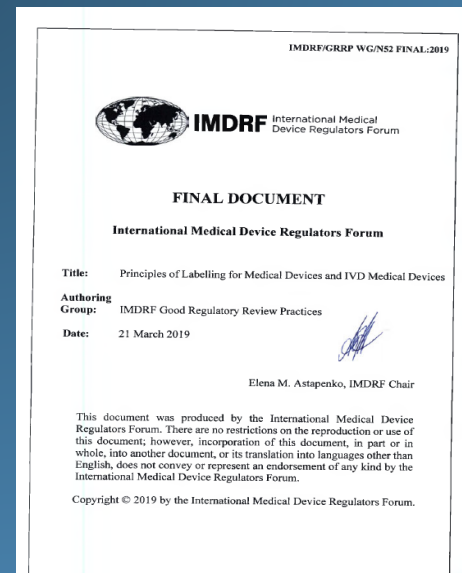
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IMDRF GRRP WG/
N40 FINAL:2017
*Competence, Training,
and Conduct
Requirements for
Regulatory Reviewers*



IMDRF GRRP WG/
N47 FINAL: 2018
*Essential Principles of
Safety and
Performance*



IMDRF GRRP WG/
N52 FINAL: 2019
Principles of Labelling

Pre-market Review Processes

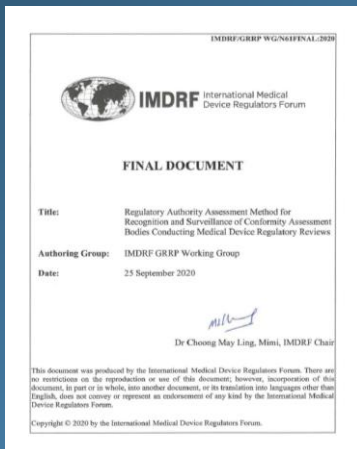


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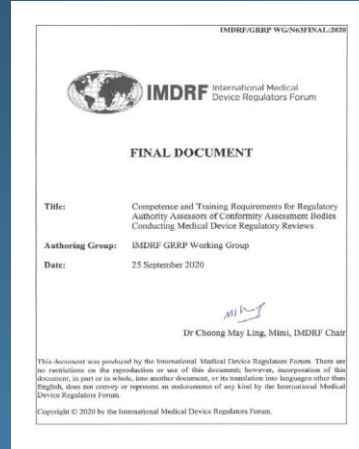
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IMDRF GRRP
WG/ N59
FINAL:2020
*Requirements for
Regulatory
Authority
Recognition of
CABs*



IMDRF GRRP
WG/ N61
FINAL:2020
*Assessment
Methods for
Recognition of
CABs*



IMDRF GRRP
WG/ N63
FINAL:2020
*Competence and
Training
Requirements for
Assessors of
CABs*



IMDRF GRRP
WG/N66 Final: 2021
*Assessment and
Decision Process for
the Recognition of
CABs Conducting
Medical Device
Regulatory Reviews*

Recognition of Conformity Assessment Bodies (CABs)



BENEFITS OF GRRP WG DOCUMENTS

- Promotes consistency, predictability and transparency in the regulatory pre-market review programs through agreed upon sets of criteria and processes.
- Provides confidence that pre-market regulatory reviews conducted by CABs are rigorous enough to meet the requirements of Regulatory Authorities.
- Provides opportunities for convergence of pre-market review requirements.
- Benefits all regulators, even those just starting to develop a regulatory medical device premarket review system.



NEW WORK ITEM EXTENSION

The GRRP WG developed a NWIE to further harmonize pre-market review processes

- Approved during the March 2021 MC meeting.
- Focuses on the development of a reporting model for medical device regulatory reviews conducted by CABs.
 - Involves the creation of a reporting template and work instruction to guide CABs in consistently evaluating marketing submissions and documenting their recommendations in marketing review reports.
- Provides the opportunity for convergence across RAs with respect to how medical devices are evaluated.



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CURRENT STATUS

- The IMDRF GRRP WG has begun working on the NWIE
 - Membership expanded to include both Regulators and representatives from CABs.
 - Initial draft reporting template developed.
 - Teleconferences held every 2 weeks.
- Goal is to submit the first draft to the MC for the March 2022 meeting for a 2-month public consultation period.



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THANK YOU

