



**IMDRF**

International Medical  
Device Regulators Forum

# **GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE**

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## GOOD REGULATORY REVIEW PRACTICES (GRRP)

### GOALS

The IMDRF Good Regulatory Review Practices (GRRP) working group has focused efforts on harmonizing premarket requirements in alignment with the IMDRF strategic priority to improve the effectiveness and efficiency of premarket review.

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

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

IMDRF GRRP  
WG/N52 FINAL:  
2019  
*Principles of  
Labelling*

NWIP:  
IMDRF GRRP  
WG/N59  
*Recognition  
Requirements for  
Premarket  
Review  
Organizations*



## CURRENT WORK ITEMS

IMDRF GRRP WG/N61: *Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews*

- Work item approved in June 2019
- Focuses on how regulatory authorities and their assessors will evaluate conformity assessment bodies for compliance to requirements in earlier documents N59 and N40, focusing on requirements for organizations conducting market reviews
  - Models the Medical Device Single Audit Program (MDSAP) by leveraging existing MDSAP documents and making modifications as necessary to accommodate premarket review requirements.
  - Utilizes some requirements outlined in ISO/IEC standards (e.g. ISO/IEC 17065)

Public consultation completed in May 2020.



## CURRENT WORK ITEMS

*IMDRF GRRP WG/N63: Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews*

- Work item approved in June 2019
- Focuses on competencies and training required for regulatory authorities and their assessors to adequately evaluate conformity assessment bodies for compliance to requirements in earlier documents N59 and N40, focusing on requirements for organizations conducting market reviews
  - Models the Medical Device Single Audit Program (MDSAP) by leveraging existing MDSAP documents and making modifications as necessary to accommodate premarket review requirements.

Public consultation completed in May 2020.



## NEW WORK ITEM

- The GRRP WG is planning for a NWIE to further develop the assessment and decision-making processes for the recognition of Conformity Assessment Bodies (CABs) performing premarket regulatory reviews
  - Intended to support IMDRF GRRP WG/N59: *Recognition Requirements for Medical Device Premarket Review Organizations*
  - Includes the development of 2 documents
  - To be submitted in the September 2020 MC meeting for review
- Goals
  - To create a complete regulatory recognition program for CABs performing premarket regulatory reviews



## NWIE

### 2 DOCUMENTS

1. Development of a decision making process for the recognition of the CABs
  - Based on IMDRF/MDSAP WG/N11 FINAL:2014: *MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization - MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization*
2. Development of audit report templates for CABs performing premarket reviews
  - Based on IMDRF/MDSAP WG/N24 FINAL:2015: *Medical Device regulatory Audit reports*



## BENEFITS

- Promotes consistency, predictability and transparency in the regulatory premarket review programs by developing an agreed upon set of criteria and processes.
- Provides assurances that premarket regulatory reviews conducted by CABs are rigorous enough to meet the requirements of Regulatory Authorities
- Benefits all regulators, even those just starting to develop a regulatory medical device premarket review system.



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## NEXT STEPS

- Submit final documents to IMDRF MC for consideration during the September 2020 IMDRF MC
- Submit NWIE to IMDRF MC for consideration during the September 2020 IMDRF MC
- Continue working on NWIE through teleconferences





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**THANK YOU**

