IMDRF International Medical Device Regulators Forum

GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

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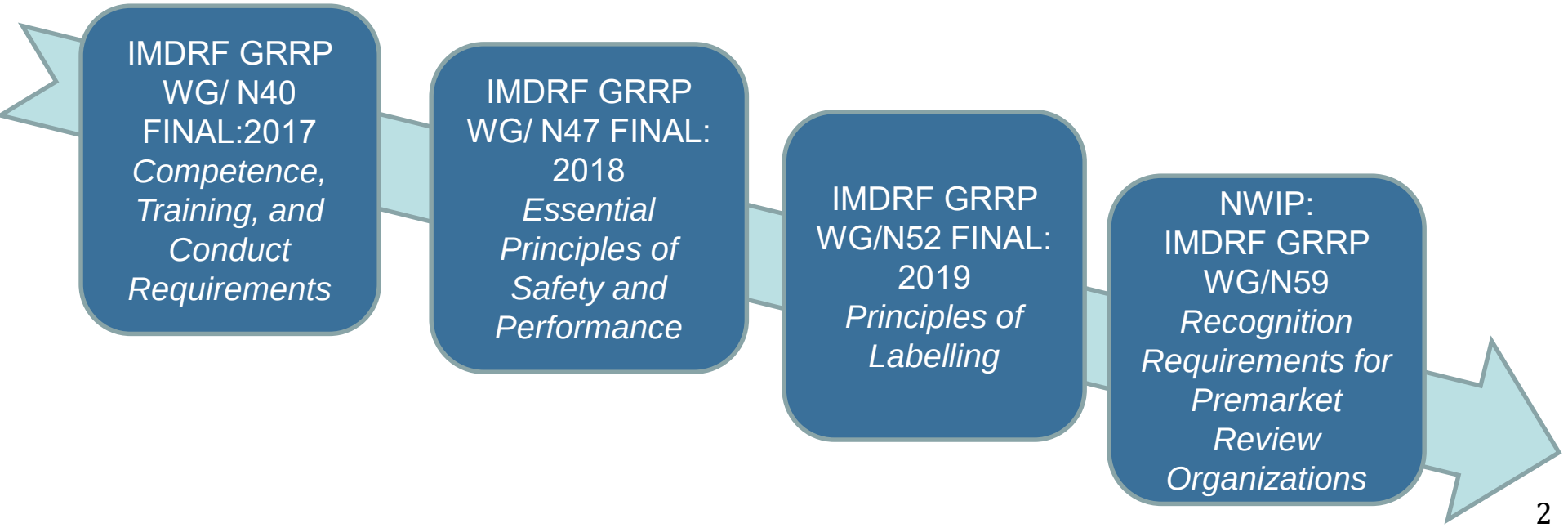
Good Regulatory Review Practices (GRRP) Goals

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.



CURRENT WORK ITEMS

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

- Work item approved in September 2018.
- Development of a conformity assessment/recognition program for medical device premarket review organizations
  - 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)

Draft document posted for public consultation →

Closes October 3, 2019

New Work Item Extension (NWIE)

- The GRRP WG submitted a NWIE to 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 3 documents
  - Approved June 2019
- Goals
  - To create a complete regulatory recognition program for CABs performing premarket regulatory reviews

NWIE
3 Documents

1. Development of an assessment process for CABs performing premarket reviews
   - Based on IMDRF/MDSAP WG/N5 FINAL:2013: *Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations* and IMDRF/MDSAP WG/N8 FINAL: 2015: *Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations.*
2. Development of training and competency requirements for the assessors of CABs
   - Based on IMDRF/MDSAP WG/N6 FINAL:2013: *Regulatory Authority Assessor Competence and Training Requirements*.
3. 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*.

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.

Next Steps

- Continue working on NWIE through teleconferences
- Face to face meeting from Nov 4-8, 2019 in Beijing to
  - Address public consultation comments and finalize *Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews*
  - Work on draft documents for NWIE
- *S*ubmit final and draft documents to IMDRF MC for consideration during the March 2020 IMDRF MC

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THANK YOU