IMDRF International Medical Device Regulators Forum

GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

Working Group Chair: Melissa Torres
US Food and Drug Administration

OVERVIEW

- IMDRF GRRP WG/N40 "Competence, Training, and Conduct Requirements for Regulatory Reviewers" draft document was posted for public consultation.
  - 90 day consultation period ended on Oct 14, 2016
  - Received ≈ 85 comments
- Face-to-face working group meeting was held in Geneva, Switzerland from Oct 24-28, 2016.
  - Comments received during the public consultation process were addressed
  - IMDRF GRRP WG/N40 was finalized
- IMDRF GRRP WG/N40 was sent to the IMDRF MC for consideration as a final document.

FINAL DOCUMENT

"Competence, Training, and Conduct Requirements for Regulatory Reviewers"

Purpose:

Defines a common set of conduct, education, experience, competence, and training requirements that shall be demonstrated and maintained by Regulatory Authorities and/or their recognized Conformity Assessment Body for personnel involved in performing regulatory reviews and any associated decision-making processes including:

- Defining knowledge, skills, and attributes.
- Defining criteria for various degrees of competence based on roles in reviews and decision-making functions.
- Assisting in staff evaluation and development.
- Providing a basis for identifying training needs.

Document Content

- Commitment to Impartiality and Confidentiality
  - Code of Conduct
- Competence Requirements
  - Foundational, Functional, and Technical
- Education
- Experience
- Training Requirements
  - Initial, Ongoing (Continual Professional Development and Maintenance)
- Competence Evaluation
- Establishing Independent Regulatory Review
- Records of Competence, Training, and Conduct
- Remediation

* Used IMDRF/MDSAP WG/N4FINAL: 2013 *Competence and Training Requirements for Auditing Organizations* and IMDRF/MDSAP WG/N6FINAL: 2013 *Regulatory Authority Assessor Competence and Training Requirements* as a basis.

ALIGNMENT WITH IMDRF STRATEGIC PRIORITY

Improve the Effectiveness and Efficiency of Pre-Market Review

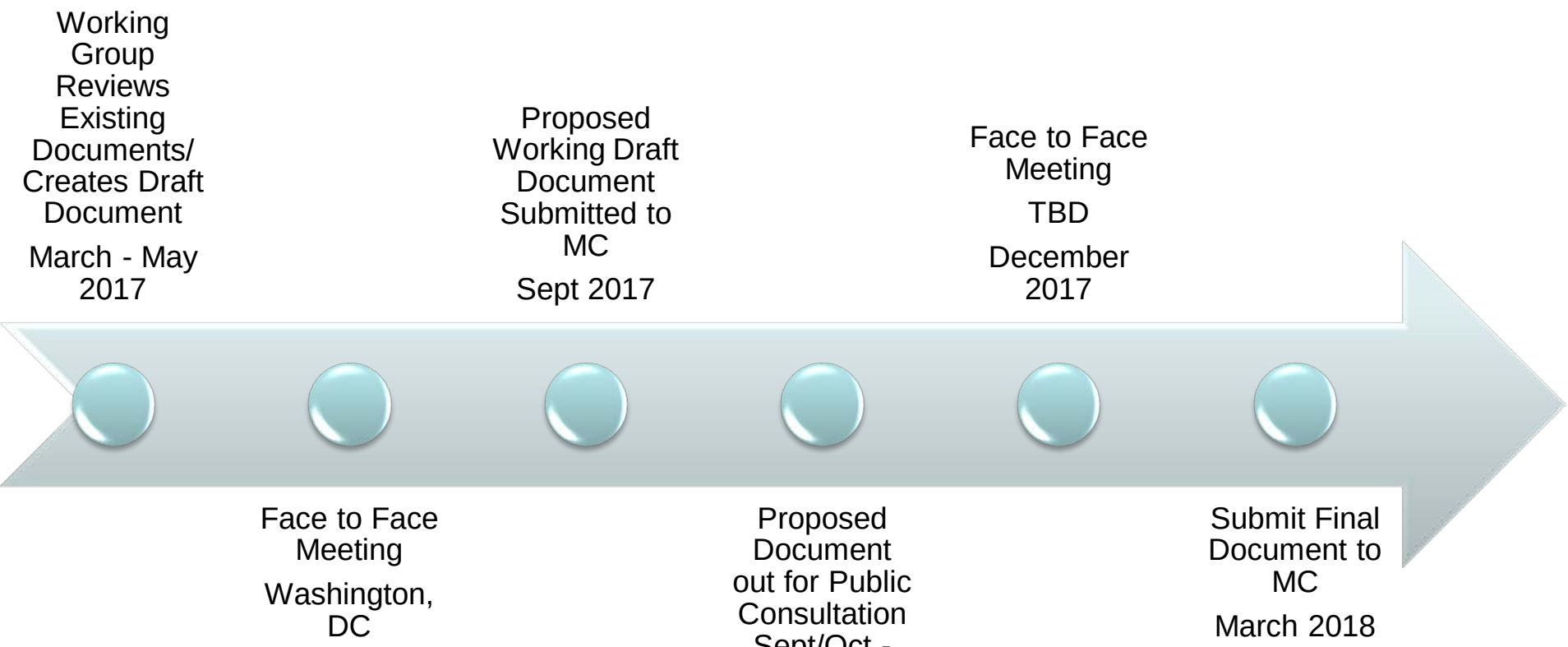
- Final document aligns with the IMDRF strategic priority and will be a first step towards improving the regulatory review process by addressing the competency, training, and conduct requirements for regulatory reviewers.

- Development of a NWIP to further improve the effectiveness and efficiency of premarket reviews.

NWIP

- WG discussed next steps at harmonizing premarket review processes during Geneva meeting.
- A NWIP was developed and submitted to the IMDRF MC for their consideration which focuses on revising GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices* to create a new/updated IMDRF document outlining essential principles that can be used as a foundation for creating a more harmonized premarket review process.
  - Feedback
  - New standards
    - ISO 16142-1:2016 *Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*
    - ISO/FDIS 16142-2 *Medical devices – Recognized essential principles of safety and performance of medical devices – Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards*

TIMELINE


Working Group Reviews Existing Documents/ Creates Draft Document
March - May 2017
Face to Face Meeting
Washington, DC
May 2017
Proposed Working Draft Document Submitted to MC
Sept 2017
Proposed Document out for Public Consultation Sept/Oct - Nov 2017
Face to Face Meeting
TBD
December 2017
Submit Final Document to MC
March 2018
Working group teleconferences

Ultimate Goal

- Development of a Medical Device Single Review Program (MDSRP) that will allow for a single regulatory premarket review to satisfy the needs of multiple regulatory jurisdictions.
  - Modelled after MDSAP
  - Aimed at promoting a harmonized approach to assessing conformity with safety and performance regulatory requirements
- Benefits may ultimately include:
  - Promoting consistency, predictability, transparency, and quality of regulatory programs and criteria for assessing premarket technical documentation for medical devices.
  - Greater global convergence of premarket requirements
  - Reduction of regulatory redundancies
  - Medical devices reaching patients quicker

MDSRP Considerations

- Examples of considerations that would need to be addressed to develop a program:
  - Training and competency requirements for the reviewer performing the assessment (already completed)
  - Types of submissions or device categories that are to be covered by the program and establishment of specific criteria for each of those
  - Legislative framework of each jurisdiction (e.g. timeframes, flexibility, specific requirements, etc.)
  - Harmonization of submission requirements (e.g. IMDRF ToC)
  - Harmonization of the review process
  - Accreditation of entities that will perform the assessments of premarket submissions
  - Programmatic implementation aspects

Next Steps

- If approved, GRRP WG will proceed with revision to GHTF/SG1/N68:2012

- GRRP WG will begin discussing considerations to start developing some of the foundational building blocks to a single review program

THANK YOU