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.
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/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*
Working Group Reviews Existing Documents/Creates Draft Document March - May 2017

Proposed Working Draft Document Submitted to MC Sept 2017

Face to Face Meeting TBD December 2017

Face to Face Meeting Washington, DC May 2017

Proposed Document out for Public Consultation Sept/Oct - Nov 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