IMDRF International Medical Device Regulators Forum

GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

Working Group Chair: Melissa Torres
Center for Devices and Radiological Health
US Food and Drug Administration

PROPOSED DOCUMENT

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

Purpose:

Define basic competence, training, and conduct requirements that shall be demonstrated and maintained by Regulatory Authorities and/or their designated 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.

Alignment with IMDRF Strategic Priority

Improve the Effectiveness and Efficiency of Pre-Market Review

- Proposed 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.
- Benefits may include:
  - Mitigating the risk of inconsistent or ineffective assessments
  - Providing greater opportunities to rely on other Regulatory Authority partners' work
  - Reducing regulatory redundancies
  - Having medical devices reach patients quicker

Current Membership

Australia	Elizabeth McGrath	TGA - Director Conformity Assessment, Medical Devices Branch
Brazil	Valter Pereira de Oliveira	ANVISA - IVD
	Thiberio Mundim Ferreira Pires	ANVISA - Equipment Office
	Camila Gonçalves Moreira	ANVISA - Materials Office
Canada	Caroline Vanneste	Health Canada - Manager, Good Review Practices Group
China	Yuxi Yang	CFDA - Reviewer, Division IV, Center for Medical Device Evaluation
	Shiqing Zhang	CFDA - Division of Quality Management, Center for Medical Device Evaluation
EU	Rob Higgins	MHRA
Japan	Aoyagi Yumiko	MHLW
	Koichi Aizawa	PMDA - Deputy Director, Office Medical Device II
	Takehiro Ichikawa	PMDA - Reviewer, Office Medical Device III
	Madoka Murakami	PMDA - Office of International Programs
Russia	Amiran Preobrazhenskiy	Roszdravnadzor - Counselor of the department of state registration of medical devices
	Vladimir Antonov	Roszdravnadzor - Assistant of the General Director of Federal State institution "Center for monitoring and clinical and economic expertise"
US	Melissa Torres (Chair)	US FDA - Associate Director for International Affairs
	Erin Keith	US FDA - Lead Product Quality Coordinator
WHO	Robyn Meurant	WHO - Prequalification Team – Diagnostics Assessment

Document Content

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

* Use of 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.

KEY CONCEPTS - CONDUCT

- Regulatory Reviewers must sign a code of conduct that is reaffirmed on a yearly basis and includes:
  - Commitment to confidentiality
  - Disclosure of any perceived, actual, or potential conflicts of interest

KEY CONCEPTS - TRAINING

- Minimum requirements for training:
  - Initial:
    - 32 hours of training in medical device law, regulations, and policy
    - 40 hours of training in scientific/technical issues
    - 8 hours of training on good regulatory review practices
  - Ongoing:
    - Continual Professional Development
      - 16 hours of training to augment existing technical competencies or acquire new technical competencies
    - Maintenance
      - Training on changes to regulatory requirements, business practices, etc.

Key Concepts - Competencies

Foundational

- Attitude, Integrity, Objectivity, Critical and Analytical Thinking, Interpersonal Skills, Adaptability, Tenacity, Perception, Cultural Sensitivity

Functional

- Information Technology, Business Processes, Teamwork, Conflict Resolution, Project Management, Communication, Time Management, Records Management, Autonomy

Technical

- Regulatory Requirements, Medical Devices, Voluntary Consensus Standards, Guidance Documents

Regulatory Review

- Completed in accordance with current regulations, guidance, standards, and/or policy
- Comprehensive and scientifically-based on the current body of knowledge
- Conducted in accordance with appropriate risk management principles
- Administratively complete

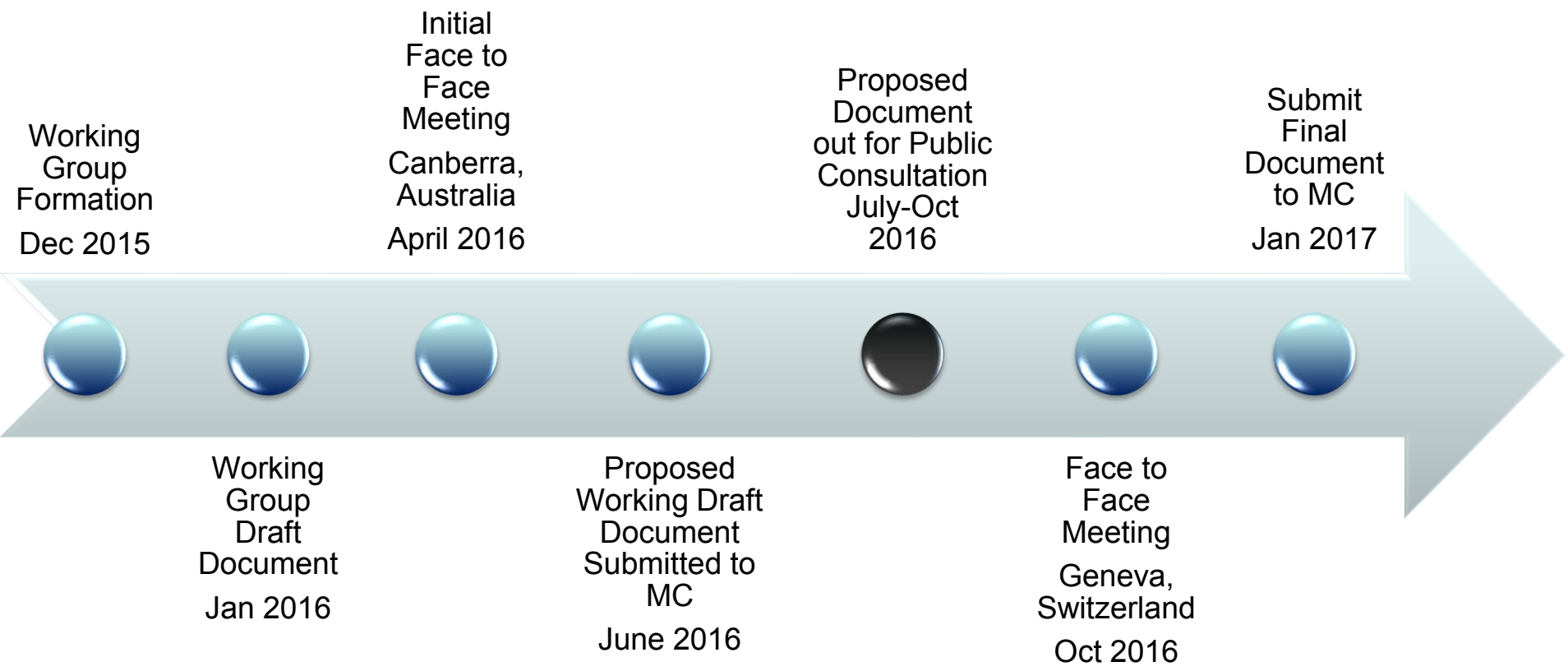
EVALUATION OF COMPETENCIES

Competence Level	Rating
Fully Demonstrated	3
Partially Demonstrated	2
To be Developed	1
Not Applicable	0

Evaluation of Foundational Competencies

Foundational Competencies	Evaluation Criteria	Rating
Attitude	Adheres to and upholds the laws, regulations, and policies of the Regulatory Authority.	
	Understands the impact of the regulatory review decisions that are made.	
Integrity	Demonstrates ethical behavior by ensuring integrity in personal and the Regulatory Authority and/or CAB's business practices.	
	Prevents and resolves any perceived, actual, or potential conflicts of interest.	
	Preserves confidentiality of classified information.	
	Is accountable for their own behavior and actions.	
Objectivity	Demonstrates the ability to judge fairly without partiality or external influence.	
Critical and Analytical Thinking	Demonstrates the ability to solve problems and make decisions based on sound logic and reasoning.	
	Utilizes reasoning to analyze, compare, and interpret information to solve problems.	
Interpersonal Skills	Connects and relates well with a diverse group of individuals including stakeholders and other individuals within the organization.	
Adaptability	Accepts feedback as an opportunity to learn and improve their skills.	

TIMELINE


Working Group Formation
Dec 2015
Working Group Draft Document
Jan 2016
Initial Face to Face Meeting
Canberra, Australia
April 2016
Proposed Working Draft Document Submitted to MC
June 2016
Proposed Document out for Public Consultation July-Oct 2016
Face to Face Meeting
Geneva, Switzerland
Oct 2016
Submit Final Document to MC
Jan 2017
Working group teleconferences

CURRENT STATUS

- Draft document posted for public consultation
  - 90 day consultation period ending on Oct 14, 2016
    - Due to timing, WG did not have the opportunity to ensure consistency in draft document with the new EU Medical Device Regulation
    - Consultation period was extended to 90 days and disclaimer added to document
    - WG will ensure all new applicable requirements in EU are incorporated/harmonized in the final document
- Face-to-face meeting in Geneva, Switzerland from Oct 24-28, 2016
  - Finalize IMDRF GRRP WG/N40 "Competence, Training, and Conduct Requirements for Regulatory Reviewers"
  - Discuss next steps for WG

THANK YOU