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

NWIP

Title: Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialists

Scope:

- Define knowledge, skills, and attributes for personnel carrying out pre-market review/assessment of technical documentation/design dossiers of "high-risk" medical devices.
- Define criteria for various degrees of competence and training needs based on roles.

GOALS

- Providing a common set of training and competency requirements can assure that certain aspects of the pre-market review process become more consistent across various Regulatory Authority partners thus allowing for greater opportunities to rely on other Regulatory Authority partners work.
- Innovative medical devices can reach the patients faster and more efficiently when Regulatory Authorities can partner and rely on consistent work performed by other Regulatory Authorities.
- Reduction of regulatory redundancies around the globe has positive effects of bringing safe medical devices to the patients around the world.

Alignment with IMDRF Strategic Priority

"Improve the Effectiveness and Efficiency of Pre-Market Review"

- This work item aligns with the strategic priority and will be a first step towards improving the pre-market review process by addressing the competencies and training requirements for pre-market reviewers.

IMDRF International Medical Device Regulators Forum

Current Membership

Australia	Dr. 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	Hideyuki Kondo	MHLW - Deputy Director, Medical Device and Regenerative Medicine Product Evaluation Division
Russia	Amiran Preobrazhenskiy	Roszdravnadzor - Counsellor 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 – Acting Associate Director, International Affairs
WHO	Robyn Meurant	WHO - Prequalification Team – Diagnostics Assessment

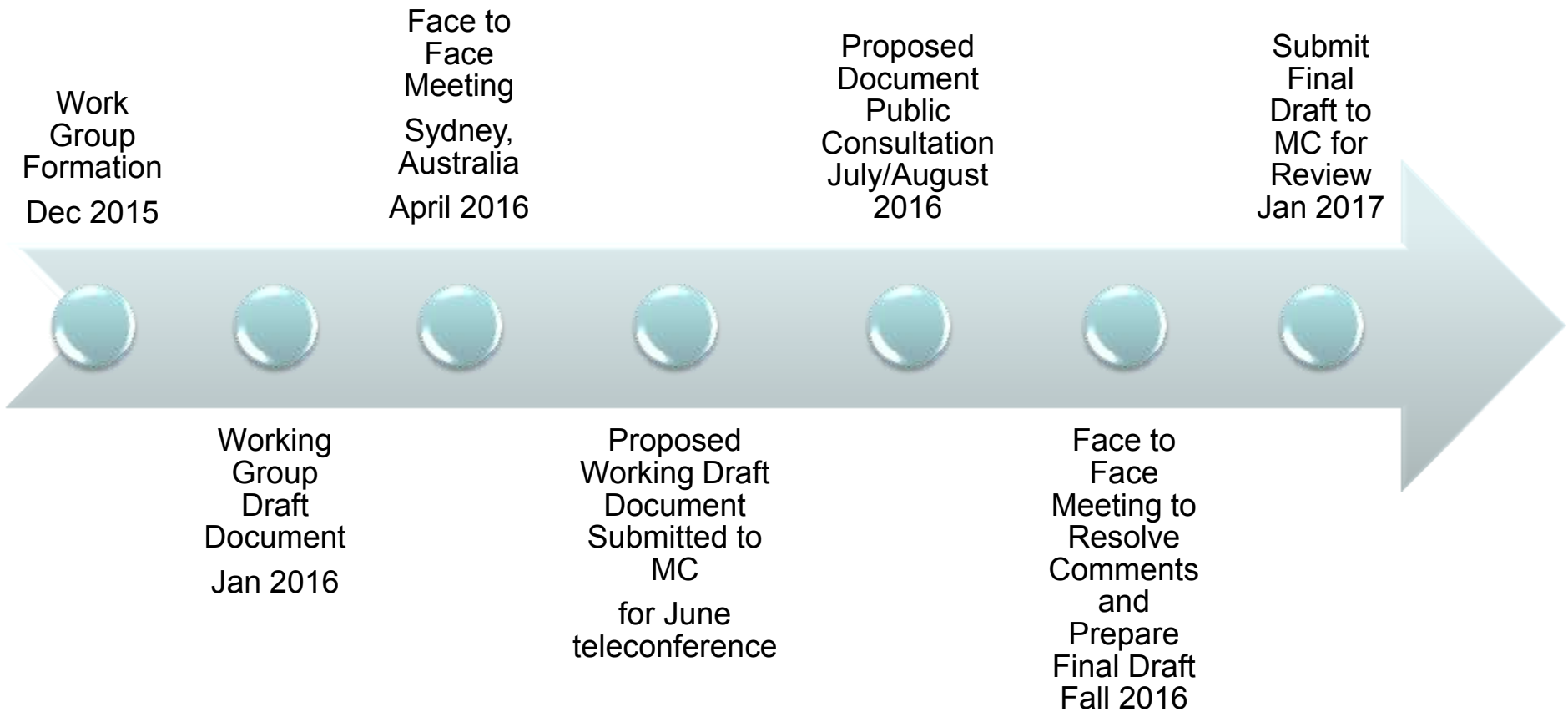
Working Draft Document

- Use of IMDRF/MDSAP WG/N4FINAL:2013 as basis.
- Proposed document content includes:
  - Commitment to Impartiality and Confidentiality
  - Entry Level Requirements
  - Training Requirements
  - Experience Requirements
  - Competence Evaluation
  - Reaffirmation of Code of Conduct
  - Records of Pre-requisites, Competence Evaluation and Monitoring
  - Remediation

Relevant Documents

- IMDRF/MDSAP WG/N4FINAL:2013
- Commission Implementing Regulation (EU) N° 920/2013
- Commission Recommendation 2013/473/EU
- Annex VI of the new EU regulation on medical devices
- US FDA Reviewer Certification Program
- Other IMDRF Members Reviewer competence or training specifications

TIMELINE


Work Group Formation
Dec 2015
Working Group Draft Document
Jan 2016
Face to Face Meeting
Sydney, Australia
April 2016
Proposed Working Draft Document Submitted to MC
for June teleconference
Proposed Document Public Consultation July/August 2016
Face to Face Meeting to Resolve Comments and Prepare Final Draft
Fall 2016
Submit Final Draft to MC for Review
Jan 2017
Routine working group teleconferences

CURRENT STATUS

- Working group formed
- Working group draft document created
- Comments received from working group on initial draft
- Routine teleconferences
- Working group gathering resources from each of their respective Regulatory Authority to ensure harmonization of requirements

THANK YOU