IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

14:00 – 14:15

Quality Management Systems (USA / EU)

Melissa Torres

Associate Director, U.S. Food and Drug Administration

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Quality Management System (QMS) Working Group Update

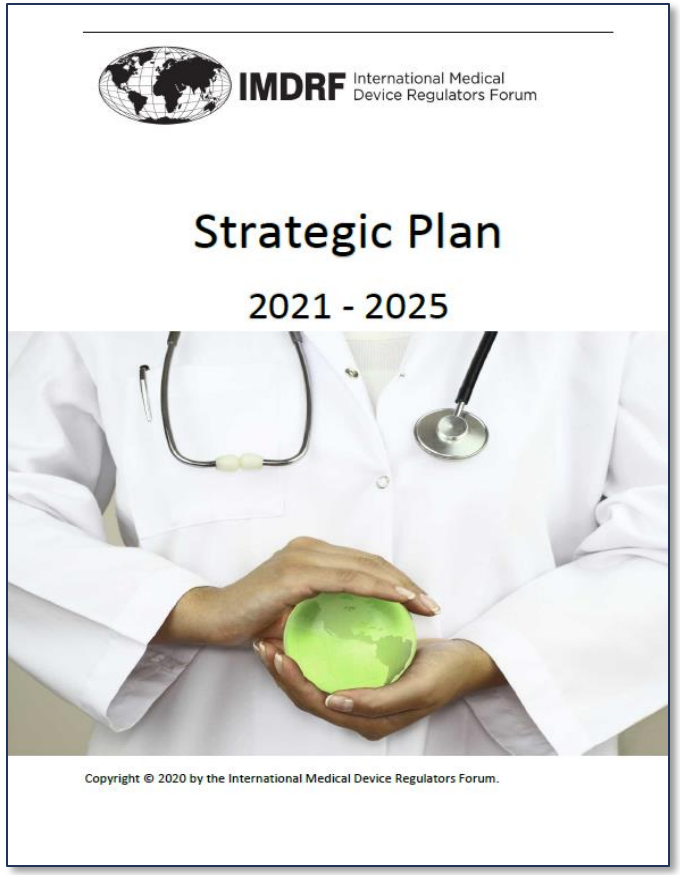
Co-Chairs:
Mairead Finucane – EC
Melissa Torres – US FDA

Background

- Quality management systems and risk management activities are integral principles to ensuring the design and manufacture of safe and effective medical devices
- While pre-market requirements can address known and foreseeable risks, an effective post-market surveillance system is necessary to manage evolving and new risks effectively
  - An effective post-market surveillance system is critical to continuously monitor feedback and implement improvements in a controlled manner under the manufacturer's quality management system to make the medical device better in its future versions or iterations
- It is important to have up to date guidance on QMS and risk management requirements outlined in ISO 13485 and ISO 14971 in order to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices.

Rationale

- Existing GHTF QS SG3 documents are outdated (2004-2010)
- QMS and risk management principles have evolved since the creation of the original GHTF documents
- Requirements within the various jurisdictions have also evolved
- GHTF documents are based on previous versions of ISO 13485 and ISO 14971 and should be updated to be in alignment with current versions of the standards
- Work is in alignment with several key objectives of the IMDRF strategic plan



Goals

Revise existing GHTF Study Group 3 Quality Systems documents:

- **GHTF/SG3/N17:2008 Guidance on the Control of Products and Services Obtained from Suppliers**
- GHTF/SG3/N18:2010 Guidance on Corrective and Preventive Action
- GHTF/SG3 N15R8: 2005 Risk Management Principles
- GHTF/SG3/N99-10:2004 Process Validation Guidance

Current Status

- New Work Item Proposal approved in September 2022
- Received agreement amongst leadership of IMDRF, GHWP, and ISO to do this work jointly amongst the 3 organizations
- Working group is currently being established
  - Call for participants/representatives from IMDRF/GHWP regulatory authorities, ISO TC 210 WG1, and industry
  - IMDRF website updates
  - Expect work to begin in the next couple of weeks

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Thank you!
Questions?

Email melissa.torres@fda.hhs.gov
Mairead.FINUCANE@ec.europa.eu