IMDRF International Medical Device Regulators Forum

Quality Management System (QMS)

Co: Chairs: Máiréad Finucane– European Commission
Melissa Torres – US FDA

About US

Background:

- QMS/risk management activities integral principles to ensuring the design and manufacture of safe & effective medical devices.
- Existing GHTF QS SG3 documents are outdated (2004-2010)
- GHTF documents are based on previous versions of ISO 13485 and ISO 14971
- QMS and risk management principles /requirements within various jurisdictions have evolved
- Necessary to update GHTF documents to reflect current state of the art.

About US

Membership:

- Co-chairs: Mairead Finucane/Maria Del Carmen Sanz, European Commission (EU) & Melissa Torres, US FDA
- Global regulators & stakeholders (including notified bodies)
- Support from TC210

Scope:

- Revision of outdated GHTF SG3 documents
- Alignment with current versions of ISO 13485 & ISO 14971

Publications (if any)

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

Ongoing work (or upcoming work if new work item)

- First Work Item: update of the ***GHTF Guidance on the Control of Products and Services Obtained from Suppliers***. The group initially met on a biweekly basis (with written collaboration in between) followed by a series of 4 consecutive intense meetings from 14 to 19th May 2025
- Completed: Final working draft of the guidance document. Complete overview of the document to align it with:
  - current ISO 13485 and ISO 14971 standards
  - best practices
  - practical examples of what is expected as the control of suppliers by a manufacturer.

Ongoing work (or upcoming work if new work item)

Next steps

Request for advancement of the Guidance on the Control of Products and Services Obtained from Suppliers document to Proposed Document stage: to be authorised by the IMDRF MC.

If the decision is positive, the document to be published in the IMDRF website for a consultation period of 3 months.

Opportunities and Challenges

- Prepare for review of (any) comments received after consultation period
- Prioritisation of work items – consider which existing GHTF document to next revise
- Consideration of face-to-face meeting of the group (quite a large number of members)
- Change of co-chairs

Thank you/Questions