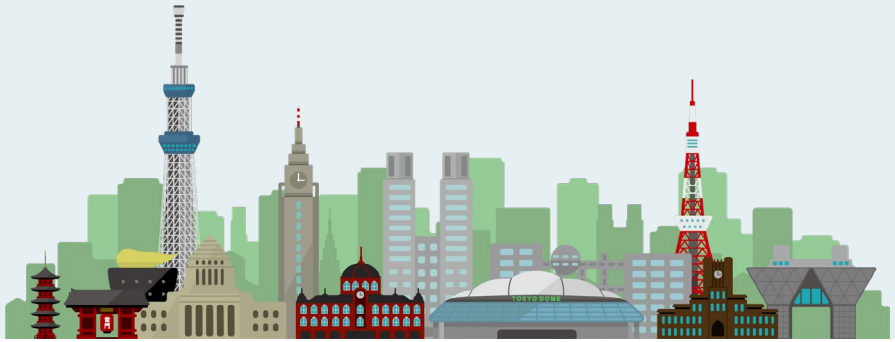
IMDRF International Medical Device Regulators Forum



# Quality Management System (QMS)

Co-chairs: Máiréad Finucane / Maria Del Carmen Sanz – EC
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- Existing GHTF QS SG3 documents are outdated (2004-2010)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- Revision of outdated GHTF SG3 documents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

- Working group nominations approved by IMDRF Management Committee 30-31 March 2023.

# Existing Publications

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

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# Ongoing work

- First Work Item: update of the GHTF Guidance on the Control of Products and Services Obtained from Suppliers. Completed:
  - Design requirements document
  - High level overview to align with current ISO 13485 and ISO 14971 standards.
  - More detailed revisions of each section of the document completed/underway

- ***A tentative planning has been agreed within the WG, with as estimation to complete the new draft of the guidance by the end of May 2025. Relevant consultations to follow.***

# Upcoming work

- Transfer other previously issued GHTF documents into IMDRF templates
- Review alignment / perform gap analysis regarding each previously issued GHTF QMS documents compared to advances in QMS and Risk Management principles
  - Propose changes needed to GHTF QMS documents and/or the need to develop additional documents
  - Revise previously issued GHTF QMS documents and if necessary, prepare outline for new document
- Publish proposed draft(s) for public comment
- Publish final documents

# Opportunities and Challenges

- 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)

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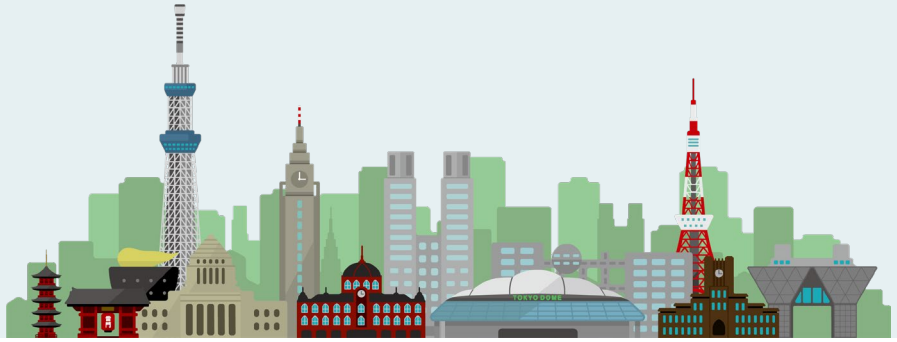

# Thank you/Questions