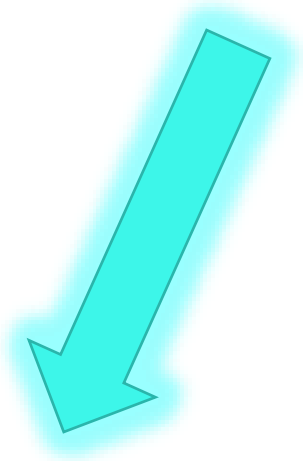
IMDRF International Medical Device Regulators Forum

Quality Management System (QMS) Working Group Update

Co-Chairs:

Máiréad Finucane / Maria Del Carmen Sanz – EC

Melissa Torres – US FDA



Provide your feedback on this Working Group!

Follow this link and let us know:

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IMDRF 24th Session – Berlin, Germany

About US

- Quality management systems and risk management activities are integral principles to ensuring the design and manufacture of safe and effective medical devices
- Existing GHTF QS SG3 documents are outdated (2004-2010)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

Therefore, the aim of the working group is 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.

Working Group Establishment

- 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 organisations
- Working group nominations have been approved by IMDRF Management Committee at last meeting. Participants/representatives from:
  - IMDRF/GHWP regulatory authorities
  - ISO TC 210 WG1
  - Industry, and
  - Notified bodies

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

Opportunities and Challenges

- Transfer of old GHTF documents into IMDRF templates
- Prioritisation of work items
- Proposal to begin with the update supplier controls (GHTF/SG3/N17:2008 Guidance on the Control of Products and Services Obtained from Suppliers)
- First meeting of the working group to be scheduled after Management Committee meeting

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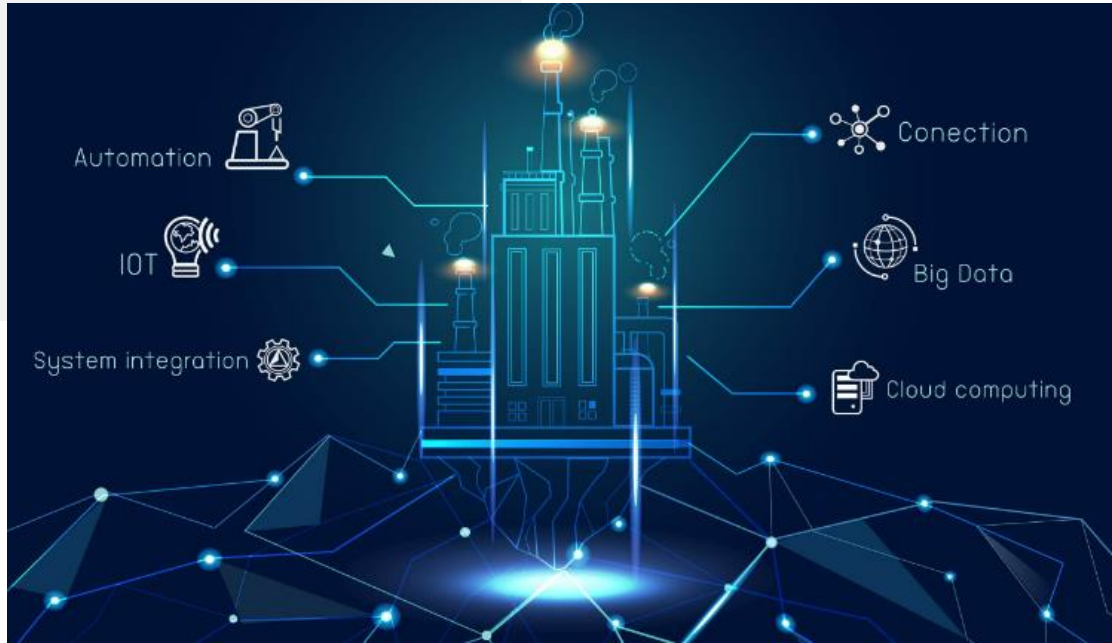

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Thank you/Questions

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