



# Q1 CHECKLIST:

## GENERAL AWARENESS & EDUCATION

Quality Management Learning Series | Foundations Certificate



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### Q1 Outcomes

By the end of Q1, participants should be able to:

- Explain the purpose and importance of ISO 13485
- Describe the core elements of a compliant QMS
- Understand foundational regulatory and audit expectations
- Recognise the importance of documentation, traceability, and risk management
- Identify key gaps or next steps within their own organisation's quality processes

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### Article 1: What Is ISO 13485?

- Understand the purpose of ISO 13485
- Learn how ISO 13485 supports product safety, quality, and regulatory compliance
- Understand the relationship between ISO 13485 and global regulations (FDA, MDR, IVDR, MDSAP)
- Recognise why ISO 13485 is important for startups and scaling companies
- Understand the role of a Quality Management System (QMS) across the product lifecycle

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### Article 2: Understanding ISO 13485

- Understand the structure and intent of ISO 13485:2016
- Understand key principles, including risk management, traceability, document control, and continuous improvement
- Learn the six core implementation questions for small medtech companies
- Understand the role of leadership and organisational accountability

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### Article 3: Understanding QMS Requirements

- Develop a basic understanding of Quality Manuals, SOPs, risk management, internal audits, CAPA processes, complaint handling, and post-market surveillance
- Understand document and record control requirements
- Learn how supplier management fits into the QMS
- Learn the purpose of the Quality Management Representative (QMR) role
- Recognise the importance of traceability and evidence retention

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### Article 4: ISO 13485 Compliance & Audits

- Understand different audit types, including certification, surveillance, internal, and unannounced audits
- Learn the stages of an ISO 13485 audit
- Understand common audit focus areas, including training records, supplier management, risk management, CAPA, complaint handling, and documentation control
- Learn the difference between minor and major nonconformities
- Review internal audit preparation best practices

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### Templates, Tools & Support

- Review the provided QMM (Quality Management Manual) template
- Review the Intended Use template
- Identify which templates and processes are applicable to your organisation
- Begin adapting templates to suit your product and regulatory pathway
- Reach out to Anne Arndt, Elevate MedTech, or the HealthTech Activator team with any questions or support needs

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### Webinar: Introduction to ISO 13485

- Watch the webinar: Introduction to ISO 13485 – Quality Management Series Webinar
- Identify any follow-up actions relevant to your organisation

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### Whitepaper

- Read the Q1 whitepaper: Building a Quality-Driven Culture in Medical Device Organisations for ISO 13485
- Highlight key implementation insights
- Identify practical actions applicable to current processes

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### Quiz & Certification

Complete the Q1 quiz assessment



Reach out to the HealthTech Activator team to receive the Q1 Certificate



Progress toward the full ISO 13485 QMS Certificate of Completion