



Q2 CHECKLIST:

IMPLEMENTATION & BEST PRACTICES

Quality Management Learning Series | Implementation Certificate

1 Q2 Outcomes

By the end of Q2, participants should be able to:

- Understand how to set up a QMS in line with ISO 13485
- Develop foundational QMS procedures and process controls
- Apply risk-based thinking to implementation activities
- Recognise common implementation challenges and how to avoid them
- Identify next steps toward audit readiness and certification

2 [Article 5: Step-by-Step Guide to Implementing a QMS That Meets ISO 13485 Standards](#)

- Understand the phased, risk-based approach to QMS implementation
- Define intended use, target markets, and product scope
- Map current processes and identify key gaps and priorities
- Develop foundational SOPs, quality documentation, and evidence records
- Conduct a pilot implementation, internal audit, and management review
- Prepare for certification readiness and audit preparation

3 [Article 6: Top 10 Common Pitfalls When Building an ISO 13485-Compliant QMS](#)

- Recognise common implementation pitfalls and how to avoid them
- Avoid overly complex or impractical procedures
- Apply risk-based thinking throughout QMS implementation
- Maintain effective document control, training, and process review practices
- Understand how implementation shortcuts can create future compliance challenges

4 [Article 7: How to Align Your QMS with ISO 13485: From Documentation to Culture](#)

- Understand the importance of leadership engagement and quality culture
- Encourage cross-functional ownership and accountability
- Support continual improvement through communication, training, and quality awareness
- Align quality processes with real-world business workflows
- Develop a scalable QMS that supports long-term growth

5 [Webinar: Implementation & Best Practices](#)

- Watch the Q2 webinar: [A step-by-step example for setting up a QMS](#)
- Review implementation case studies and practical examples
- Identify practical implementation actions relevant to your organisation

6 [Whitepaper:](#)

- Read the Q2 whitepaper: [Implementation & Best Practices: Building a QMS Compliant with ISO 13485 and Beyond](#)
- Understand eQMS, AI/ML, and cybersecurity
- Understand risk management across the lifecycle
- Review implementation roadmaps and common pitfalls
- Identify practical implementation approaches

7

[Quiz & Certification](#)

[Complete the Q2 quiz assessment](#)



Reach out to the [HealthTech Activator](#) team to receive the Q2 Certificate



Progress toward the full ISO 13485 QMS Certificate of Completion