



Q3 CHECKLIST:

GENERAL RISK & EFFICIENCY

Quality Management Learning Series | Risk & Efficiency Certificate

1 Q3 Outcomes

By the end of Q3, participants should be able to:

- Understand how risk management integrates into a compliant QMS
- Apply lean, risk-based thinking across QMS processes
- Recognise opportunities to improve efficiency without reducing compliance
- Understand how quality systems can support commercial and strategic goals

2 Article 8: Risk Management in QMS

- Understand how ISO 14971 risk management integrates into ISO 13485
- Understand the difference between product risk and QMS process risk
- Learn how risk-based thinking supports safer and more effective devices
- Understand how risk management should be applied across the product lifecycle
- Learn how risk management supports FDA, MDR, IVDR, and TGA compliance

3 Article 9: Lean & Risk-Based Compliance

- Understand how lean, risk-based QMS approaches reduce unnecessary complexity
- Learn how risk tiers guide SOPs, audits, CAPA, validation, and supplier controls
- Understand how severity and occurrence influence risk-based decisions
- Recognise common causes of over-documentation and administrative burden
- Understand how digital tools and eQMS systems can support high-risk processes

4 Article 10: Compliance as a Competitive Advantage

- Understand how ISO 13485 certification can support commercial growth and market trust
- Learn how a mature QMS can improve operational efficiency and reduce rework
- Understand how post-market surveillance and complaint data can support product improvements
- Recognise how strong quality systems can support innovation, investors, and strategic partnerships

5 Webinar: Risk & QMS

- Watch the Q3 webinar: [Driving Quality Forward - Risk & Efficiency Strategies for ISO 13485 Success](#)
- Review practical examples of risk-based quality management and implementation strategies
- Understand how risk management supports compliance, efficiency, and continual improvement
- [Read the webinar summary](#)

6 Whitepaper

- [Read the Q3 whitepaper: Risk & Efficiency in ISO 13485: A Practical Guide to Lean, Risk-Based Quality Management Systems](#)
- Identify opportunities to apply lean, risk-based thinking within your organisation

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Quiz & Certification
[Complete the Q3 quiz assessment](#)



Reach out to the [HealthTech Activator](#) team to receive the Q3 Certificate



Progress toward the full ISO 13485 QMS Certificate of Completion