Q4 CHECKLIST:
AUDITS & INSPECTIONS

Quality Management Learning Series | Audits & Inspections Certificate

1 Q4 Outcomes

By the end of Q4, participants should be able to:

- ☐ Understand how to prepare for ISO 13485 audits and inspections
- ☐ Apply audit readiness principles across documentation, records, and processes
- ☐ Understand how internal audits support continual improvement
- ☐ Recognise common causes of recurring quality issues and how CAPA addresses them
- ☐ Identify opportunities to strengthen audit readiness within their organisation

2 Article 11: Audit Strategies in MedTech – Start-ups vs Established Companies

- ☐ Understand how audit expectations differ between startups and established manufacturers
- ☐ Learn practical audit strategies appropriate to different stages of company maturity
- ☐ Recognise what auditors look for during certification, surveillance, and partner audits
- ☐ Understand how to build audit readiness from day one
- ☐ Learn how audit findings can support business improvement

3 Article 12: Preparing for a Successful ISO 13485 Audit: Checklist and Tips

- ☐ Understand the three key areas auditors assess: completeness, implementation, and effectiveness
- ☐ Learn how to prepare documentation, records, and evidence for audit day
- ☐ Understand the importance of audit readiness across the entire organisation
- ☐ Learn practical techniques for reducing audit stress and improving confidence
- ☐ Review a structured ISO 13485 audit preparation checklist

4 Article 13: Internal Audits for ISO 13485: How to Build an Effective Process

- ☐ Understand the requirements of ISO 13485 internal audits
- ☐ Learn how risk-based thinking should influence audit planning and scheduling
- ☐ Recognise common internal audit challenges including impartiality, auditor competency, and finding classification
- ☐ Understand how internal audits support continual improvement
- ☐ Learn practical approaches for managing audit findings and corrective actions

5 Article 14: CAPA in an ISO 13485-Compliant QMS: Avoiding Recurring Issues

- ☐ Understand the difference between correction, corrective action, and preventive action
- ☐ Learn how to conduct effective root cause investigations
- ☐ Recognise common reasons why quality issues recur
- ☐ Understand how CAPA integrates with complaints, audits, supplier controls, and risk management
- ☐ Learn how effectiveness checks verify long-term improvement

6 Webinar: Risk-Driven Internal Audits: Turning ISO 13485 Checks into Real Insight

- ☐ Watch the webinar: Risk-Driven Internal Audits: Turning ISO 13485 Checks into Real Insight
- ☐ Understand how risk-based internal audits create value beyond compliance
- ☐ Learn practical approaches for developing meaningful audit programmes
- ☐ Read the webinar summary

7 Whitepaper: Audits & Inspections

- ☐ Audit-Ready by Design Turning ISO 13485 Audits and Inspections into a Strategic Advantage
- ☐ Identify opportunities to apply lean, risk-based thinking within your organisation

8 Quiz & Certification

Complete the Q4 quiz assessment → Reach out to the HealthTech Activator team to receive the Q4 Certificate → Progress toward the full ISO 13485 QMS Certificate of Completion