



QUALITY AND PRODUCTIVITY | QP-022

Medical Device Quality Management (ISO 13485)

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Course content

Why Attend

Medical device manufacturers must maintain quality management systems that meet ISO 13485 and regulatory requirements such as the EU Medical Device Regulation. Compliance is essential for market access and patient safety.

This Aractech course explains ISO 13485 requirements, risk management links, design and development controls, purchasing and supplier controls, production and process validation, complaint handling and vigilance, CAPA and regulatory interfaces. Participants assess gaps in a case quality system.

Course Methodology

- Standard walkthroughs
- Case studies
- Gap assessment exercise
- Group discussions
- Documentation reviews

Course Objectives

- Explain ISO 13485 structure and requirements
- Apply design and development controls
- Manage suppliers and purchasing
- Validate production processes
- Handle complaints, vigilance and CAPA
- Prepare for audits and regulatory inspections

Target Audience

- Medical device quality professionals



Course content

- Regulatory affairs staff
- Design engineers
- Production managers

Course outline

Detailed course outline

Day-by-day outline for Medical Device Quality Management (ISO 13485).

Day 1 - ISO 13485 Overview

- 09:00-09:39 | Medical device regulation context
- 09:39-10:18 | Structure of ISO 13485
- 10:18-10:57 | Differences from ISO 9001
- 10:57-11:00 | Documentation
- 11:00-11:30 | Coffee break
- 11:30-12:05 | Documentation (continued)
- 12:05-12:43 | Management responsibility
- 12:43-14:00 | Exercise: Gap assessment start

Day 2 - Design and Risk

- 09:00-09:54 | Design and development controls
- 09:54-10:48 | Design reviews and verification
- 10:48-11:00 | Risk management links
- 11:00-11:30 | Coffee break
- 11:30-11:45 | Risk management links (continued)
- 11:45-12:12 | Usability
- 12:12-13:06 | Design transfer
- 13:06-14:00 | Workshop: Design control review

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Day 3 - Suppliers and Production

- 09:00-09:39 | Supplier controls
- 09:39-10:18 | Purchasing
- 10:18-10:57 | Process validation
- 10:57-11:00 | Sterilisation and cleanliness
- 11:00-11:30 | Coffee break
- 11:30-12:05 | Sterilisation and cleanliness (continued)
- 12:05-12:43 | Traceability
- 12:43-14:00 | Exercise: Process validation plan

Day 4 - Post-Market Processes

- 09:00-09:39 | Complaint handling
- 09:39-10:18 | Vigilance reporting
- 10:18-10:57 | CAPA
- 10:57-11:00 | Recalls
- 11:00-11:30 | Coffee break
- 11:30-12:05 | Recalls (continued)
- 12:05-12:43 | Post-market surveillance
- 12:43-14:00 | Case study: Device complaint

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Day 5 - Audits and Improvement

- 09:00-09:45 | Internal audits
- 09:45-10:30 | Notified body audits
- 10:30-11:00 | Management review
- 11:00-11:30 | Coffee break
- 11:30-11:45 | Management review (continued)
- 11:45-12:30 | Continuous improvement
- 12:30-13:15 | Regulatory updates
- 13:15-14:00 | Capstone: Quality system gap report

Seminar dates

Available seminar dates

Live dates and pricing for Medical Device Quality Management (ISO 13485) generated from the course details page.

Date	Location	Format	Fee
16 - 20 November 2026	Vienna	Classroom	€3,225
7 - 11 December 2026	Barcelona	Classroom	€2,815
11 - 15 January 2027	Rome	Classroom	€3,460
8 - 12 February 2027	Munich	Classroom	€3,225
8 - 12 March 2027	Amsterdam	Classroom	€2,830
12 - 16 April 2027	London	Classroom	€2,315
10 - 14 May 2027	Istanbul	Classroom	€1,978
14 - 18 June 2027	Vienna	Classroom	€3,225
12 - 16 July 2027	Barcelona	Classroom	€2,815
9 - 13 August 2027	Rome	Classroom	€3,460

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13 - 17 December 2027	Istanbul	Classroom	€1,978
16 - 20 November 2026	Online / Live	Online / Live	€1,815
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14 - 18 June 2027	Online / Live	Online / Live	€1,815
12 - 16 July 2027	Online / Live	Online / Live	€1,815
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