

QUALITY & OPERATIONAL EXCELLENCE | COURSE BROCHURE

Medical Device Quality Systems Awareness

5 days | Classroom training | English

SMART HORIZON

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Course content

Why attend

Medical device manufacturers and suppliers must meet strict quality system requirements. This course provides awareness of medical device quality systems: ISO 13485, regulatory frameworks, design controls, risk management with ISO 14971, process validation, complaints and vigilance, post-market surveillance and supplier controls.

Medical device quality failures can harm patients and halt market access. You will understand the key requirements and how they fit together.

Professional Problems This Course Is Designed to Solve

• Difficulty translating subject knowledge into practical workplace decisions.
• Inconsistent approaches to the activities covered in the course outline.
• Lack of a structured plan for applying and reviewing new skills.

Course methodology

Standard walkthroughs, case studies of recalls, risk management exercises and document reviews.

Course objectives

By the end of this course, participants will be able to:
• Explain medical device regulatory frameworks
• Understand ISO 13485 requirements
• Describe design controls
• Apply risk management principles
• Understand process validation requirements
• Manage complaints, vigilance and post-market surveillance

Target audience

This course is suitable for:
• Quality staff in medical device companies
• Engineers and production staff
• Suppliers to medical device manufacturers
• Regulatory affairs staff
• Auditors



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Target competencies

Participants will develop competencies in:

- Regulatory awareness
- QMS requirements
- Risk management
- Validation
- Post-market surveillance

Course outline

Day 1: Medical Device Regulation

09:00–10:08	Regulatory frameworks
10:08–11:00	Device classification
11:00–11:30	**Coffee break**
11:30–11:45	Device classification (continued)
11:45–12:53	Market access
12:53–14:00	Exercise

Day 2: ISO 13485

09:00–10:08	Structure
10:08–11:00	Key requirements
11:00–11:30	**Coffee break**
11:30–11:45	Key requirements (continued)
11:45–12:53	Documentation
12:53–14:00	Workshop

Day 3: Design and Risk

09:00–10:08	Design controls
10:08–11:00	ISO 14971 risk management
11:00–11:30	**Coffee break**



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11:30–11:45	ISO 14971 risk management (continued)
11:45–12:53	Usability
12:53–14:00	Exercise

Day 4: Production

09:00–10:08	Process validation
10:08–11:00	Supplier controls
11:00–11:30	**Coffee break**
11:30–11:45	Supplier controls (continued)
11:45–12:53	Traceability
12:53–14:00	Case study

Day 5: Post-Market

09:00–10:08	Complaints
10:08–11:00	Vigilance
11:00–11:30	**Coffee break**
11:30–11:45	Vigilance (continued)
11:45–12:53	Post-market surveillance
12:53–14:00	Action plan

The timings provided are estimates and may vary depending on the number of participants and the discussions taking place during the sessions. They are indicative only and do not constitute a binding commitment.



Course content

Dates, venues and fees

Current published course plans. Fees are per participant in EUR, excluding unconfirmed taxes.

Venue	Start date	End date	Fee (EUR)
Vienna Confirmed dates	23 Nov 2026	27 Nov 2026	**€2,940.–**
Online Confirmed dates	23 Nov 2026	27 Nov 2026	**€1,250.–**
Cape Town Confirmed dates	14 Dec 2026	18 Dec 2026	**€1,890.–**
Online Confirmed dates	14 Dec 2026	18 Dec 2026	**€1,250.–**
Rome Confirmed dates	18 Jan 2027	22 Jan 2027	**€2,450.–**
Online Confirmed dates	18 Jan 2027	22 Jan 2027	**€1,250.–**
Dubai Confirmed dates	8 Feb 2027	12 Feb 2027	**€3,150.–**
Online Confirmed dates	8 Feb 2027	12 Feb 2027	**€1,250.–**
London Confirmed dates	22 Feb 2027	26 Feb 2027	**€2,450.–**



Course content

Dates, venues and fees (continued)

Venue	Start date	End date	Fee (EUR)
Online Confirmed dates	22 Feb 2027	26 Feb 2027	**€1,250.–**
Rome Confirmed dates	15 Mar 2027	19 Mar 2027	**€2,450.–**
Online Confirmed dates	15 Mar 2027	19 Mar 2027	**€1,250.–**
Amsterdam Confirmed dates	5 Apr 2027	9 Apr 2027	**€2,540.–**
Online Confirmed dates	5 Apr 2027	9 Apr 2027	**€1,250.–**
Dubai Confirmed dates	26 Apr 2027	30 Apr 2027	**€3,150.–**
Online Confirmed dates	26 Apr 2027	30 Apr 2027	**€1,250.–**
Barcelona Confirmed dates	17 May 2027	21 May 2027	**€2,840.–**
Online Confirmed dates	17 May 2027	21 May 2027	**€1,250.–**



Course content

Dates, venues and fees (continued)

Venue	Start date	End date	Fee (EUR)
Paris Confirmed dates	31 May 2027	4 Jun 2027	**€2,860.-**
Online Confirmed dates	31 May 2027	4 Jun 2027	**€1,250.-**
Istanbul Confirmed dates	21 Jun 2027	25 Jun 2027	**€2,650.-**
Online Confirmed dates	21 Jun 2027	25 Jun 2027	**€1,250.-**
Dubai Confirmed dates	12 Jul 2027	16 Jul 2027	**€3,150.-**
Online Confirmed dates	12 Jul 2027	16 Jul 2027	**€1,250.-**
London Confirmed dates	2 Aug 2027	6 Aug 2027	**€2,450.-**
Online Confirmed dates	2 Aug 2027	6 Aug 2027	**€1,250.-**
Barcelona Confirmed dates	23 Aug 2027	27 Aug 2027	**€2,840.-**



Course content

Dates, venues and fees (continued)

Venue	Start date	End date	Fee (EUR)
Online Confirmed dates	23 Aug 2027	27 Aug 2027	**€1,250.-**
Cape Town Confirmed dates	6 Sept 2027	10 Sept 2027	**€1,890.-**
Online Confirmed dates	6 Sept 2027	10 Sept 2027	**€1,250.-**
Frankfurt Confirmed dates	27 Sept 2027	1 Oct 2027	**€2,650.-**
Online Confirmed dates	27 Sept 2027	1 Oct 2027	**€1,250.-**
Kuala Lumpur Confirmed dates	18 Oct 2027	22 Oct 2027	**€1,450.-**
Online Confirmed dates	18 Oct 2027	22 Oct 2027	**€1,250.-**
Rome Confirmed dates	8 Nov 2027	12 Nov 2027	**€2,450.-**
Online Confirmed dates	8 Nov 2027	12 Nov 2027	**€1,250.-**



Course content

Dates, venues and fees (continued)

Venue	Start date	End date	Fee (EUR)
Vienna Confirmed dates	29 Nov 2027	3 Dec 2027	**€2,940.-**
Online Confirmed dates	29 Nov 2027	3 Dec 2027	**€1,250.-**
Cape Town Confirmed dates	13 Dec 2027	17 Dec 2027	**€1,890.-**
Online Confirmed dates	13 Dec 2027	17 Dec 2027	**€1,250.-**

Plan your next step

Dates, availability, exact venue, taxes, inclusions and payment terms require written confirmation. This brochure is not a quotation, registration, booking confirmation or visa invitation. Participants receive a Smart Horizon certificate of attendance; programmes are not externally accredited and do not award a professional qualification or designation. Confirm arrangements before booking travel.

For group or in-house training, contact our learning team to discuss your objectives and delivery arrangements.

Contact Smart Horizon

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View the latest course details online