Management system standards

ISO 13485:2016 — Medical Devices

Two days to understand and apply ISO 13485:2016, the international reference for quality management systems for medical devices. Regulatory requirements, risk management, design, supplier control, traceability, complaints and post-market surveillance are linked to the obligations of Law No. 84-12 and worked on your procedures and device files.

Duration : 2 days

Objectives

1. Explain the structure of ISO 13485:2016 and what distinguishes it from ISO 9001
2. Build the applicable regulatory requirements, including those of Law No. 84-12, into the processes of the system
3. Apply a risk-based approach to design, production and suppliers
4. Organise traceability, complaint handling, vigilance reporting and corrective and preventive actions
5. Assess the gap between your system and the standard and draw out priorities

Programme

Day 1 — morning

• Medical devices: expectations of authorities and customers, place of ISO 13485:2016

• Differences from ISO 9001: integrated regulatory requirements, more extensive documentation, maintaining the effectiveness of the system

• Law No. 84-12: establishment declaration, registration, good practices, vigilance reporting

• Quality management system, medical device file, control of documents and records

Day 1 — afternoon

• Management responsibility, management representative, management review

• Resources: competence, infrastructure, work environment and contamination control

• Risk management throughout product realisation, in connection with ISO 14971

• Exercise: link the regulatory obligations of your activity to the processes of your system

Day 2 — morning

• Design and development: planning, verification, validation, transfer, design files

• Purchasing and supplier control proportionate to risk

• Production: process validation, cleanliness, sterilisation where applicable, identification and traceability

• Preservation of product and control of monitoring and measuring equipment

Day 2 — afternoon (workshop)

• Feedback, complaints, notification to authorities, internal audit

• Nonconforming product, corrective and preventive actions

• Workshop: gaps in your system against ISO 13485:2016 and priorities

• Knowledge test and presentation of the work

Teaching methods

• Guided reading of the standard, clause by clause
• Exercises on your procedures, your device files and your complaint forms
• Mapping of the obligations of Law No. 84-12 to your processes
• Case study: from a customer complaint to notification and corrective action
• Mid-course quiz and final test

Assessment and documents

Mid-course quiz and knowledge test at the end of the session, post-course evaluation at D+1. Numbered training certificate, verifiable online, for each participant; training report and the gap analysis produced in the workshop handed to the company.

Bilingual materials for every participant; each classroom course comes with its digital twin on OmniLearn.

Good to know

Internal auditors continue with “ISO 13485 Internal Auditor” (2 days). Testing laboratories aiming for accreditation should turn to “ISO/IEC 17025:2017 — Laboratories”.

Practical information

Duration	2 days
Audience	Management, quality and regulatory affairs managers, production, design and purchasing staff of medical device manufacturers, importers and distributors
Prerequisites	No prerequisites; knowledge of ISO 9001 makes reading easier
Group size	Groups of 6 to 12 participants, in-company
Format	In-company, face to face on your site
Language	French, Darija or English; bilingual materials
Funding	OFPPT special training contracts (TFP), GIAC, Maroc PME: we prepare the applications with you, at no extra cost.
Programme customisation	Programme adapted to your procedures, your equipment and your audience

Frequently asked questions

Is ISO 13485 mandatory in Morocco?
Law No. 84-12 does not cite ISO 13485. It requires, among other things, an establishment declaration, good practices and registration before placing on the market. ISO 13485:2016 remains the reference that many customers and foreign authorities expect as proof of quality control.

Does a site certified to ISO 9001 have to start over?
No, but the gap is real: regulatory requirements, risk management, device files, process validation, traceability and vigilance go further than ISO 9001. The course shows what can be reused and what must be added.

Is the course relevant to importers and distributors?
Yes. The scope of the system adapts to the company’s role: design can be excluded where it does not apply and the regulations allow it, while purchasing, storage, traceability and complaints remain at the heart of the subject.

Who should attend?
Management, the quality and regulatory affairs manager, production, purchasing and, where relevant, design. The presence of management matters: the management review and the appointment of a representative are its responsibility.