Management system standards

ISO 13485 Internal Auditor

Two days to train internal auditors in the specifics of an ISO 13485:2016 system: regulatory requirements, device files, process validation, traceability, complaints and vigilance. The method follows the guidelines of ISO 19011:2026. On the second day, participants audit a process at your site and write nonconformities tied to a requirement and a piece of evidence.

Duration : 2 days

Objectives

1. Build an internal audit programme suited to device risks and regulatory requirements
2. Prepare an audit plan and checklists specific to the processes of a manufacturer or a distributor
3. Check device files, process validation and traceability in the field
4. Formulate precise nonconformities proportionate to the risk to the patient and the user
5. Write an audit report and follow corrective and preventive actions

Programme

Day 1 — morning

• ISO 13485:2016 requirements on internal audit and the place of audit in the system

• Principles of auditing under ISO 19011:2026: integrity, impartiality, evidence-based approach

• Audit programme: critical processes, previous results, complaints, regulatory changes

• Audit plan and preparation: documents to read, samples to request

Day 1 — afternoon

• What the auditor checks in design and development: reviews, verification, validation, transfer

• Production and special processes: validation, cleaning, contamination control, sterilisation where applicable

• Traceability, complaints, notification to authorities, corrective and preventive actions

• Exercise: list of questions for a process at your site

Day 2 — morning

• Conducting interviews and observation in the production or storage area

• Sampling of records: batch records, complaint forms, traceability registers

• Formulating nonconformities: requirement, evidence, finding; grading according to risk

• Role play: interview with the complaints manager

Day 2 — afternoon (workshop)

• Practical audit in pairs of a process in your company

• Writing the report and closing meeting

• Follow-up of actions and verification of their effectiveness

• Knowledge test and feedback

Teaching methods

• Interview role plays on situations specific to medical devices

• Writing nonconformities from batch records and complaint forms

• Practical audit of a process at your site, in pairs

• Templates for audit programme, plan, checklist and report

• Knowledge test and assessment of the practical audit by the trainer

Assessment and documents

Knowledge test and assessment of the practical audit (preparation, interviews, nonconformities, report), post-course evaluation at D+1. Numbered training certificate, verifiable online; training report and the report of the practical audit handed to the company.

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

Good to know

This course assumes knowledge of the requirements of the standard: the course “ISO 13485:2016 — Medical Devices” (2 days) presents them. For auditors who also cover ISO 9001 or ISO 14001, see “Internal Auditor — ISO 19011:2018”.

Practical information

Duration	2 days
Audience	Future internal auditors, quality and regulatory affairs managers in the medical device sector
Prerequisites	Knowledge of the requirements of ISO 13485:2016
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

How does it differ from the general internal auditor course?
The audit method is the same. This course spends half its time on the points specific to medical devices: device files, process validation, traceability, complaints, vigilance and regulatory requirements.

Do I need to have taken the course on the requirements of ISO 13485?
It is recommended, because an auditor must know the standard being audited. A participant who already works on their company’s ISO 13485 system can take this course directly.

Can the internal audit cover the requirements of Law No. 84-12?
Yes. ISO 13485:2016 requires applicable regulatory requirements to be built in: the audit programme can therefore check the establishment declaration, the registration of devices or vigilance reporting, in the same way as the requirements of the standard.