



## QUALITY, ISO STANDARDS AND AUDITING

# Medical Device Quality Management to ISO 13485

5 day course

Classroom, online or in-house

## Course overview

A medical device recall usually traces back to a design input that was never verified or a sterilisation process that was never validated. Delegates work through ISO 13485 as regulators read it: the regulatory requirements that sit alongside it, risk management to ISO 14971 across the product life, design and development controls with the design history file, process validation for sterilisation, sealing and software, supplier controls, traceability and unique device identification, complaint handling, vigilance reporting and recall. The programme also covers how the standard differs from ISO 9001, particularly its weight on documented evidence over continual improvement, and how African regulators such as SAHPRA in South Africa approach device establishments. Delegates leave able to build or tighten a device quality system that holds up under regulatory inspection.

## What you will learn

- Explain how ISO 13485 differs from ISO 9001 in intent and documentation
- Apply ISO 14971 risk management across the device life cycle
- Plan design and development controls and maintain a design history file
- Validate special processes such as sterilisation, sealing and software
- Specify supplier controls proportionate to device risk
- Implement traceability and unique device identification
- Manage complaints, vigilance reporting and field safety corrective action
- Interpret regulatory expectations for device establishments in African markets

## Who should attend

- Quality managers at medical device manufacturers and distributors
- Regulatory affairs officers
- Design and development engineers for medical products
- Production and sterilisation supervisors
- Hospital procurement staff who assess device suppliers

## Course outline

- 01 The regulatory setting for medical devices
- 02 ISO 13485 compared with ISO 9001
- 03 Risk management to ISO 14971
- 04 Design controls and the design history file
- 05 Process validation for sterilisation, sealing and software
- 06 Supplier controls and purchasing
- 07 Traceability and unique device identification
- 08 Complaints, vigilance and recall
- 09 Preparing for regulatory inspection

## Upcoming dates



| Dates                              | Venue                   | Format    | Fee per delegate |
|------------------------------------|-------------------------|-----------|------------------|
| 16 to 20 November 2026             | Cape Town, South Africa | Classroom | R19,950          |
| 28 December 2026 to 1 January 2027 | Pretoria, South Africa  | Classroom | R19,950          |
| 4 to 8 January 2027                | Lusaka, Zambia          | Classroom | USD 1,325        |
| 15 to 19 March 2027                | Online                  | Online    | R8,500           |

### Fees and how to register

This 5 day course is **R8,500** per delegate online, **R19,950** in the classroom in South Africa, Botswana, Namibia, Lesotho and Eswatini, and **USD 1,325** in the classroom elsewhere in Africa. In-house training is quotation on request. Book 2 or more delegates on this course and save 10%.

To register or request an in-house proposal, visit [www.afrisciencegroup.com](http://www.afrisciencegroup.com), email [info@afriScience.co.za](mailto:info@afriScience.co.za), or WhatsApp us on **+27 63 479 1136**.

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