CONCEPT

# SFDA Medical Device Registration Course: MDMA, Classification and Authorised Representative

21 – 25 November 2027
Jeddah - Corniche four-star



# SFDA Medical Device Registration Course: MDMA, Classification and Authorised Representative

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## Introduction:

SFDA medical device registration, covering MDMA, classification and the authorised representative, is the subject of this 1-week course for regulatory affairs, quality and registration staff at manufacturers, authorised representatives and importers, ending with an MDMA Submission Readiness Pack. Devices reach the market late, or are held at clearance, when classification is wrong, technical files are incomplete or the authorised representative and establishment licences are not in place. Nominees already prepare or support device registrations, and teaching is by case study on sample technical files and GHAD submission records. CoreConcept Training Center delivers this SFDA medical device registration course.

## Course Objectives:

- Explain the Medical Devices and Supplies Law, SFDA market placement routes and the duties of manufacturers, authorised representatives and importers
- Classify devices into classes A to D under MDS-G008 and decide when related devices can share one MDMA
- Compile an MDMA technical file that meets MDS-REQ 1 and submit it through the GHAD electronic system
- Prepare Arabic and English labelling and quality management evidence for professional and lay-user devices
- Meet post-market obligations for NCMDR vigilance, UDI data, import clearance and advertising approval
- Produce an MDMA Submission Readiness Pack for a device in the participant's own portfolio

## Target Audience:

- Regulatory affairs staff who prepare and submit device registrations and answer deficiency requests
- Quality and compliance staff who maintain technical files, quality system evidence and labelling
- Authorised representative staff who manage submissions and vigilance for overseas manufacturers
- Importer and distributor staff responsible for establishment licences, clearance and storage records
- Product and market access staff who plan the launch of new medical devices

## Course Outline:

### Day 1: Regulatory Framework and Market Placement Routes

- Medical Devices and Supplies Law and Implementing Regulation Overview
- SFDA Market Placement Routes for Manufacturers and Importers
- Authorised Representative Role, Contract and Legal Duties
- MDS-REQ 9 Establishment Licensing for Importers and Distributors
- GHAD Electronic System Accounts, Roles and Application Flow

### Day 2: Device Classification and MDMA Requirements

- MDS-G008 Classification Rules for Classes A to D
- Classification Rule Application to Invasive and Active Devices
- MDS-REQ 1 MDMA Requirements and Technical File Assessment
- CE and 510k Evidence Used as Supporting Documentation
- MDS-G028 Bundling of Device Families, Systems and Procedure Packs

### Day 3: Technical File Preparation and Submission

- Technical File Structure with Device Description and Intended Use
- Safety and Performance Evidence Compilation for the File
- ISO 13485 Quality System Evidence Following MDS-G024 Guidance
- Arabic and English Labelling and Instructions for Lay Users
- GHAD MDMA Application Entry and Deficiency Response Handling

### Day 4: Post-Market Obligations and Compliance Risks

- NCMDR Vigilance Reporting Clocks for Incidents and Threats
- MDS-REQ 7 UDI Assignment and Device Identifier Database Submission
- MDS-REQ 5 Importation and Shipment Clearance Checks
- MDS-REQ 8 Advertising Approval and Promotional Material Control
- MDMA Renewal, Change Notifications and Common Rejection Causes

### Day 5: Case Study Practice and the MDMA Submission Readiness Pack

- Case Device Classification and Registration Route Decision
- Case Technical File Gap Review Against MDS-REQ 1
- Case Vigilance Report Drafting for a Serious Incident
- Regulatory Calendar for Renewals, UDI Data and Licences
- MDMA Submission Readiness Pack Completion and Peer Review

## Skills You Will Gain:

- Device Risk Classification
- Technical File Compilation
- Regulatory Submission Management
- Deficiency Response Writing
- Labelling Compliance Review
- Vigilance Reporting
- UDI Data Management
- Regulatory Calendar Planning

## Why Attend This Course:

- Deliver an MDMA Submission Readiness Pack to the regulatory affairs lead and the commercial launch team
- Decide a device's class, its registration route and whether it can be bundled with related products
- Avoid rejected applications, shipments held at clearance and late vigilance reports that delay sales
- Brief colleagues in quality, sales and logistics on labelling, advertising and incident reporting duties

## Conclusion:

Back at work, the participant hands the MDMA Submission Readiness Pack to the regulatory affairs lead and the commercial launch team, who use it to confirm each device's class and route, schedule submissions through GHAD and set launch dates that registration can support. Quality and logistics teams use its checklists for labelling, UDI data and import clearance. After the first submission decision, the unit should compare the deficiency points raised with the pack's gap review and update any checklist that missed them.

## Frequently Asked Questions FAQ:

### What should participants know before an SFDA medical device registration course?

Participants should already work in regulatory affairs, quality or registration and understand basic device terminology. Bringing an anonymised technical file, label or instructions for use from their own portfolio makes the case study work more useful.

### How does an SFDA medical device registration course differ from a general medical device regulatory affairs course?

It concentrates on the SFDA route: MDMA requirements, classification under MDS-G008, the authorised representative, GHAD submissions and post-market duties. General regulatory affairs courses compare several international systems and cover each in less procedural detail.

## Can a CE mark or 510k clearance replace SFDA medical device registration?

No. The MDMA is a product-specific authorisation based on a technical-file assessment under MDS-REQ 1. CE marking and 510k clearance are accepted as supporting evidence within the technical file, not as substitutes for the MDMA.

## What do participants take back from the SFDA medical device registration course?

Participants take back an MDMA Submission Readiness Pack: a classification record, a technical file gap review, labelling and UDI checklists, a vigilance reporting procedure and a regulatory calendar for renewals and licences, ready to apply to their own devices.