

# GCC Regulatory & Dossier Compliance Checklist

Step-by-step technical requirements for laboratory equipment, reagents, and diagnostic exporters targeting Saudi Arabia (SFDA) and the UAE (MOHAP).

## 1. Saudi Food & Drug Authority (SFDA) Requirements

SA Saudi Arabia

- ☐ **Saudi Authorized Representative (AR) License**  
Appoint an officially licensed Saudi AR entity and secure a valid Medical Device Establishment License (MDEL) prior to filing product dossiers.
- ☐ **STED Technical File Preparation**  
Compile technical dossiers according to Summary Technical Documentation (STED) standards, including risk analysis, verification/validation testing data, and ISO 13485 certification.
- ☐ **GHAD System Listing & MDMA Approval**  
Register capital lab equipment and IVD reagents on the SFDA Global Harmonization System (GHAD) to obtain Medical Device Marketing Authorization (MDMA).
- ☐ **SABER Certificate of Conformity (CoC) & Fasah Release**  
Generate shipment-specific CoCs via SABER and link customs clearance applications directly with the national *Fasah* portal.

## 2. UAE Ministry of Health & Prevention (MOHAP)

AE United Arab Emirates

- ☐ **Product Classification & Registration**  
Submit diagnostic kits, biological reagents, and consumables for MOHAP classification to determine whether medical device or chemical compliance controls apply.
- ☐ **Pre-Arrival Import Permit Clearance**  
Obtain pre-approved MOHAP import permits for restricted biological samples, cell culture media, or active reagents before port arrival in Dubai or Abu Dhabi.
- ☐ **Department of Health (DoH) Sandbox Standards**  
Utilize expedited regulatory pathways for clinical trial materials and specialized research systems registered within Abu Dhabi's HELM cluster.

### 3. Labeling, Barcoding & Technical Packaging

 Regional Standards

#### ☐ **GS1 DataMatrix Barcoding**

Ensure primary and secondary packaging features 2D GS1 DataMatrix barcodes encoding GTIN, Lot/Batch Number, Expiration Date, and Serial Number for track-and-trace auditability.

#### ☐ **Dual-Language (Arabic / English) Inserts**

Incorporate compliant dual-language Instructions for Use (IFU), technical specifications, and safety warnings on outer cartons and documentation inserts.

#### ☐ **Storage & Temperature Markings**

Prominently display standardized ISO storage symbols and temperature range indicators (e.g., 2°C to 8°C, -20°C, Dry Ice) matching Certificate of Analysis (CoA) records.