KSA Healthcare Market Access (SFDA)

Presented by
Mohsen Al Muslimani
Chief Executive Officer

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Agenda

- About SFDA
- SFDA Requirements, Timeline, and Fees
- About MRG

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Saudi Food & Drug Authority (SFDA)

- Established in 2003 to ensure the **safety, efficacy, and quality** of food, drugs, medical devices, biological & chemical substances, cosmetics, pesticides, veterinary pharmaceuticals, and animal health products in Saudi Arabia.

- **A Royal Decree was issued in 2007** to establish the Saudi Food and Drug Authority **(SFDA)** as An independent corporate body directly linked to the **Prime Minister**.

- In 2023 SFDA became **the third national regulator** worldwide to reach ML4 **for medicines & vaccines regulation** announced by **WHO alongside EMA and US FDA**.

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Regulating the Future: AI, Software & Smart Devices

- **SFDA** recognized as **the shortest timeframe** for registration and approval.
- **The first framework** in the region to address **AI/ML-based Medical devices** issued by **SFDA**
- **Innovative and first-in-market devices** defined and supported under SFDA regulation, facilitating early access while maintaining safety.
- Since **2020**, SFDA has been issuing **direct registration certificates** for qualifying devices and software without requiring external authority endorsement, reinforcing national regulatory independence.

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Expanding Opportunities for Rare & Specialty Therapies

- **Clinical trials for rare diseases** such as **thalassemia, sickle cell disease, and gene-editing therapies (Exa-cel)** are already registered under SFDA's **Saudi Clinical Trials Registry**.
- SFDA's framework facilitates **advanced biologics, cell and gene therapies**, and **innovative medical devices**, not only generics.
- This makes Saudi Arabia a **regional launch hub** for specialty therapeutics and novel technologies.

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SFDA Requirements, Timeline, and Fees

Presented by:

Hamoud Al Sahli

Head of Regulatory & Office Manager

SFDA law and regulations

- Registration process
- Legal Authorize representative
- Pre-market
- Technical file assessment requirements
- Bundling criteria
- Timeline & Fees/NUPCO/GHC
- Post market
- UDI/MDIL/Clearance

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SFDA law and regulation

Authorize representative :

- To enter the Saudi market, a medical device manufacturer must appoint a Legal Authorized Representative to act on behalf of the Manufacturer in dealing with SFDA regarding regulation and registration process.
- Annual fees for the AR is 2,600 SAR (710 USD)
- Timeline for the process is 2-5 working days

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SFDA law and regulation

Pre-Market: Product Registration

- Pathways for Registration:
    - TFA: Technical File Assessment.

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SFDA law and regulation

Technical File Assessment Requirements

- General Manufacturer Info , Design Facility , Critical Subcontractor , External approval (Optional)
- Devices and Accessories Information Label , IFU , Marketing material
- Deferent Between the products , Classification as per the SFDA guideline
- Manufacturing Processes for the products , Design Traceability , Design Stages , Manufacturing Structure
- Manufacturer QMS Evidence ISO 13485
- Latest audit report

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SFDA law and regulation

Technical File Assessment Requirements

- Essential Principles Checklist (as per the SFDA Guideline)
- Complete Risk Management File
- Clinical evaluation report, the clinical evaluation plan
- Product Verification and Validation , shelf life , product stability
- Post-market surveillance Plan and Report
- Declarations of Conformity – DOC (as per the SFDA Guideline) , Other Supporting Documents

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SFDA law and regulation

Bundling Criteria

- A maximum of 5 Technical Files are allowed per application
- Total number of listed products per application shall not exceed 50 items

Type Of Bundling:

- Medical Device Family
- Medical Device System
- Medical Device Procedure Pack
- **IVDs**

SFDA law and regulation

Pre-Market: Product Registration

- Fees for a new application:
  - **Class A**: 15,000 SAR (4,015 USD)
  - **Class B**: 18,000 SAR (5,082 USD)
  - **Class C**: 21,000 SAR (5,615 USD)
  - **Class D**: 23,000 SAR (6,150 USD)
- Fees for update and renewal application is 5,000 SAR (1,350 USD)
- Timeline for the process 35-60 working days
- NUPCO – MDMA certificate is required for NUPCO tender participation.
- GHC (GCC Gate) - MDMA certificate required for participation in GCC centralized procurement/platform listings.

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SFDA law and regulation

Post Market

Stage 1: Recall / Adverse Events

- Required only for events occurring inside KSA

Permitted Period (Adverse Events):
No more than 5 working days (Acknowledgment letters can be provided later)

- **Period of Reporting**:
  - Not later than **2 working days**: Serious Public Health Threat
  - Not later than **10 working days**: Unanticipated Death or Serious Injury
  - Not later than **30 calendar days**: Not associated with high risks
  - Not later than **5 working days**: If SFDA initiates a report of an adverse event

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SFDA law and regulation

Unique Device Identification (UDI)/MDIL/Clearance

- As per SFDA guidance, Since December 2024 UDI for all products category for lower risk Device class A to the higher risk Device-class D are mandatory
- The product UDI information must be issued from one of the UDI Issuing Agencies (GS1, HIBCC, and ICCBBA), and the UDI-DI shall be globally unique at all levels
- **Only the Authorized Representative**, who is responsible for the Product Certificate, can access the UDI Database and submit the related information
- No SFDA fees For the UDI
- MDIL/Demo – The demo service is intended for exhibition, research, and training use.
- Clearance (E-Faseh)

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Presented by:

Abdulkareem K. Arrowsmith

Area Manager

About MRG

- **MRG** is a group of regulatory service providers & consultancy companies founded in **2012**.
- Covering the whole MENA region with offices located in **KSA, Egypt, UAE,** and **Syria.**
- MRG provides regulatory services for:
  - **1,000+** manufacturers
  - **45+** countries
  - **60+** distributors
  - **400K+** successful registrations

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MRG Services

- **Medical Devices:**
  Pre-market services: Legal Authorized Representatives, registration, update, renewals.
  Post-market services: Recalls & adverse event, UDI, MDIL.

- **Pharmaceuticals:**
  Registration, eCTD publishing/sequencing, Pharmacovigilance (PV).

- **Food Supplements:**
  Registration and compliance support

- **Cosmetics:**
  Product listing and notification

- **Quality:**
  Support for manufacturers and distributors in obtaining QMS certifications

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Exclusive E-mail & Number for Global Health Exhibitors

Thank you

Hamoud Al Sahli

Head Of Regulatory & Office Manager KSA

Hamoud.alsahli@mrg.com.sa

+966 566569909
+966 112934961
WeChat: Hamoud-3

GHE@mrg.som.sa

Abdulkareem K. Arrowsmith

Area Manager

Abdulkareem.kamal@mrg.com.sa

+966 566021808
+966 112934961
WeChat: Abdulkareem-97

For more information visit our website www.mrg.com.sa