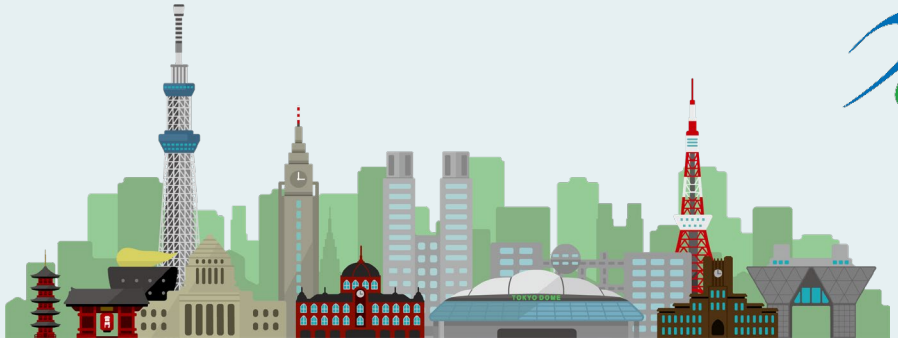
IMDRF International Medical Device Regulators Forum



Regulatory Updates

(Saudi Food & Drug Authority)

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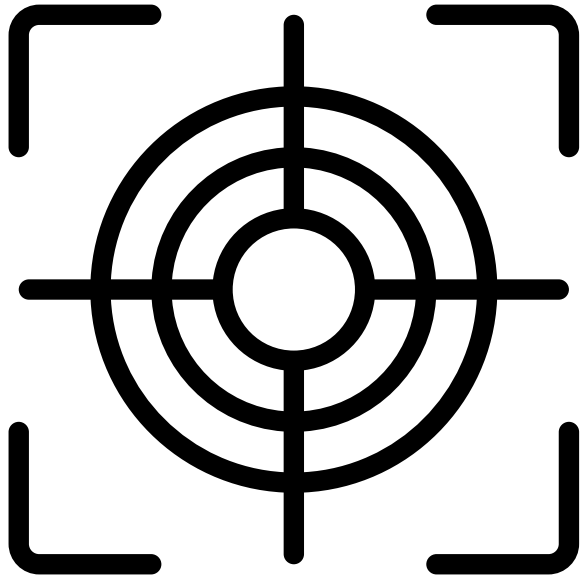
Contents

- ❑ SFDA MD Regulatory Overview
- ❑ New and updated MD Guidance
- ❑ Update on Electronic System
- ❑ Update on SFDA Programs

Medical Devices strategical objectives

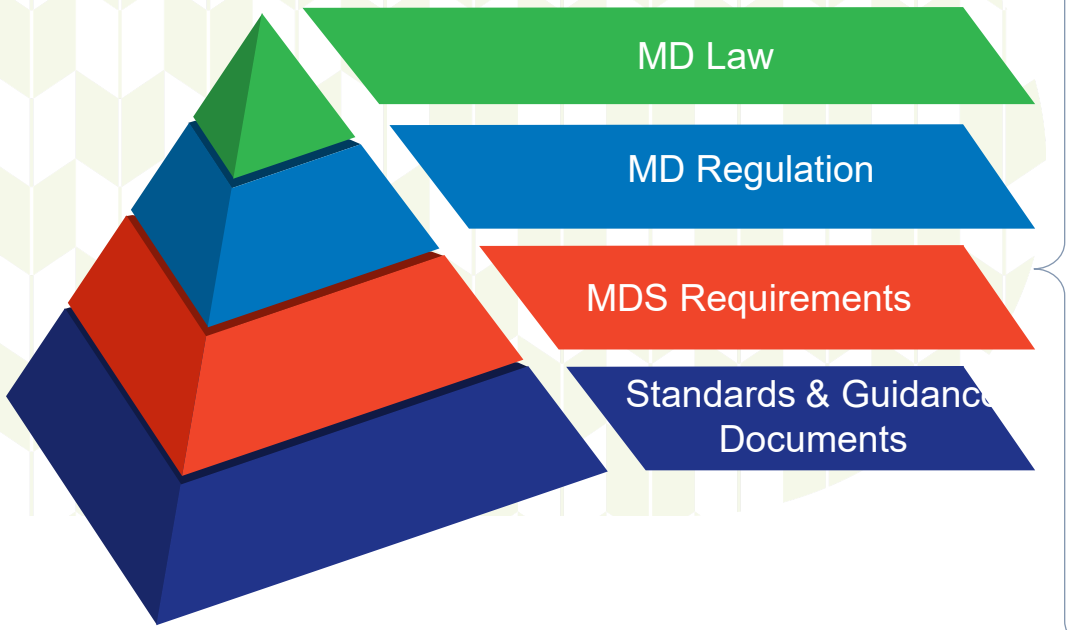
- Support **Research and Innovation** (Pathways for innovators and Clinical Trials).
- **Enhancing** requirements of new technology and bio-tech products to be align an updated with all international requirement
- **Strengthen** international collaboration with IMDRF, WHO, GHWP, ISO, IEC…
- **Improving Communication** and Awareness with Health Care Providers and Public



SFDA MD Regulatory scheme

MD Life Cycle

CONCEPTION AND DEVELOPMENT | MANUFACTURE | PACKAGING AND LABELING | CLEARANCE | ADVERTISING | SALE | USE | DISPOSAL



REQ No	SCOPE
MDS-REQ1	Medical Devices Marketing Authorization
MDS-REQ2	Clinical Trials of Medical Devices
MDS-REQ3	Safe Use of Medical Devices
MDS-REQ4	Medical Imaging and Accelerators Used for Medical Applications
MDS-REQ5	Shipments Clearance and Importation
MDS-REQ6	Radioactive Materials Used in Medical Applications
MDS-REQ7	Unique Device Identification (UDI)
MDS-REQ8	Advertising of Medical Devices
MDS-REQ9	Establishments Licensing
MDS-REQ10	Inspection and Quality Management System
MDS-REQ11	Post-Market Surveillance
MDS-REQ12	Transportation and storage of medical devices

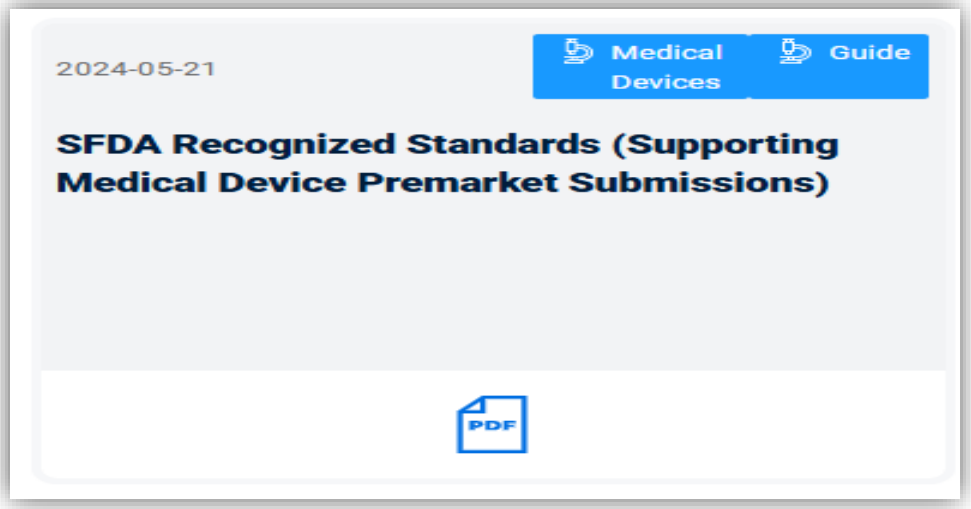
New SFDA-MD Guidance

- To clarify regulatory and technical requirements to be taken into consideration during the design and manufacturing stages of biotechnology-based medical devices.

- Defines and clarifies the requirements of manufacturers of point of care (POC) medical devices.
- Outlines the development and post market activities for In-house in vitro diagnostic (IH-IVD) medical devices.

Updated SFDA-MD Guidance

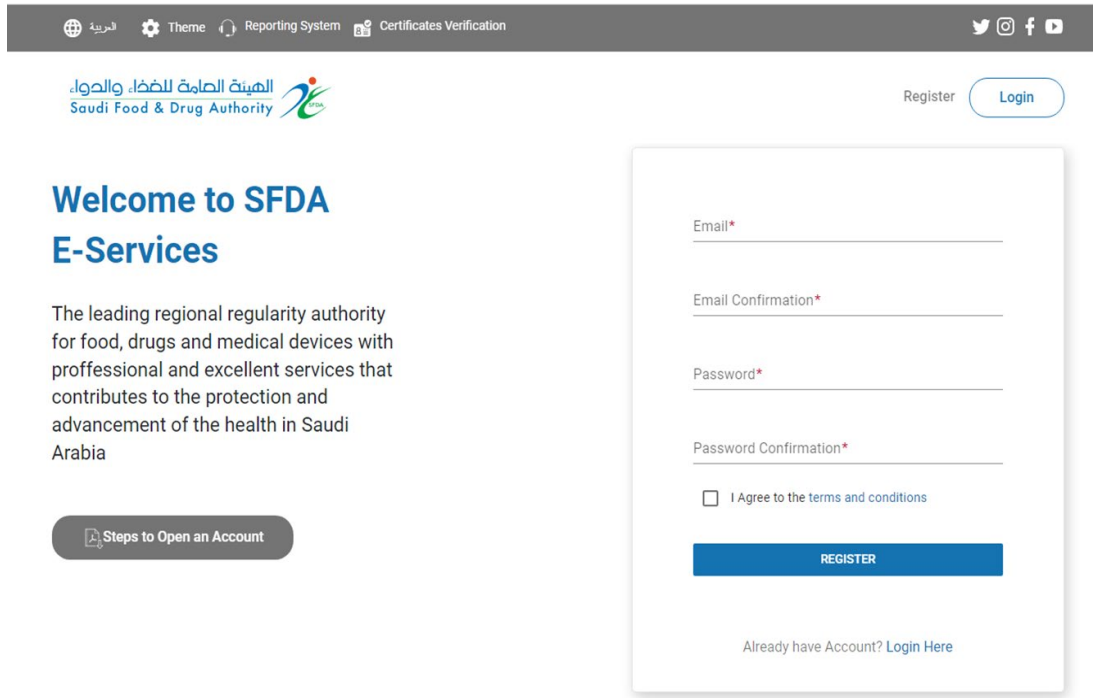
- To specify the designated criteria for Innovative Medical Devices.
- Outlines the requirements for applying through the Innovative Medical Devices Pathway, and to explain the submission process.



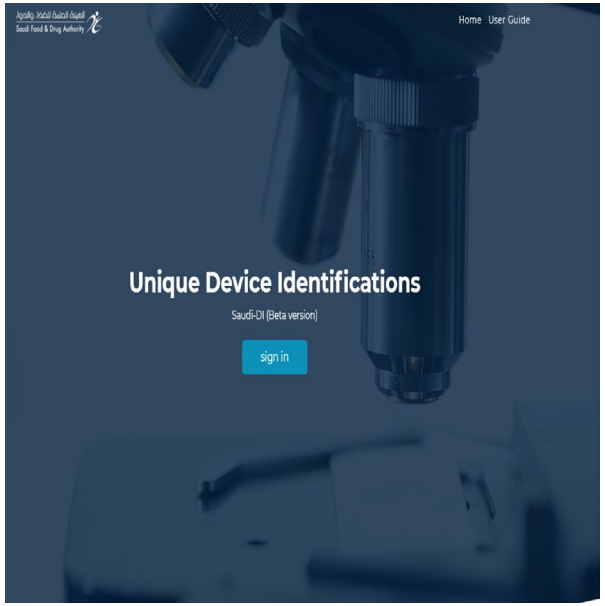
- To Support MD Manufacturers to fulfill premarket requirements through complying with the Essential Principles during MDs life cycle .

Updates Electronic System

1 Overseas MD Manufacturer' Account



2 Unique Device Identifications (Saudi-DI)



# of Devices	425290
# of Accessories	44422
# of Manufacturers	1648

SAUDI-DI

SFDA New Approval and License

1. Point of Care (POC)
2. Medical Device Software Developers

Healthcare providers and Patient Engagement Program

Based on benchmarking, working closely with international expertise and cooperation with leading institutions in the field , SFDA published three policies regarding the engagement with healthcare providers and patients based on best practice :

- Policy for Engagement with Healthcare Practitioners (MDS-G017)
- Policy for collecting of Patient Experience (MDS-G 018)
- Policy for Engagement with Patients (MDS-G 019)

In addition , more than **30 workshops** were conducted with a total number of 2220 HCP attendees in 2024.

SFDA –MD **developed a feedback mechanism** from these workshops to measure the impact for improving the communication and risk identifications.

National Diagnostic Reference Levels (NDRLs)

- SFDA has led the first governmental initiative to establish the Saudi National Diagnostic Reference Levels (NDRLs) in the Kingdom of Saudi Arabia.
- This aims to promote dose optimization in alignment with international guidance as well as the (SFDA) strategic objectives.
- SFDA has established the Saudi (NDRLs) for the following imaging modalities:
  - Adult CT
  - Pediatric CT
  - General X-ray
  - Mammogram
  - Nuclear Medicine
- The Saudi (NDRLs) were published on the International Journal of Radiation Physics and Chemistry.

Capacity building program

- Conducted **two training programs** that covered the following topics:

  - Analytical Performance
  - Clinical Evaluation
  - Companion Diagnostics
  - Artificial Intelligence
  - Biocompatibility

- **Conducted 6 workshops** in cooperation with Universities and research centers about the Technical Requirements for Medical Devices based on Biotechnology, AI. Also the requirements for Conducting Clinical trials.

- In addition, **more than 56 workshops** were held **covering 27 technical topics** to explain and clarify the requirements for MD manufacturers in 2024.

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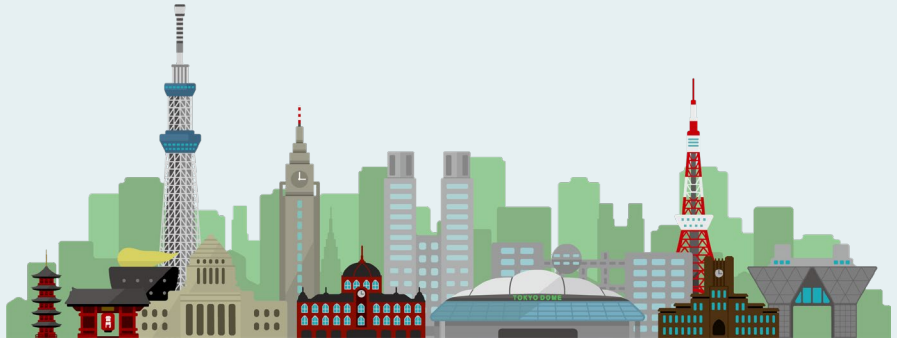

Thank you