الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Regulation

(SFDA Overview and Updates)

GHWP 27th Annual Meeting

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Director, MD Regulations & Registration Support

30/11/2023

WWW.SFDA.GOV.SA

Content

SFDA 4th Strategic Plan

Vision To be a leading international science-based regulator to protect and Promote public health.

Mission Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed.

Themes → Products Safety | Local and International Partnerships | Operational Excellence

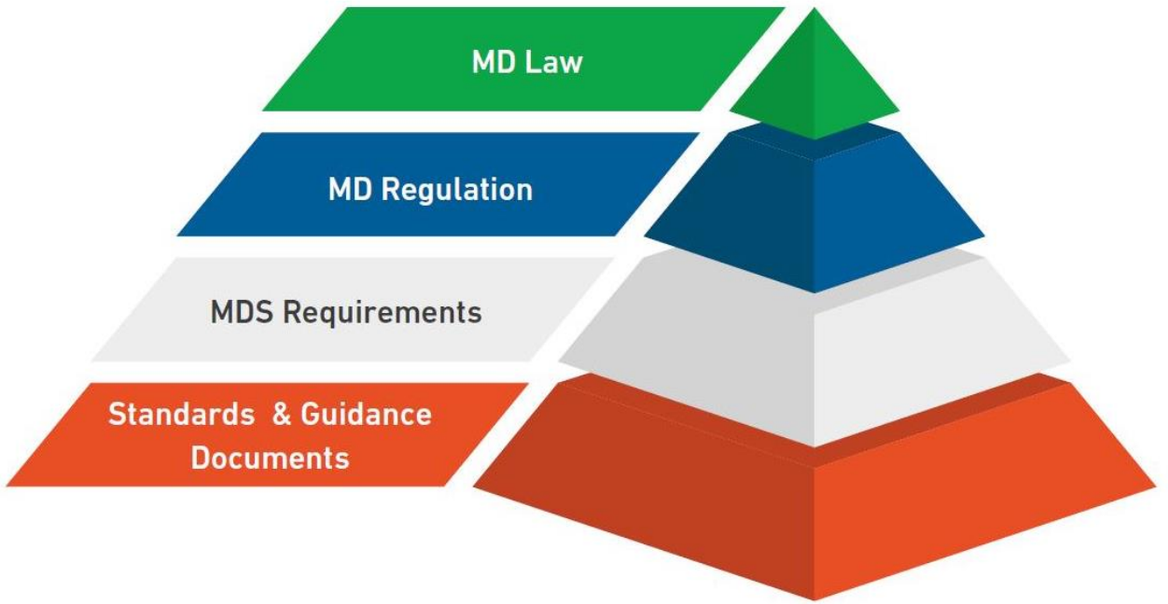
Strategic Objectives

Beneficiaries	Developing the Regulatory System	Improving Communication and Awareness	Enhancing Products Availability	Enhancing International Leadership
Financial Sustainability	Diversification of Revenue Resources			
Internal Processes	Developing Regulations and controls of new technology and bio-tech products	Support Research and Innovation	Enable Investors	
SFDA Capabilities	Human capital Development	Increase The Use of Advanced Digital Technology		

Values

- Keep Learning and Developing
- Community Health is Top Priority
- Effective & Transparent Communication
- Sharing Responsibility
- Striving to Achieve Leadership & Excellence

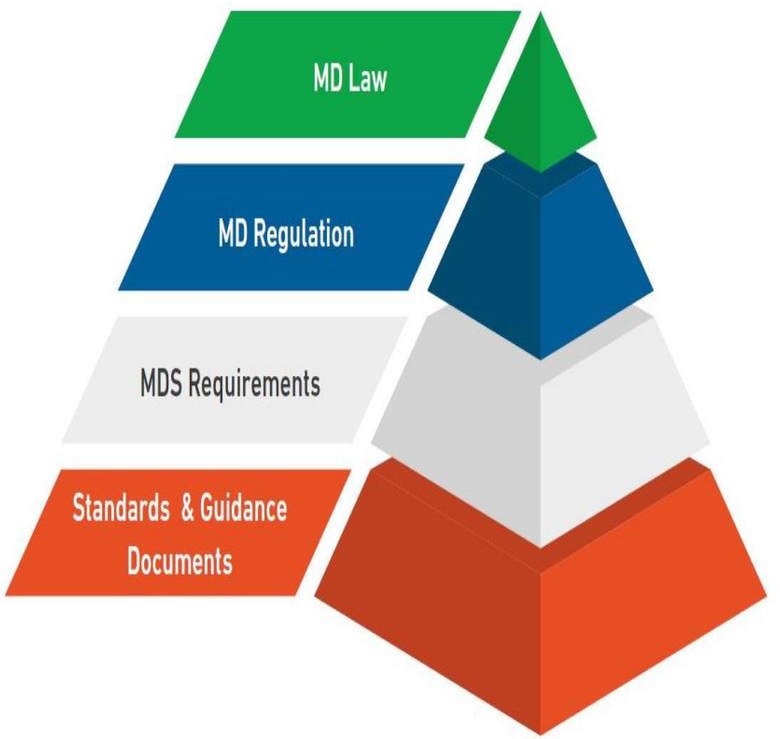
SFDA Medical Devices Regulation Framework



- ✓ **Support innovation** and medical devices technology development.
- ✓ **Enhance the Kingdom's leading role** internationally in the medical devices field.
- ✓ **Protect the public health &** patient's safety in KSA.
- ✓ **Support investments** & encourages manufactures to launch branches in the Kingdom.
- ✓ **Effective economic impact** for the Saudi market.

SFDA Medical Devices Regulation Framework (MDS - Requirements)

REQ number	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



SFDA Medical Devices Regulation Framework (MDS-Guidance Documents)

- **In addition, several guidelines covering MD Advanced Technology and Applications**

✓ Medical devices **Cybersecurity**

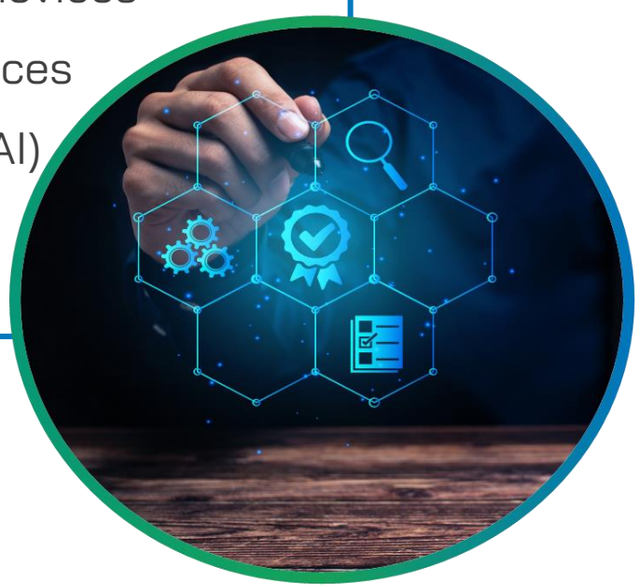
✓ **Software** as a Medical Device

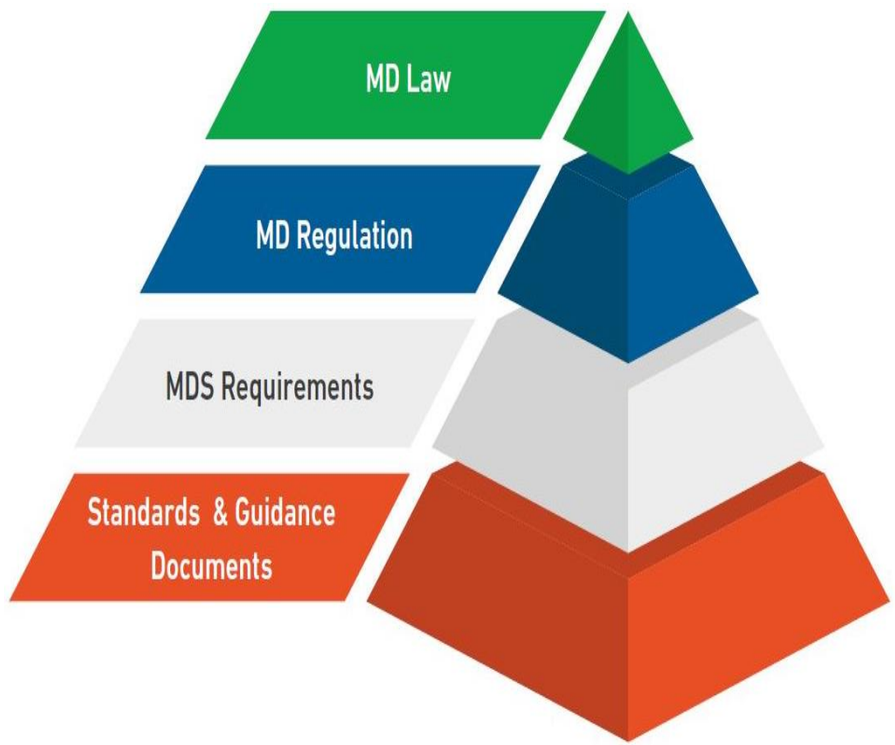
✓ **3D printing** in medical devices

✓ **Innovative** Medical Devices

✓ **Artificial intelligence** (AI)

✓ **MD Biotechnology**



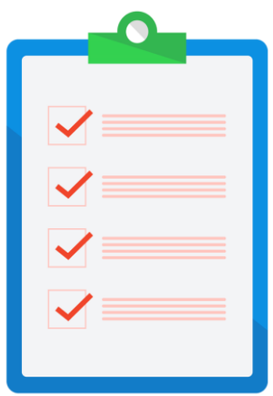


Requirements for Obtaining a Medical Device Marketing Authorization (MDMA)

- Local and Overseas MD Manufacturers Shall establish, document and maintain an effective Quality Management System (QMS).

  Reference: SFDA MDS-REQ 10

- Overseas Manufacturer shall assign Authorized Representative (AR) established within the KSA (By a written mandate from the manufacturer to act on his behalf for specified tasks).



- Local Manufacturer shall obtain an Establishment License from SFDA

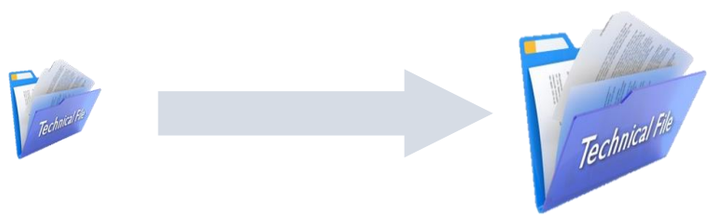
  Reference: SFDA MDS-REQ 9

Requirements for Obtaining a Medical Device Marketing Authorization (MDMA)

- Submit Technical File for Scientific Evaluation including the followings:

1. Device Description and Specification, and Accessories
2. Information to be Supplied by the Manufacturer
3. Design and Manufacturing Information
4. Essential Principles of Safety and Performance
5. Benefit-risk Analysis and Risk Management
6. Product Verification and Validation
7. Post-market Surveillance Plan
8. Periodic Safety Update Report (PSUR) and Post-market Surveillance Report

Class A | Class B | Class C | Class D



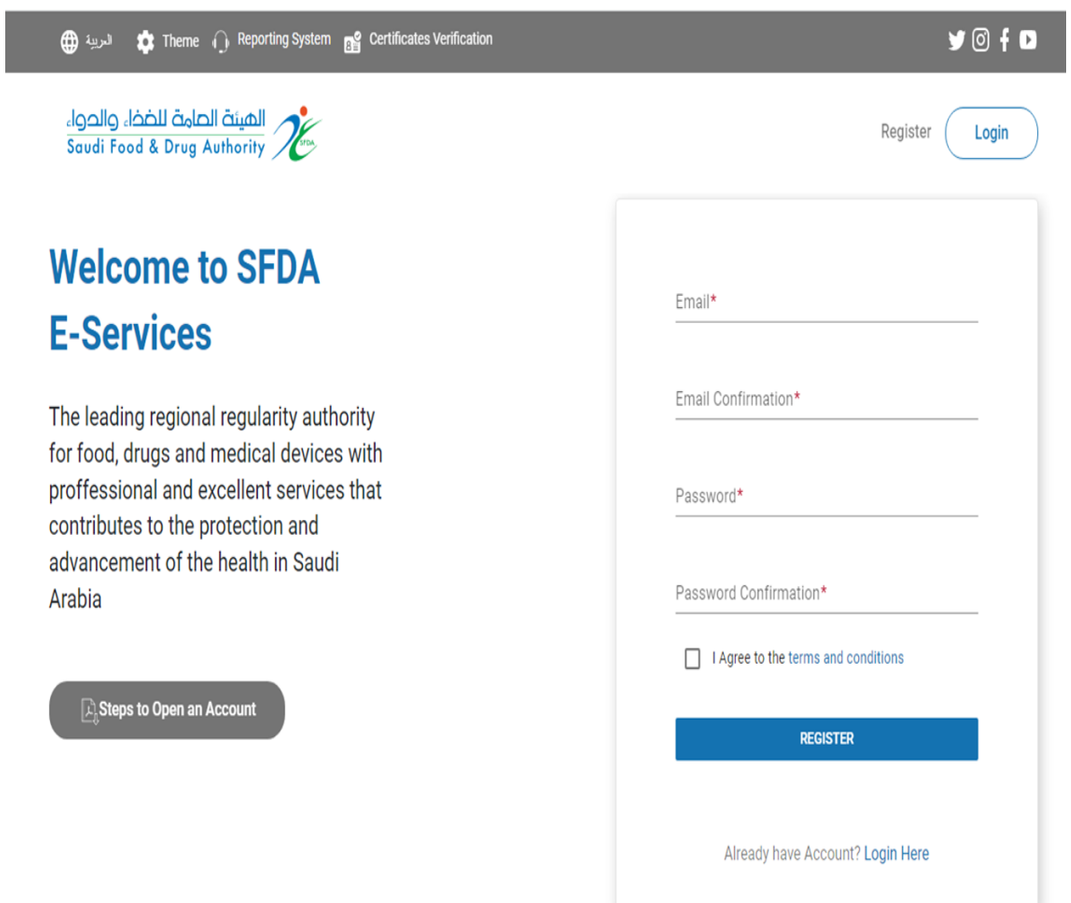
Reference: SFDA MDS-REQ 1

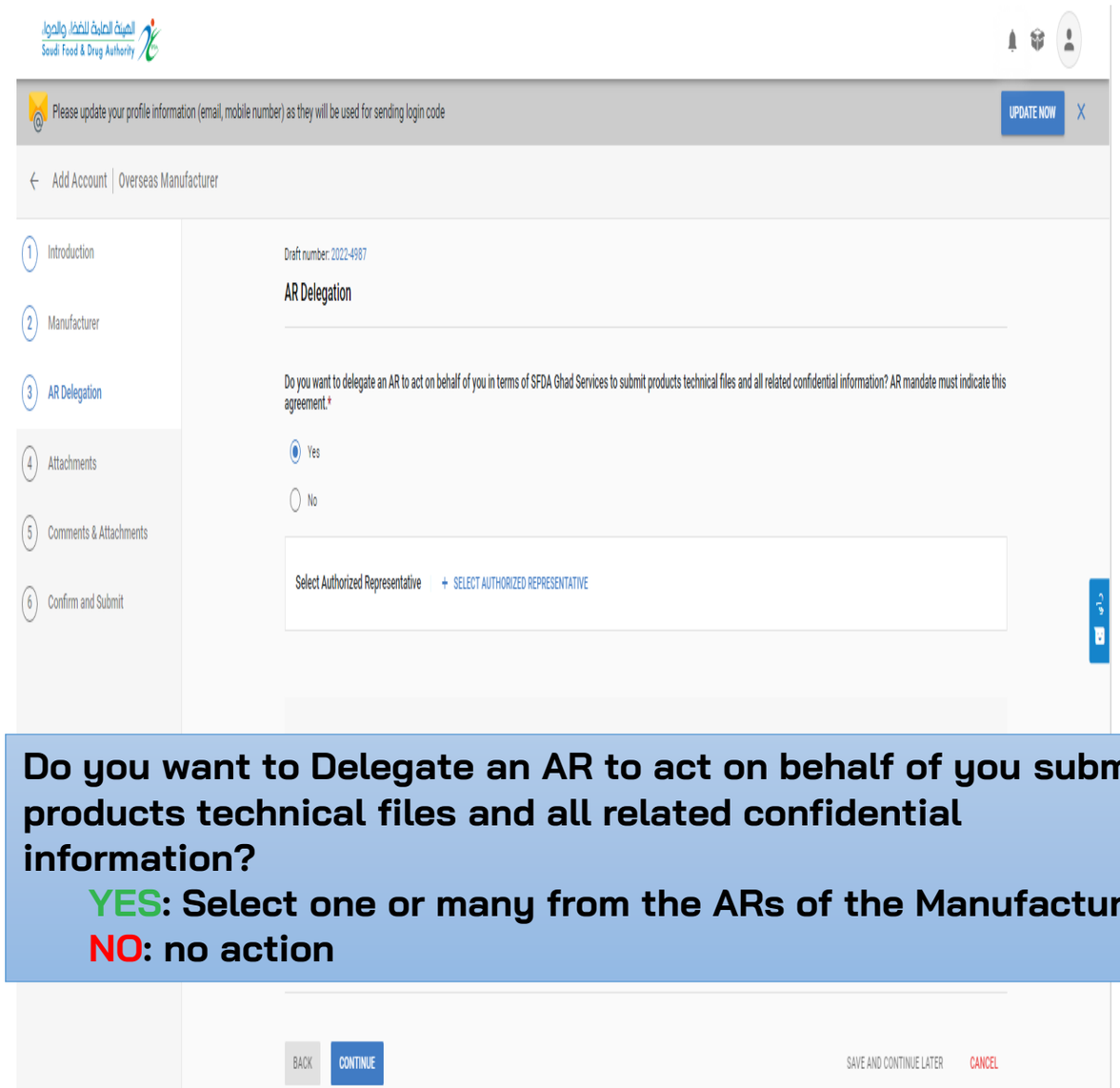
2023 Updates : Announcements, Documents, Procedures and Statistics

- Overseas MD Manufacturer' Account
- UDI Compliance Timeframe
- Guidance Documents Published in 2023
- Post-market Surveillance
- Clinical Trials
- Standards

2023 Updates : Announcements, Documents, Procedures and Statistics

Overseas MD Manufacturer' Account





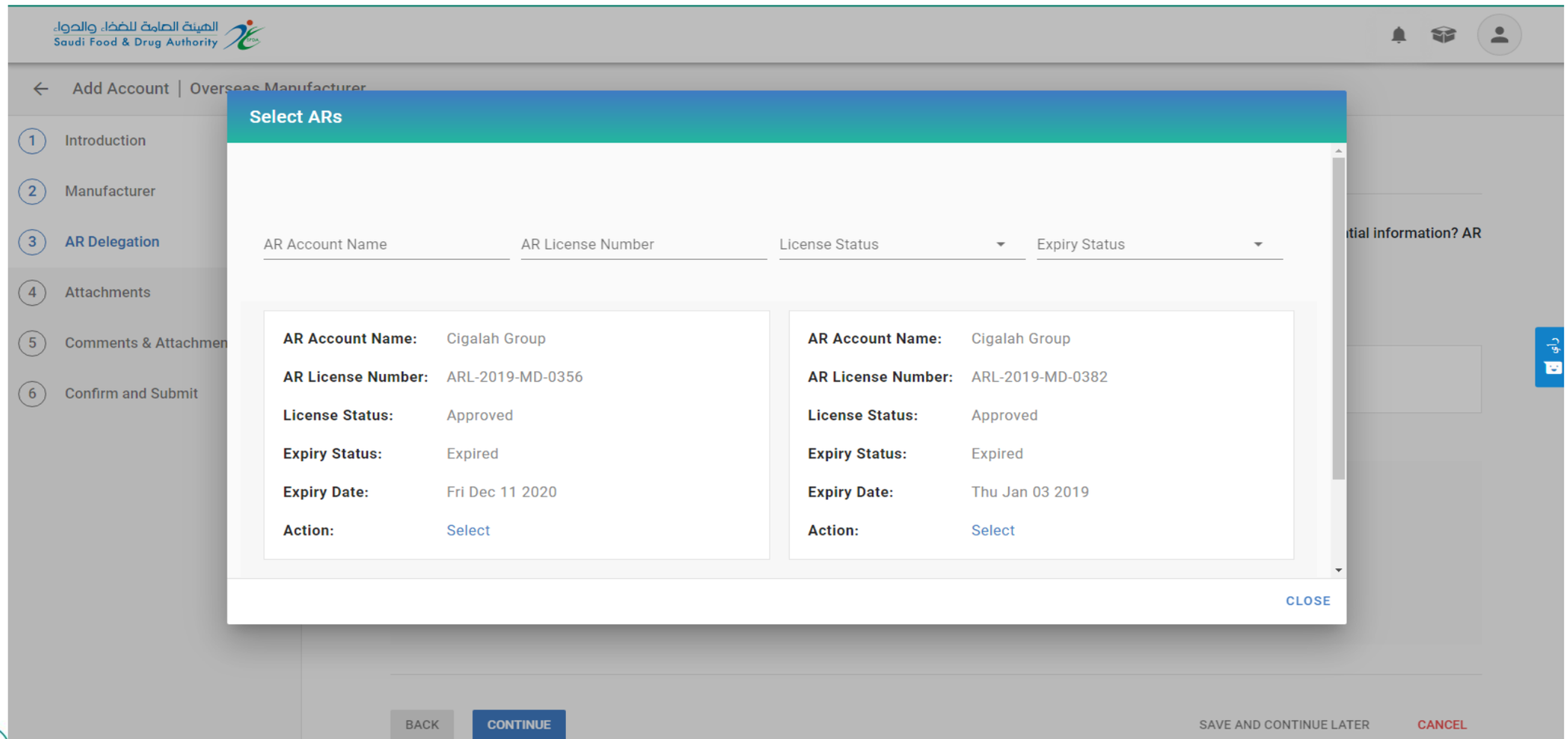
Do you want to Delegate an AR to act on behalf of you submit products technical files and all related confidential information?

YES: Select one or many from the ARs of the Manufacturer.

NO: no action

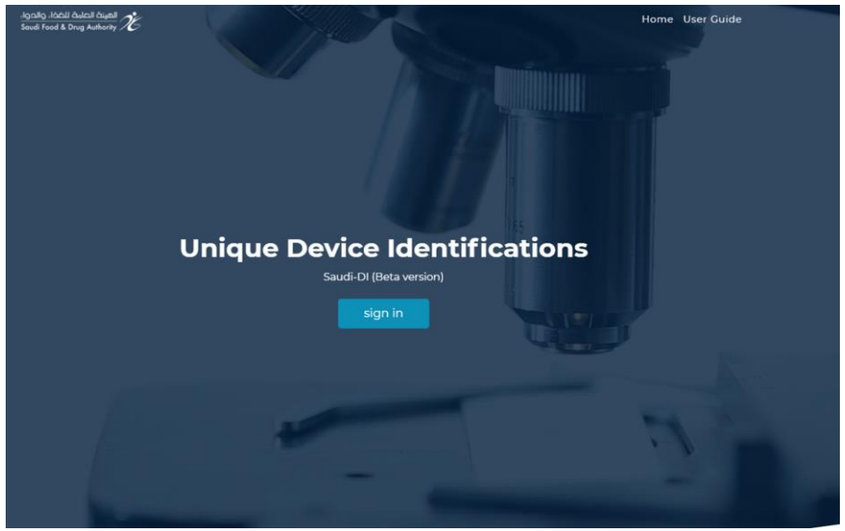
2023 Updates : Announcements, Documents, Procedures and Statistics

Overseas MD Manufacturer' Account



2023 Updates : Announcements, Documents, Procedures and Statistics

SAUDI-DI



#of Devices	283246
#of Accessories	32322
#of Manufacturers	1105

Announcement (MDS-CIR-002-V2/

(following the Announcement (01) 8/2021)

SUBJECT: Updates on the compliance timeframe for the requirements of medical devices unique device identification (Saudi -DI).

ADDRESSES: Local and Overseas Medical Devices Manufacturers, Authorized Representatives.

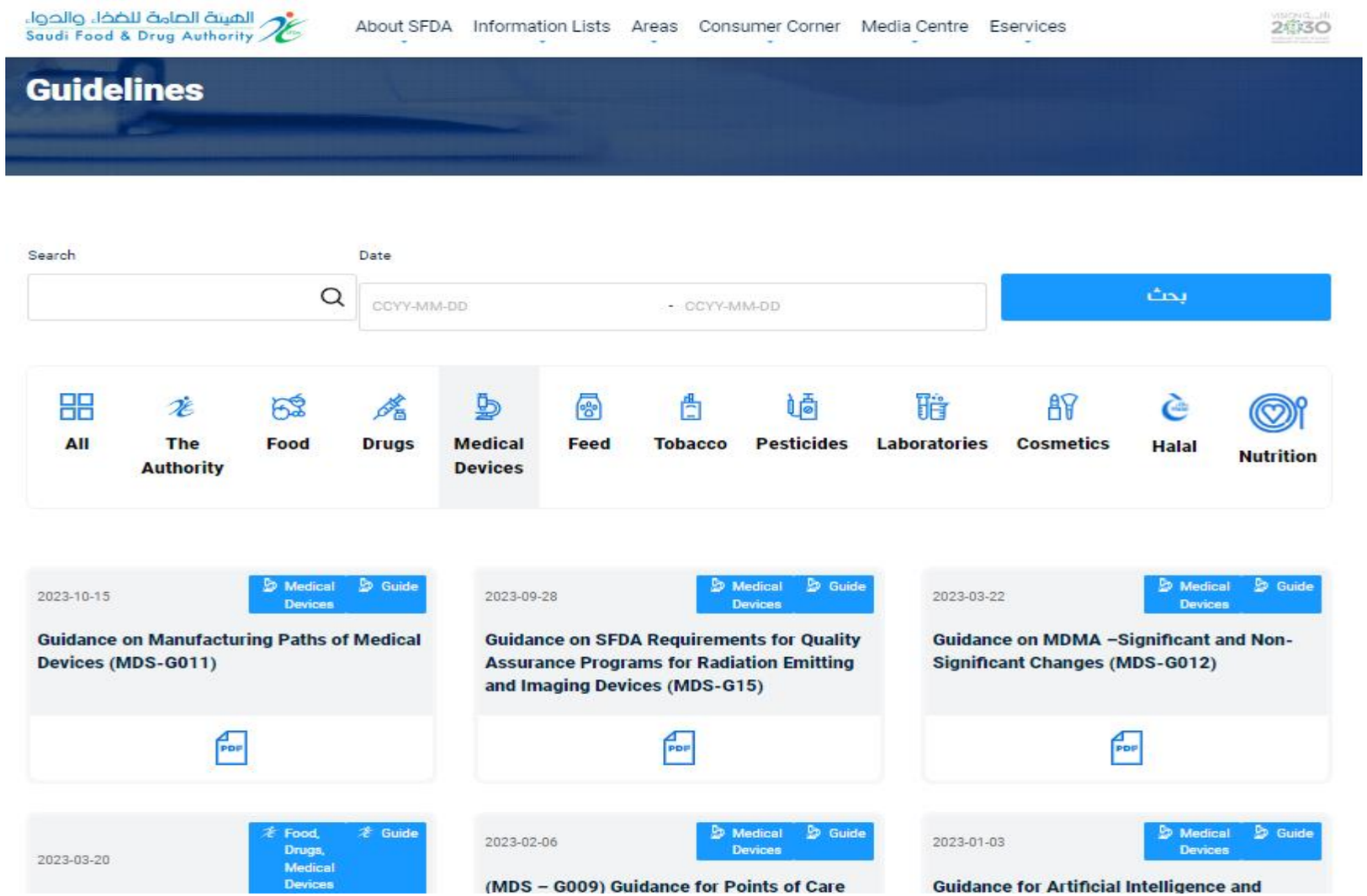
Reference to the published requirements for medical devices unique device identification (Saudi-DI) by Saudi Food & Drug Authority. And after launching the UDI database (Saudi-DI), therefore, SFDA has approved the postponed timeframe for UDI compliance as follows:

Compliance Timeframe	
Launching the UDI database and starting optional registration for all type of devices	1st October 2020
Risk Class	**Compliance date**
Class B & C (Medium risk) Class D (High risk)	1st September 2023
Class A (Low risk)	1st September 2024

- Requirements for Unique Device Identification (UDI) for Medical Devices (MDS – REQ 7)
- UDI database (Saudi-DI): https://udi.sfda.gov.sa/

For further inquiries regarding this announcement, please contact md.rs@sfda.gov.sa or call 19999.

2023 Updates : Announcements, Documents, Procedures and Statistics



SFDA-MD Regulations, Requirements and Guidelines

2023 Updates : Announcements, Documents, Procedures and Statistics

2023-02-06

Medical Devices | Guide

(MDS – G009) Guidance for Points of Care (POC) Medical Devices Manufacturing

PDF

Purpose

The purpose of this document is to define and clarify the requirements for manufacturing medical devices at Points of Care (POC).

Scope

- This document applies to healthcare providers wishing to manufacture medical devices within their facilities for their own use and for non-industrial scale (with regard to the magnitude and methods of production).
- This document applies to the following activities:
  1. Manufacturing of medical devices using 3D printer inside a healthcare facility.
  2. Manufacturing according to the Medical Device Production System (MDPS).
  3. In-House IVD.
  4. All Medical Devices modified or developed within Healthcare facility.

2023-01-03

Medical Devices | Guide

Guidance for Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices (MDS – G010)

PDF

Purpose

The purpose of this guidance is to clarify the requirements for obtaining Medical Devices Marketing Authorization (MDMA) for Artificial Intelligence (AI) and Machine Learning (ML) based medical devices, in order to place them on the market within KSA.

Scope

This guidance applies to Artificial Intelligence (AI) and Machine Learning (ML) technologies-that diagnose, manage or predict diseases by analyzing medical data.

2023 Updates : Announcements, Documents, Procedures and Statistics

2023-10-15

Medical Devices | Guide

Guidance on Manufacturing Paths of Medical Devices (MDS-G011)

PDF

Purpose

The purpose of this document is to clarify paths of manufacturing medical devices locally (including the transfer of its technology and its settlement in the KSA), its circulation, distribution within the KSA and exportation, in addition to guide manufacturers to the SFDA requirements published on its website.

Scope

This document applies to local manufacturers of medical devices.

2023-03-22

Medical Devices | Guide

Guidance on MDMA –Significant and Non-Significant Changes (MDS-G012)

PDF

Purpose

The purpose of this document is to clarify the requirements , with examples, of reporting or notifying the SFDA of significant and non-significant changes to marketing authorized medical devices/supplies, referred to in "Executive Regulation of Law of Medical Devices"/article (10-8), and "Requirements for Medical Devices Marketing Authorization (MDS-REQ1)"/Section (5).

Scope

This document applies to change(s) made to medical devices (including IVDs) held MDMA.

2023 Updates : Announcements, Documents, Procedures and Statistics

➢ Postmarket Surveillance Updates (Jan- Nov 2023)

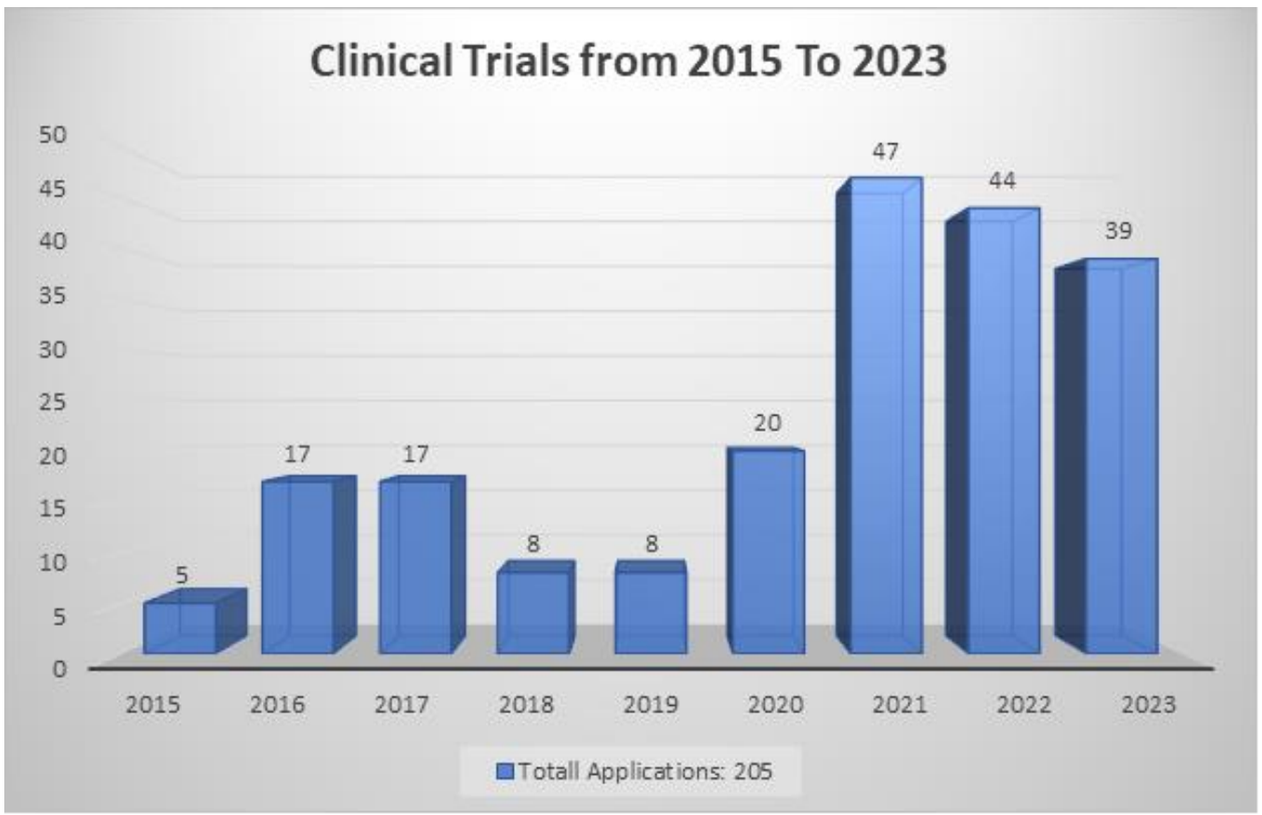
Safety Alerts

# Safety Alerts	357	
Action Types	Correction	Removal
	255	102
# Medical Devices Affected	+6 millions	

Adverse Events & Complaints

Received AE & Complaints reports	11800		
Type of Reports	(Adverse Events)	(Complaints)	Maintenance Reports, Inquiries, and Others

2023 Updates : Announcements, Documents, Procedures and Statistics



- Since 2015, the SFDA has evaluated more than 200 applications for MD Clinical trials (39 applications in 2023).
- A total of 112 approval letter has been issued to conduct clinical trials located within different cities around Saudi Arabia.

All the requirements are clearly specified in SFDA MDS-REQ 2.

2023 Updates : Announcements, Documents, Procedures and Statistics

- Currently, SAUDI ARABIA participates (P- member) in 18 international technical committees for MD standards in ISO and IEC. In addition to Advisory Groups:

AG SNAIG

Software Network and Artificial Intelligence advisory Group

Scope

Monitor and analyse available information from outside sources and advise IEC TC 62 on Artificial Intelligence (AI) and connected topics (e.g. Machine Learning, Big Data, Data Analytics, Robotics, Internet of Things) including data aspects. Additionally, software, hardware and the integration with IT-networks are included.

JAG 5

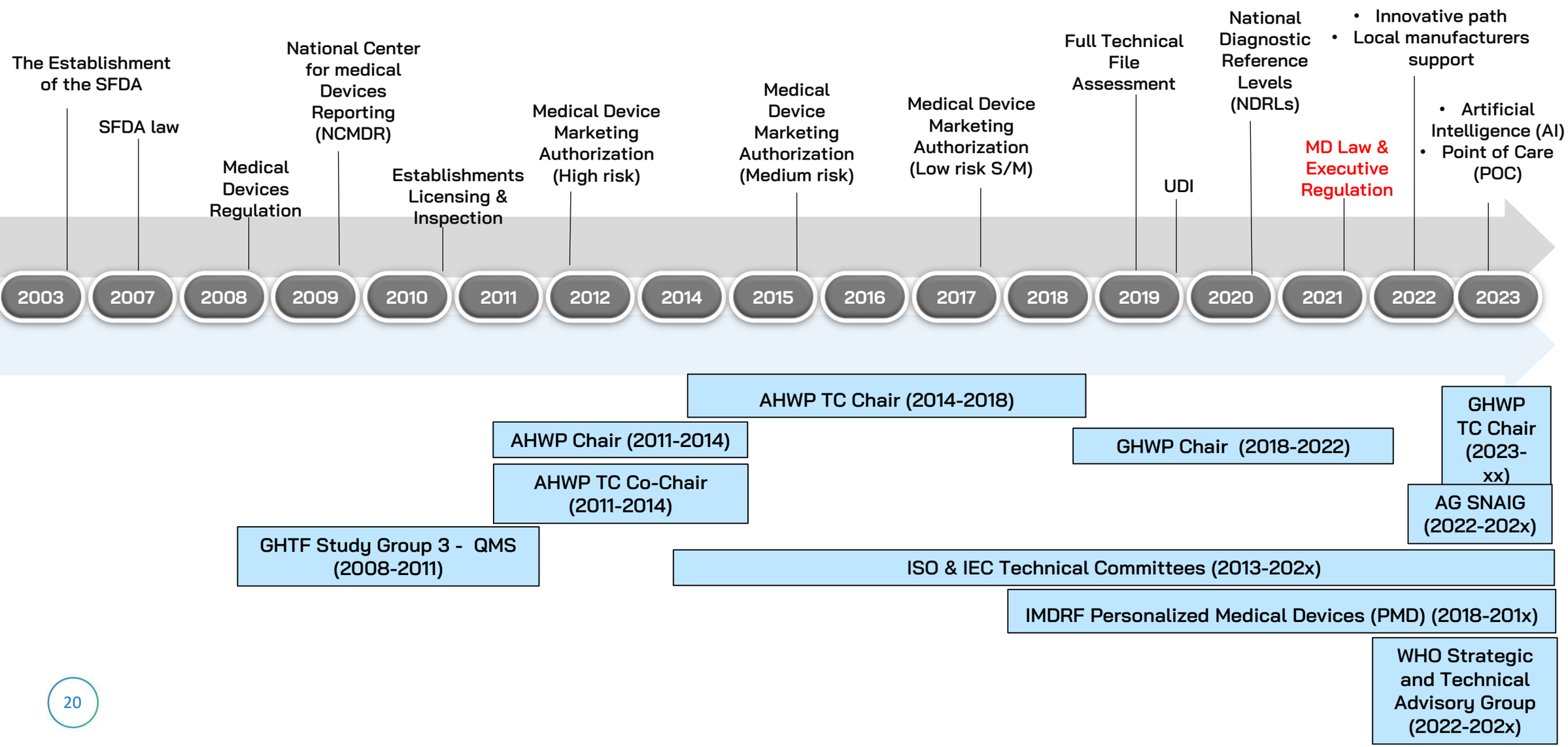
Joint Advisory Group on Life Cycle Aspects for Medical Devices

2023 Updates : Announcements, Documents, Procedures and Statistics

WHO Collaborating Centre for medical devices regulations at SFDA

- The main aim of the center is to build capacities in medical devices regulations regionally and globally.
- The center became a global center in 2022 to support Eastern Mediterranean region (EMR) and African countries.
- Two training programs in medical devices regulations are conducted annually by the center for regulators from EMR and African countries

A Summary of SFDA-MD Regulations & Efforts



شكراً
THANK YOU

To access SFDA-MD Regulations and Requirements

بالأهـم نهتـم

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