الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Regulation and Requirements

(SFDA Updates)

Eng. Abdullah Alghuraibi
Director, Regulations and Registration Support Dept.
Medical Devices Sector
Saudi Food And Drug Authority

Nov 14th 2019

Agenda

- *Introduction*
- *Recent Updates*
- *Medical Devices Evaluation*
- *Post Market Surveillance*
- *Radiological Health*
- *Contributions and Collaborations*

Mission & Vision

The updated vision and mission statements emphasize the importance of a global and scientific approach to ***promote public health and protect the community***

الرؤية
Vision

To be a leading international science-based regulator to protect and promote public health

الرسالة
Mission

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

Values


صحة المجتمع أولويتنا
Health of the community comes first
نفكر بإيجابية
We think positively
نتواصل بفعالية وشفافية
We communicate effectively and transparently
نسعى لنكون الأفضل
We aim to be the best
كلنا مسؤول
We are all responsible

In the 3rd strategic plan, SFDA is focusing on achieving measurable outcomes to promote the safety and health of the community we serve

Strategic Plan	Focus Areas
1st Strategic Plan *(2007-2011)*	• Focus on building regulatory framework • Build-up essential capabilities required to assume regulatory responsibilities
2nd Strategic Plan *(2012-2016)*	• Continue building-up operational capabilities • Address gaps in SFDA mandate • Develop organizational capabilities, policies and procedures
3rd Strategic Plan *(2018-2022)*	• Focus on ***outcomes*** **and measurable** value to stakeholders • Efficient and ***effective operations*** utilizing existing capabilities • Rely on ***scientific evidence*** and ***risk assessment*** • ***Work with partners*** to effectively monitor and control different components of the value chain

SFDA has made some changes and updates

AHWP 24th Annual Meeting

AHWP 23rd Annual Meeting

1- Developing a NEW Law for Medical Devices

Supporting Vision 2030

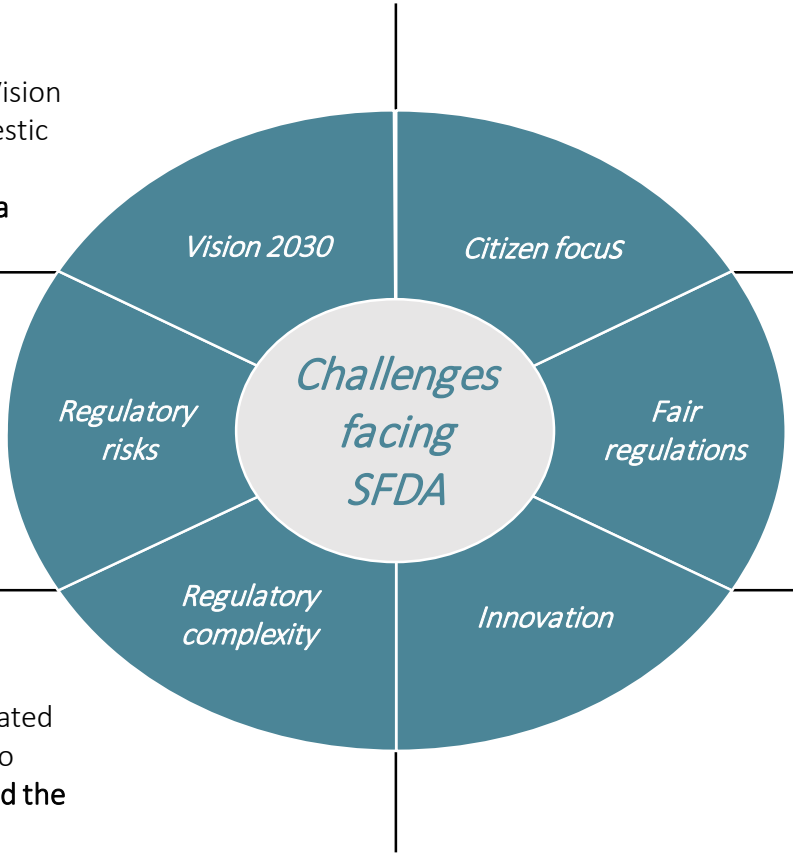
SFDA is committed to supporting the Vision 2030 as it relates to encouraging domestic companies, privatising public services, **promoting innovation and establishing a regional logistics hub**

Managing regulatory risks

SFDA must **manage complex risks associated** with one of the broadest mandates among regulators, including inspections of the facilities it regulates

Addressing growing regulatory complexity

With increasing global trade and integrated supply chains, SFDA is under pressure to **balance product safety requirements and the need for timely access to markets**



Meeting citizen expectations

With increased consumer awareness and access to information, SFDA must **improve its communication methods and be transparen**t about its results

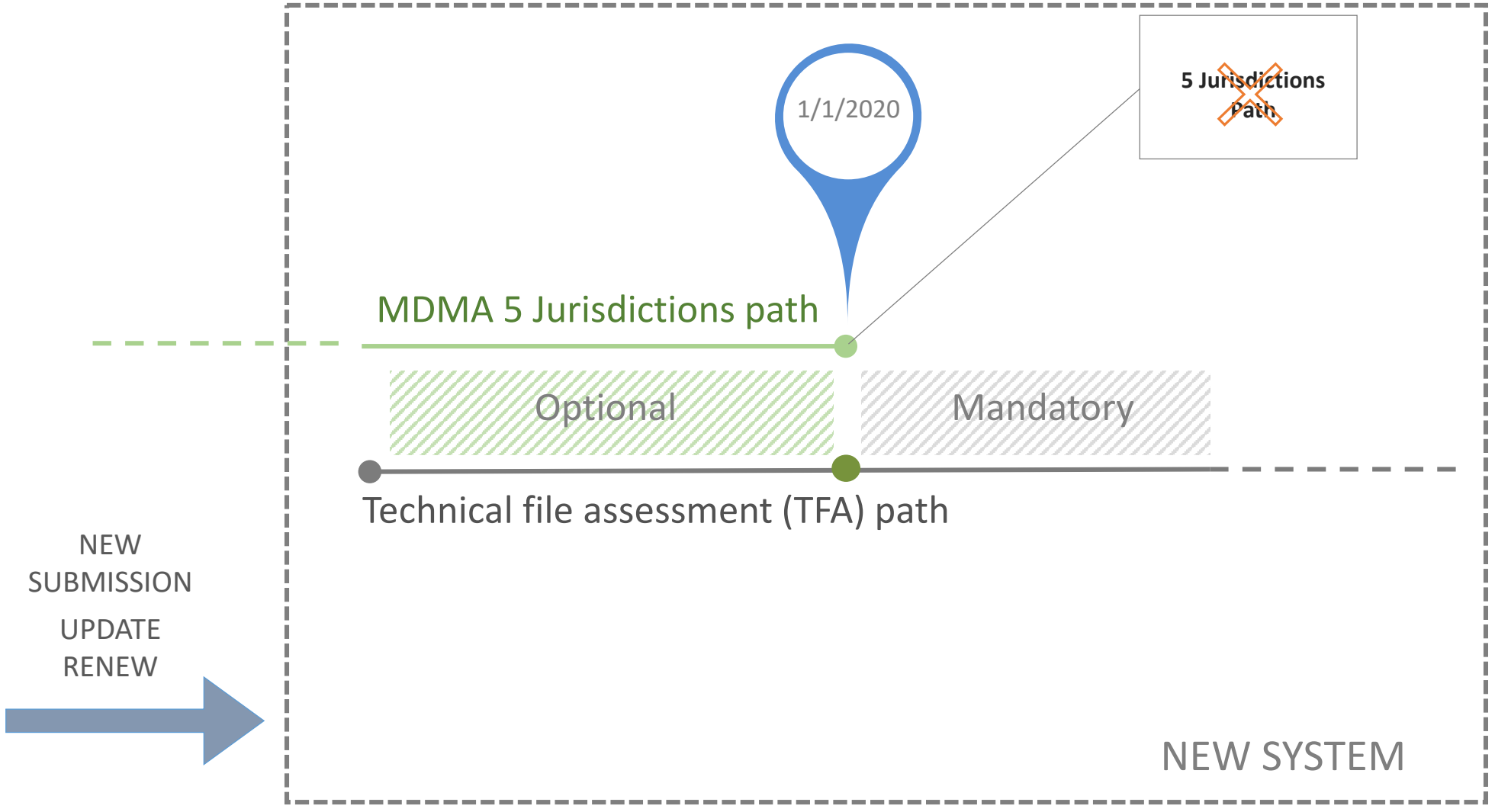
Ensuring a level playing field

SFDA intends to support Saudi companies in domestic and exports markets by **ensuring equal regulatory treatment** for domestic and international products

Keeping up with innovation

SFDA must **remain flexible and responsive** to the rapid pace of innovation with products, processes and practices in the sectors it regulates

2- A New Submission Path - Technical File Assessment (TFA)



3- Guidance on Requirements for Unique Device Identification (UDI)

SAUDI-D


MDS-G34

Guidance on Requirements for
Unique Device Identification (UDI) for Medical Devices

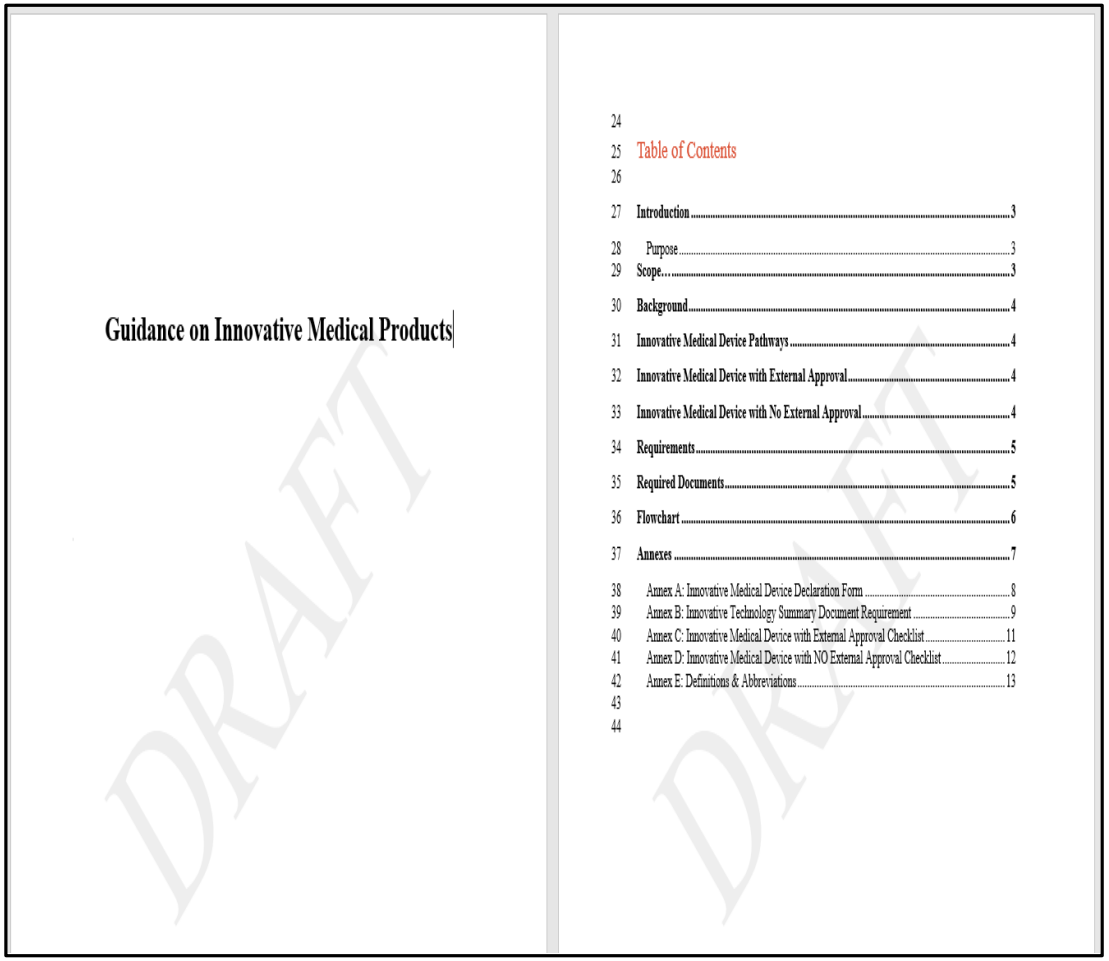
Version Number: 1.0
Version Date: 8/4/2019

This document has been published after being distributed for public comments dated on 10/12/2018 for 30 days.

4- Guidance *for Innovated Medical Devices*

- The definition of Innovative Medical Devices.
- The required documentation for Innovative Medical Devices.
- **WHAY?**

  To accelerate the access to Innovative medical devices while ensuring safety and effectiveness



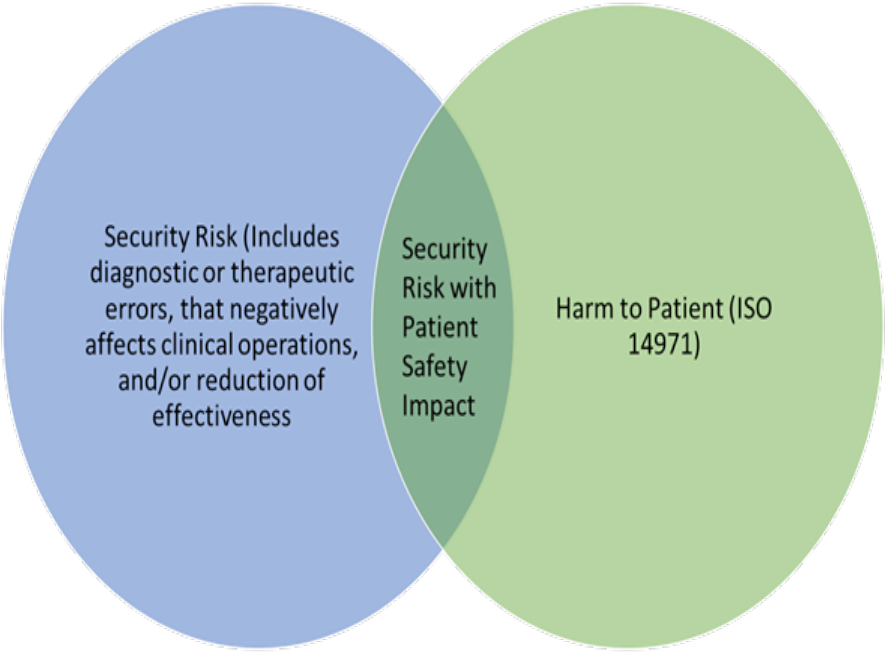
Guidance on Innovative Medical Products

DRAFT

Table of Contents

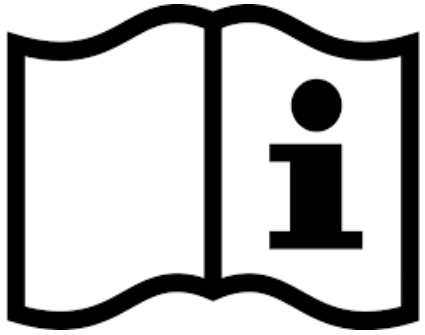
DRAFT

5- *Publishing Guidances of Medical Devices <u>Cybersecurity</u> Requirements*



- ***Requirements for Pre-Market & Post-Market*** *Cybersecurity of Medical Devices.*
- *Security of the* ***Design***
- *Device cybersecurity* ***Risk Management***
- *Cybersecurity* ***Verification and Validation Testing***
- *To* ***eliminate the potential risk*** *of cyber-attacks*

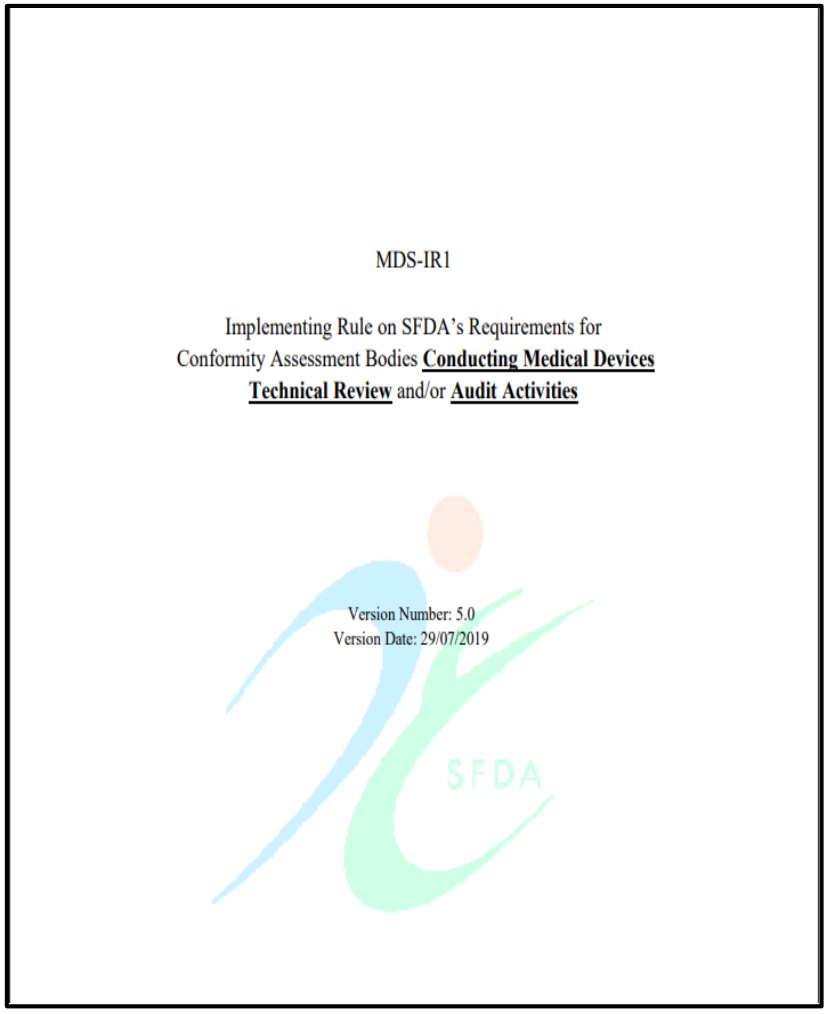
6- Guidance on Requirements for Electronic Instructions for Use (e-IFU) of Medical Devices



- This Guidance clarifies the requirements for:
  - Format.
  - Information in the IFU.
  - Risk Assessment.
  - Websites.

7- *Updating Requirements for QMS Auditing Organization and Conformity Assessment Bodies*

- Responsibilities
- Technical Requirements
- Resources
- Independence and impartiality
- Competence and Training Requirements


MDS-IR1

Implementing Rule on SFDA's Requirements for Conformity Assessment Bodies **Conducting Medical Devices Technical Review** and/or **Audit Activities**

Version Number: 5.0
Version Date: 29/07/2019

SFDA

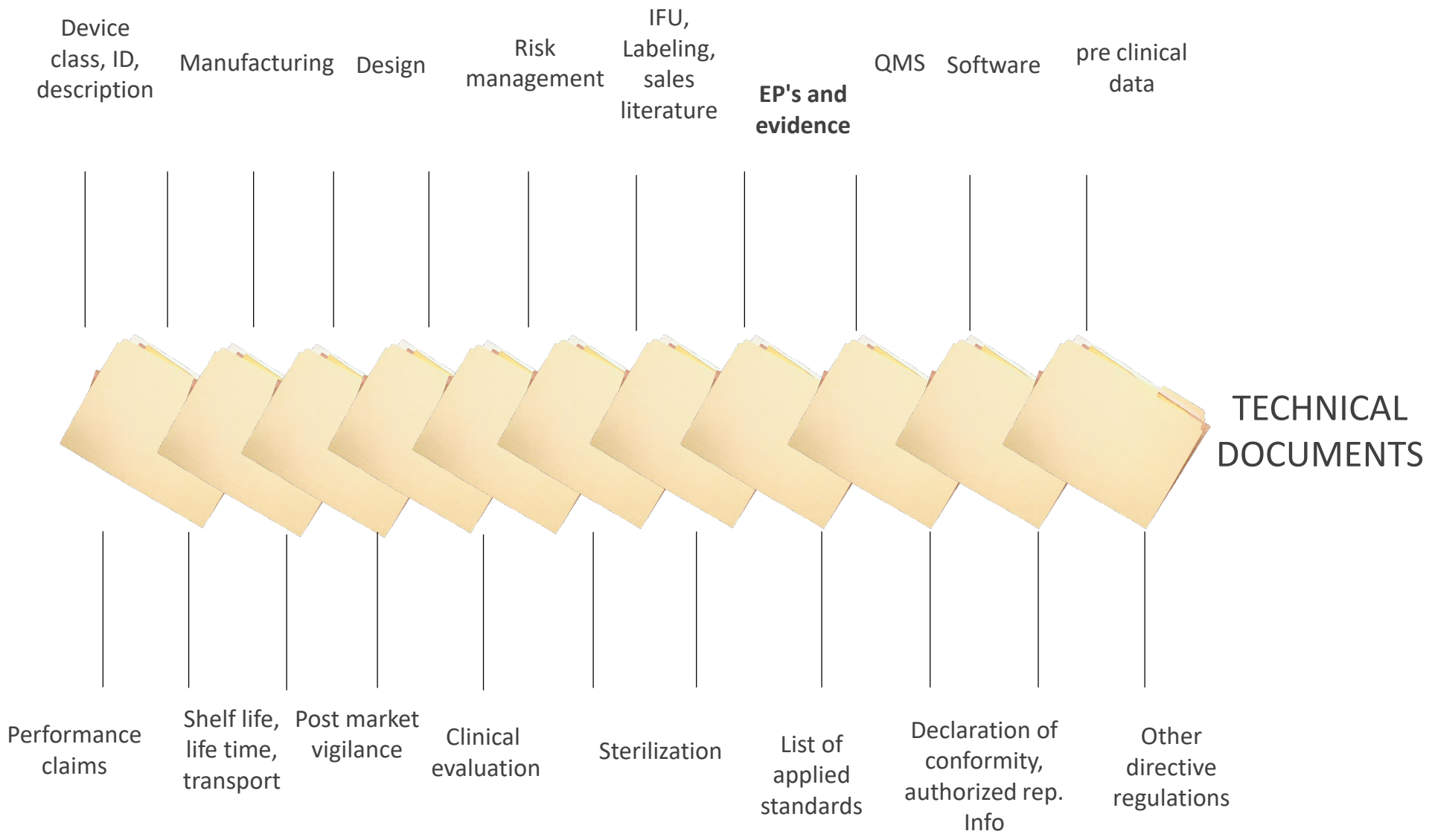
8- *Publishing a guidance for Post Market Clinical Follow-up Studies*

- ***The purpose of this document*** is to provide a guidance on planning to prepare and design postmarket clinical follow up studies related collecting and submitting clinical data for medical devices, in order to investigate and assess the residual risks of devices placed on the market.

Medical Device Evaluation

MD Technical File Assessment

Medical Device Technical file assessment



The Technical Documentation comprises of the following major sections, which are

- **Premarket technical documentation:**

1. Device description and specification, including variants and accessories.
2. Information to be supplied by the manufacturer
3. Design and manufacturing information
4. Essential principles
5. Benefit-risk analysis and risk management
6. Product verification and validation

- **Post market technical documentation:**

7. Post-market surveillance plan
8. Periodic Safety Update Report (PSUR) and post-market surveillance report

Post Market Surveillance

Proactive /Reactive surveillance

SFDA improves Post Market Surveillance (PMS) through better reporting of adverse events/ incidents and comprehensive surveillance system

Proactive

❑ **Gathered / received incidents and reports from :**

- Manufacturers
- Health care providers
- Public

❑ **Safety Signal detection from :**

- Published/ unpublished reports
- Claims
- Risk Assessment Studies
- Post-market clinical evaluation studies

❑ **Safe use of Medical Devices including radiation emitting Medical Devices.**

- Site Evaluation visits to ensure compliance with SFDA requirements.

Reactive

- **FSCA (Field Safety Corrective Action)**
- **Corrective Action follow up**
- **Safety Communication letters**
- **Workshops/ seminars**

Post Market Surveillance Plan

This include:

- **Sources** of potential post market surveillance **data**
- **Scientific methods** to assess the post-market collected data
- **Risk assessment** methods to handle properly :
  - Incidents/Adverse event investigation
  - Field safety corrective action (FSCA)
  - Trend Analysis reports
- **Communication channels** with regulatory bodies.

Periodic Safety Update Report and Post Market Surveillance Report

- **PERIODIC SAFETY UPDATE REPORT (PSUR)** is summarize of the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan (For classes A, B,C and D)
- Manufacturers of class C and D devices shall update the PSUR at least annually
- Manufacturers of class B devices shall update the PSUR when necessary and at least every two years
- Manufacturers of class A devices shall prepare a POST-MARKET SURVEILLANCE REPORT summarizing the results and conclusions of the analyses of the post-market surveillance data

SFDA monitors facilities with radiation-emitting devices to ensure proper compliance

Safe use of medical devices

Radiological Health function

SFDA Medical Devices Radiological Health Department	
Radiological Health Role	**Impact of Devices and SFDA Role**
Publish National Diagnostic Reference Level for radiation dosing	**High risk/ wide-spread impact:** Radiological products are used on many patients over the device lifespan and can impact millions of patients
Publish best practices for safe use of medical devices covering healthcare providers and cosmetic clinics	**Device performance over time:** Performance of radiological devices will evolve with use necessitating continuous maintenance and calibration
Monitor radiological products and their operating environments	**Low level of external support:** There is a capability gap in other agencies to adequately assess and monitor radiological facilities within the Kingdom
	SFDA monitoring: SFDA monitors facilities that use radiation-emitting devices within the Kingdom, including: • Hospitals • Dental clinics • Polyclinics • Cosmetic clinics
	External support: SFDA has option to outsource activities to consultation offices and CABs. SFDA is also working with CBAHI & MoH so they adopt requirements

The collaborative WHO Centre in SFDA

World Health Organization
REGIONAL OFFICE FOR THE Eastern Mediterranean

Providing the required support requested by WHO in medical devices regulations through:

- **consultations** by SFDA expert staff.
  -Involvement in reviewing WHO guidance documents
    - Decommission of medical devices
    - WHO nomenclature of medical devices.

- **workshops** to exchange the current knowledge and expertise:
  - Workshop in Lebanon (September 2019)

- **customized training** and support to effectively cover the requested support.
  - Training in Egypt (August 2019)

SFDA is Participant (P-Member) in ISO and IEC Medical Devices' Technical Committees

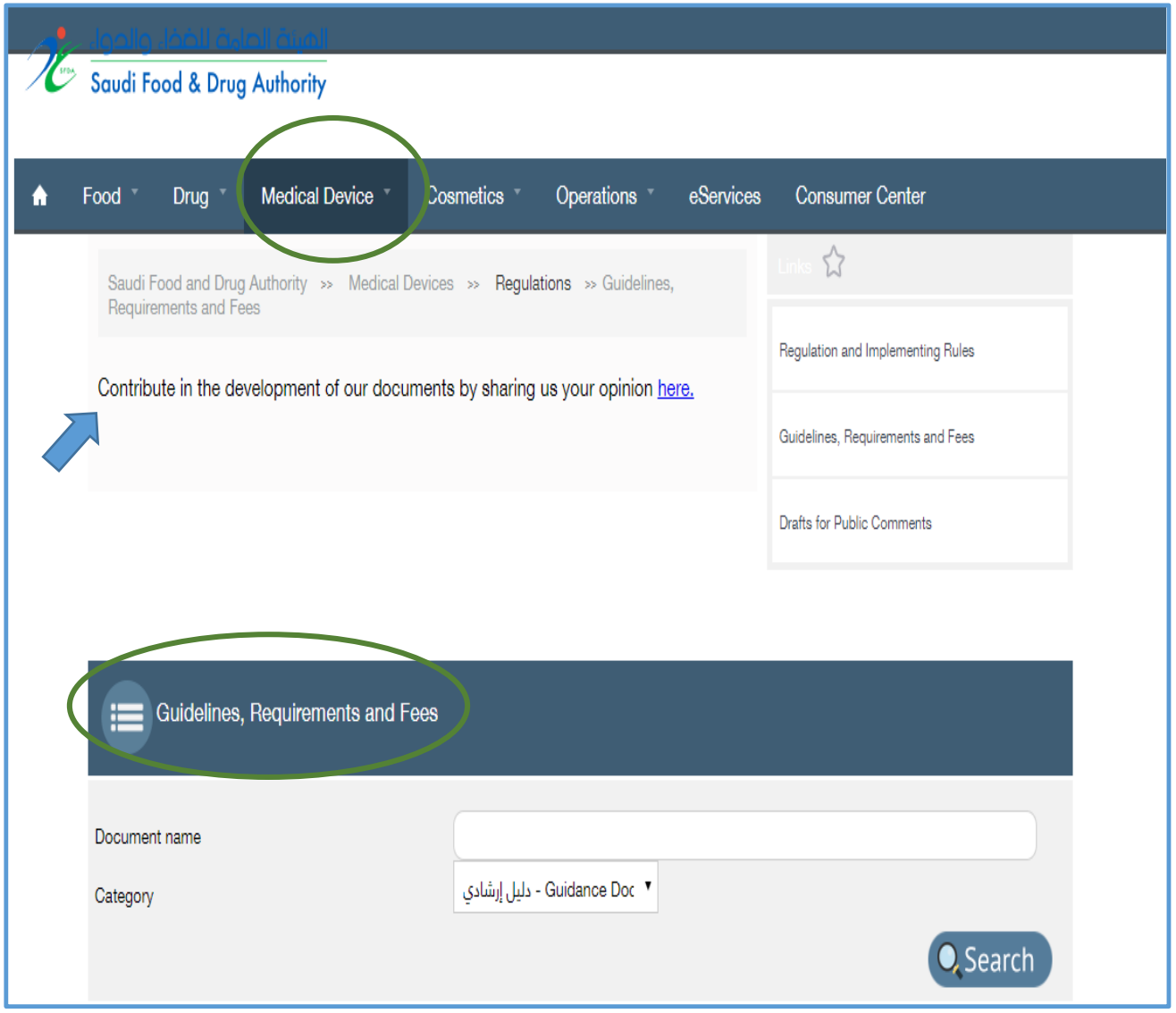
1	ISO-TC 076	Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use
2	ISO-TC 084	Devices for administration of medicinal products and intravascular catheters
3	ISO-TC 106	Dentistry
4	ISO-TC 121	Anaesthetic and respiratory equipment
5	ISO-TC 150	Implants for surgery
6	ISO-TC 168	Prosthetics and orthotics
7	ISO-TC 170	Surgical instruments
8	ISO-TC 172	Optics and photonics
9	ISO-TC 173	Assistive products for persons with disability
10	ISO-TC 194	Biological evaluation of medical devices
11	ISO-TC 198	Sterilization of health care products
12	ISO-TC 210	Quality management and corresponding general aspects for medical devices
13	ISO-TC 212	Clinical laboratory testing and in vitro diagnostic test systems
14	IEC-TC 62	Electrical equipment in medical practice
15	OIML-TC 18	Medical measuring instrument

New Participation:

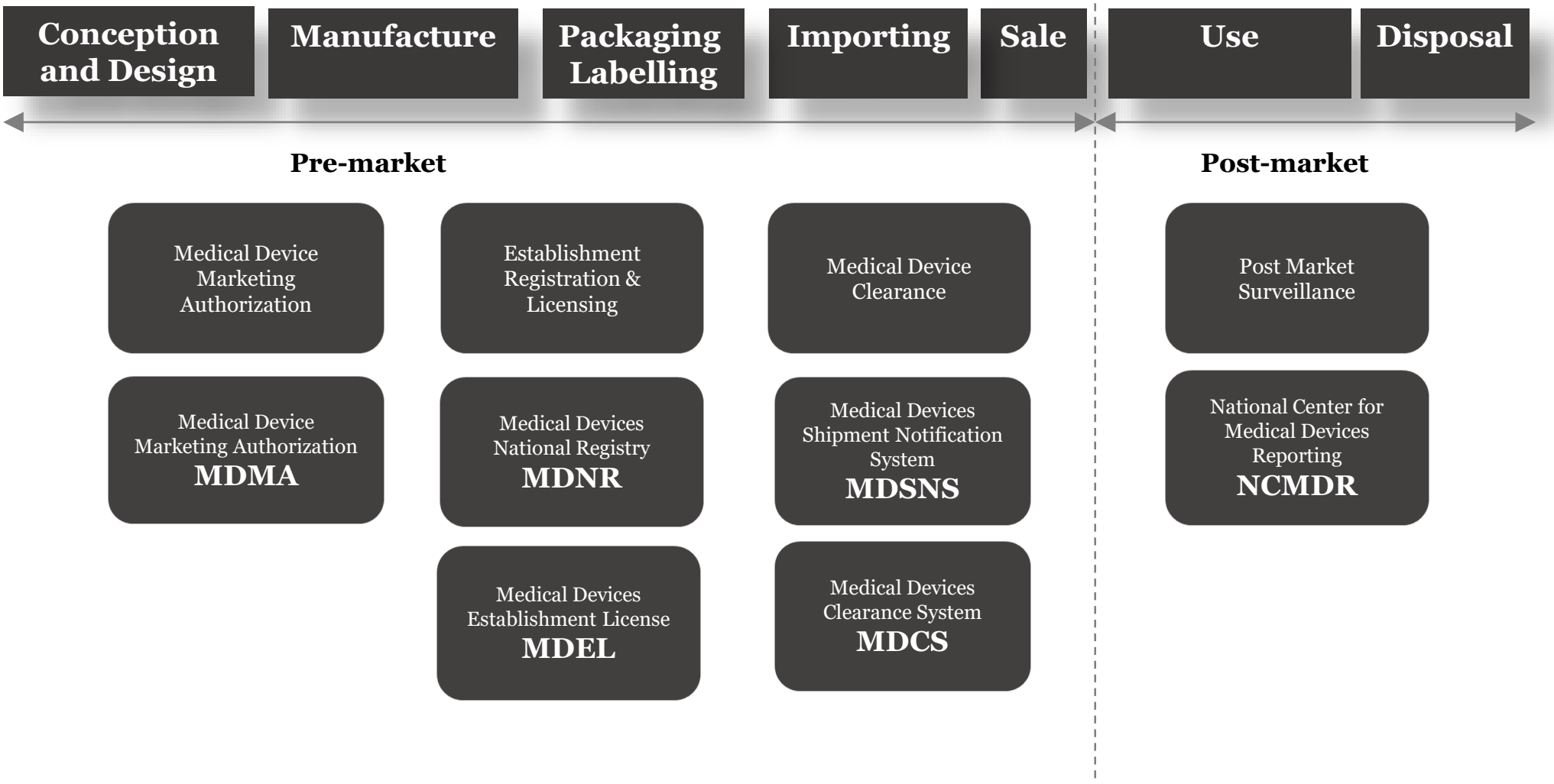
P- Member in ISO TC215 (Health Informatics)

SFDA Web-Page for Regulations and Guidances

https://www.sfda.gov.sa/en/medicaldevices/regulations/Pages/RequirementsAndConditions.aspx



Overview of Medical Devices Regulation



Patients Are At The Heart of What We DO

Having access to high quality, safe and effective medical devices is SFDA top priority

Why?

To Protect Patients and Promoting Public Health

How?

- Establishing a robust medical device regulatory system
- Implementing a comprehensive post-market surveillance plan.

MD.RS@SFDA.GOV.SA

Call : 19999

THANK YOU

شكراً لكم