Introduction of Saudi Arabia Medical Device Regulatory System

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IMDRF Meeting. 20 -22 March,2018. Shanghai, China
Saudi Food and Drug Authority (SFDA) was established under the council of Ministers resolution No (1) Dated 07/01/1424 H (March 10, 2003 G), as an independent body corporate.
Medical Device Sector

Vision
To be a regionally distinguished regulatory authority for medical devices and related electronic products, working toward safeguarding the public health of Saudi Arabia.

Mission
To ensure safety, effectiveness and quality of medical devices and their performance according to their intended purpose and to ensure the safety of related electronic products.
MDS Areas of Responsibilities

- Medical devices
- Medical In Vitro Diagnostics
- Prescription eye glasses
- Laser surgical equipment for cosmetic and their accessories
- Radiation emitting electronic devices
- Contact lenses and their solutions

Areas of responsibility
Medical Device Regulation Millstones

- 2003: Establishment of the SFDA
- 2007: Establishment of the SFDA law by royal decree
- 2008: Medical Devices Interim Regulation
- 2009: Medical Device Regulation Millstones
- 2010: Medical Device Regulation Millstones
- 2011: Medical Device Regulation Millstones
- 2012: Medical Device Regulation Millstones
- 2014: Medical Device Regulation Millstones
- 2015: Medical Device Regulation Millstones
- 2016: Medical Device Regulation Millstones
- 2017: Medical Device Regulation Millstones
- 2018: Medical Device Regulation Millstones

- MDNR: Medical Devices National Registry
- NCMDR: National Center for Medical Devices Reporting
- MDEL (I/D): Medical Device Listing
- MDEL (AR): Designation and Oversight of Conformity Assessment Bodies
- MDMA: High risk, Medium risk, Low risk (non-sterile and non-measuring)

E-Systems

Regulations
1. AHWP
   - AHWP Chair 2011-2014
   - AHWP TC Co-Chair 2008-2011 reelected 2014
   - AHWP TC Chair 2014-2017 reelected 2020
   - Former Chair WG1, Chair WG6, Member STG (U&N).

2. GHTF

3. IMDRF
   - MDSAP WG 2012-2014 as AHWP TC rep.
   - Personalized Medical Devices WG as AHWP TC rep.

4. GMDN
   Member, PAG – GMDN.

5. ISO, IEC.
   - Member in various TCs.

6. Gulf Health Console- GHC
   - Chair, GCC Central Medical Devices Registration Committee.

7. Gulf Standard Organization- GSO
   - Chair & Secretary, TC for medical devices and supplies.

8. WHO:
Update on SFDA Regulatory developments

• Medical Devices Interim Regulation requires local manufacturers, authorized representatives, importers, distributors, healthcare providers importing medical devices, and any party who is involved in importing medical devices, to register their establishments with the SFDA’s Medical Device National Registry (MDNR) and obtain MDEL.

• To obtain marketing authorization, medical devices shall comply with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA, and additionally with provisions specific to the KSA concerning labeling and conditions of supply and/or use. SFDA may issue marketing authorization in accordance with SFDA requirements.

• Saudi FDA QMS

• Clinical trails (registration licensing and evaluation)
**Is:** An organized system that collects data for scientific, clinical, policy purposes and a specific set of demographic and health data on identifiable persons. Observation on current patterns of practice w/out influencing the treatments or interventions.

**Advantages:**

- Tracing & contacting implant recipients via Healthcare provider for FSN’s/Recall’s
- Monitor & capture the performance data of implanted devices (long term & short term)
- Credible reference database that enlists medical implants data and all related data (Scientific, health)
Thank you