The 25th AHWP/GHWP Annual Meeting

Chinese Taipei Regulatory Update

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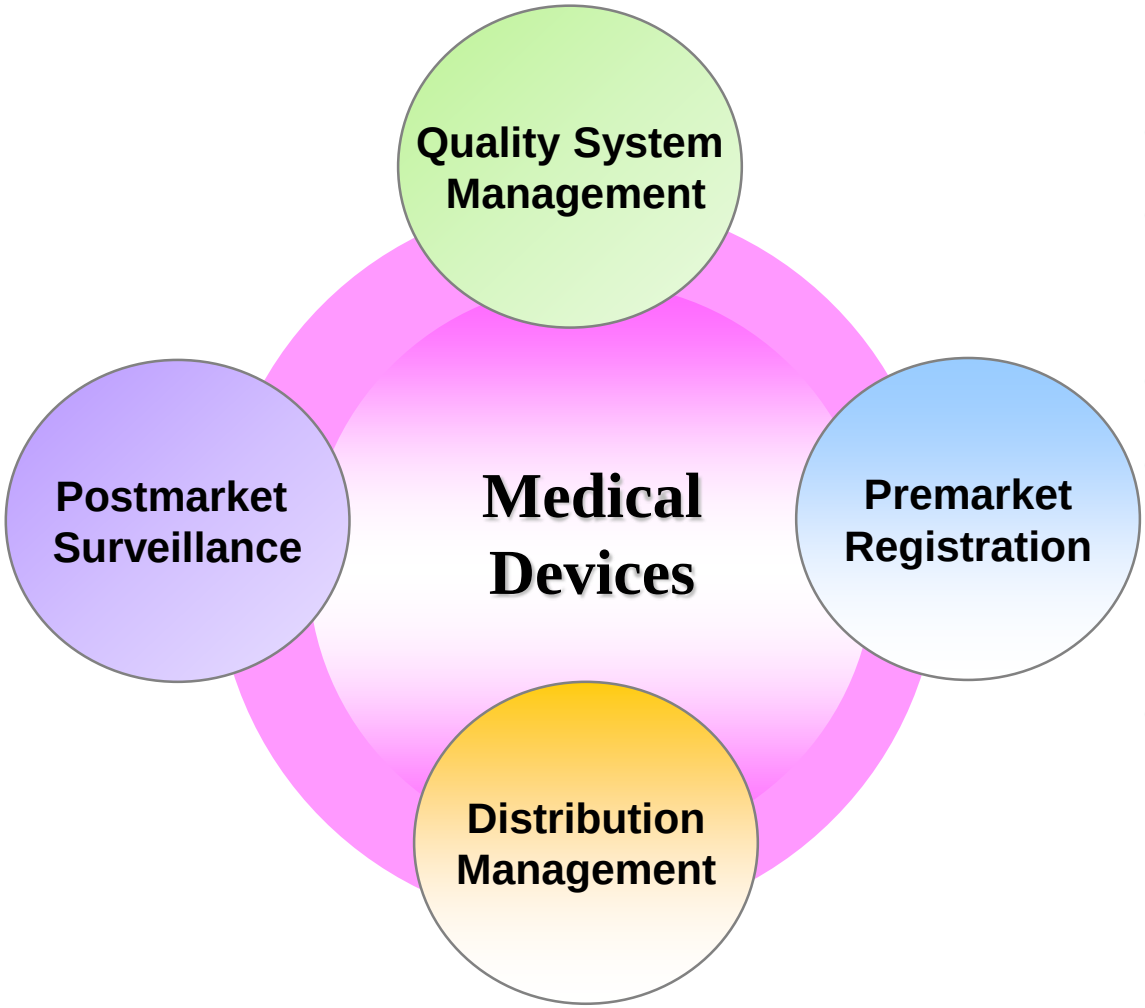
衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration
http://www.fda.gov.tw/

Outline

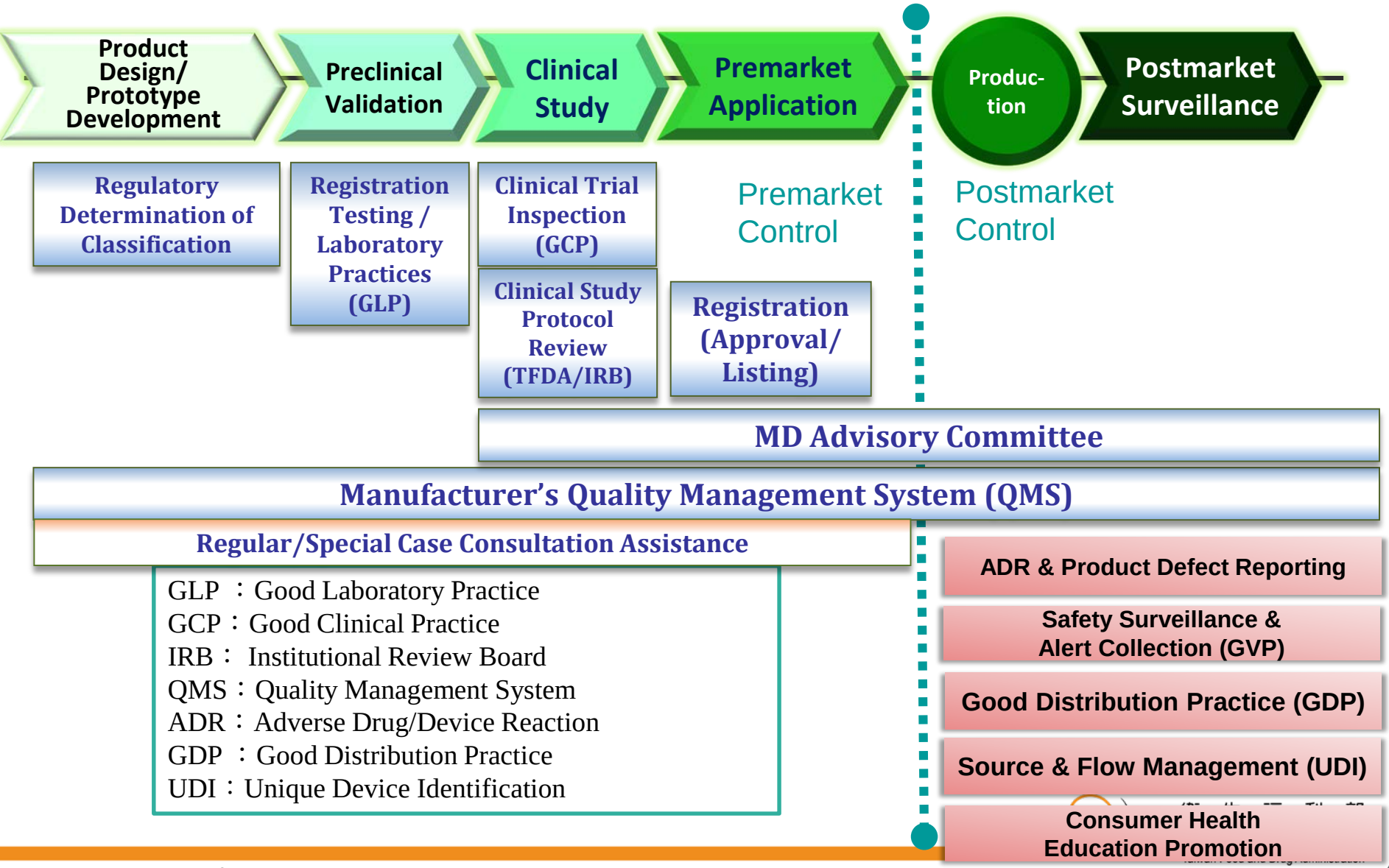
- Regulation overview
- Premarket requirements
- Postmarket mechanisms
- Activity highlights
- Key policies

Medical Device Regulatory Framework

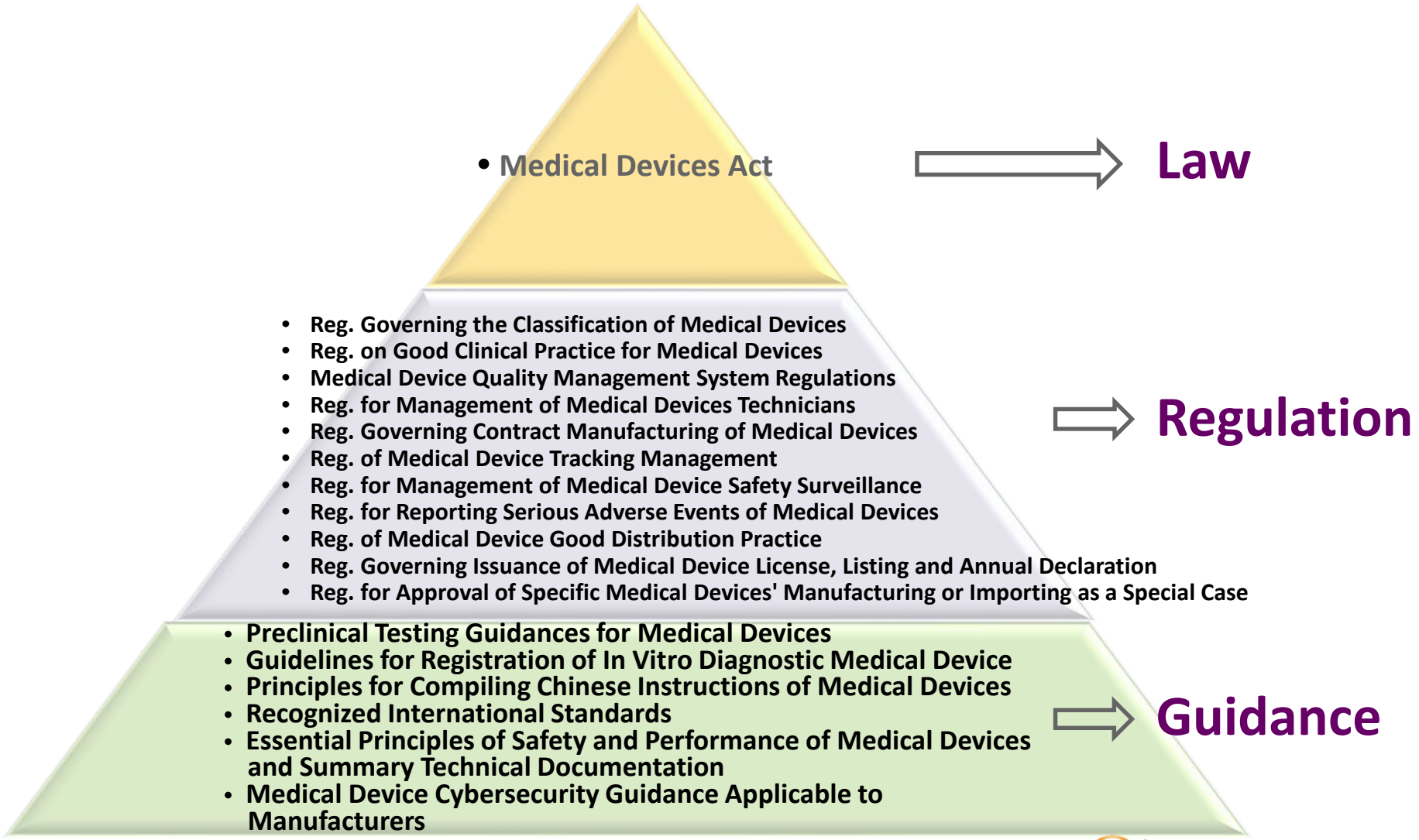


- Beginning of registration: 1973
- GMP implementation: 1999 (or QMS since May 2021)
- Reclassification: 2000
- No. of registered & listed MD: 50,546 (as of Oct. 2021) (74% Imported; 26% Domestic)
- No. of registered domestic MD manufacturers: 1,964 (as of 2020)

Medical Device Life Cycle Management



Basis of Medical Device Regulation



Key Points of Medical Devices Act

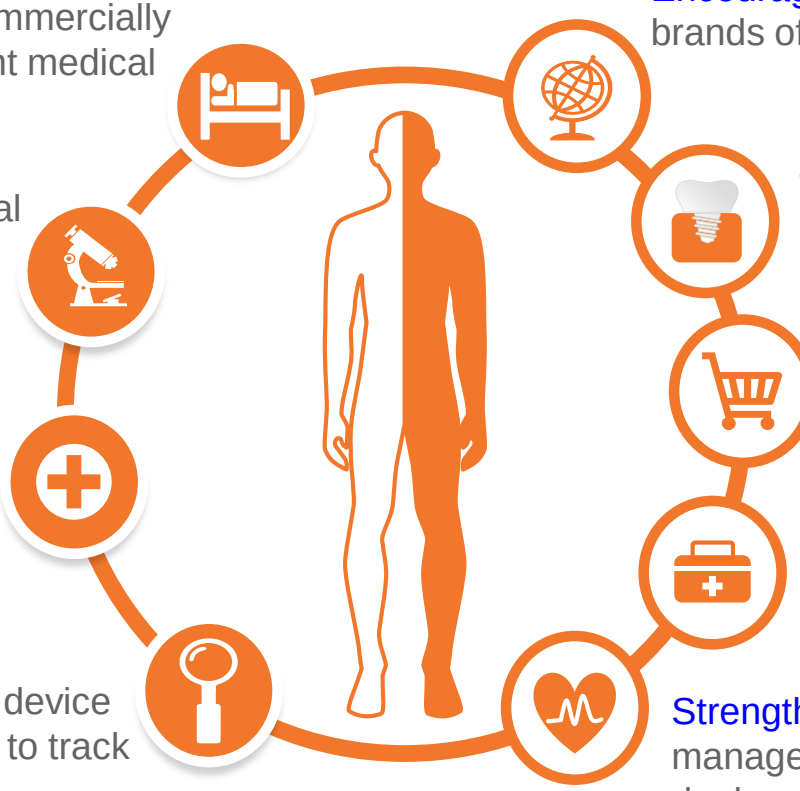
The Medical Devices Act (MDA) takes effect from May 1, 2021
(authorizes the announcement of 22 regulations and 16 legal orders).

Speed up procedures for new medical devices to be made commercially available to meet urgent medical demands

Simplify clinical trials of medical devices and speed up R&D of domestically manufactured medical devices

Improve management of medical device dealers and enhance consumer protection

Establish medical device flow management to track product and flow



Encourage R&D to develop local brands of medical devices

Implement risk management and simplify procedures for low-risk medical devices

Control the management of new sales types for business development

Establish good distribution practice to ensure product quality

Strengthen autonomous management of medical device dealers and postmarket surveillance

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Risk Based Classification

Class 1	Class 2	Class 3
QMS/QSD*	QMS/QSD*	QMS/QSD*

3 Classes

➢ **Paper Submission**

- Class 1
  - Admin doc
  - Basic product info (if necessary)
  - Technical doc (for some devices)
- Class 2
  - Admin doc
  - Basic product info
  - Technical doc**
  - Clinical evidence info**
- Class 3
  - Admin doc
  - Basic product info
  - Technical doc
  - Clinical evidence info**

➢ **Online Listing**
(for certain devices)

*QSD: Quality System Documentation

**Exemption or replacement may apply for devices with predicates

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Medical Device Categories

A. Clinical Chemistry and Clinical Toxicology Devices
B. Hematology, Pathology, and Genetics Devices
C. Immunology and Microbiology Devices

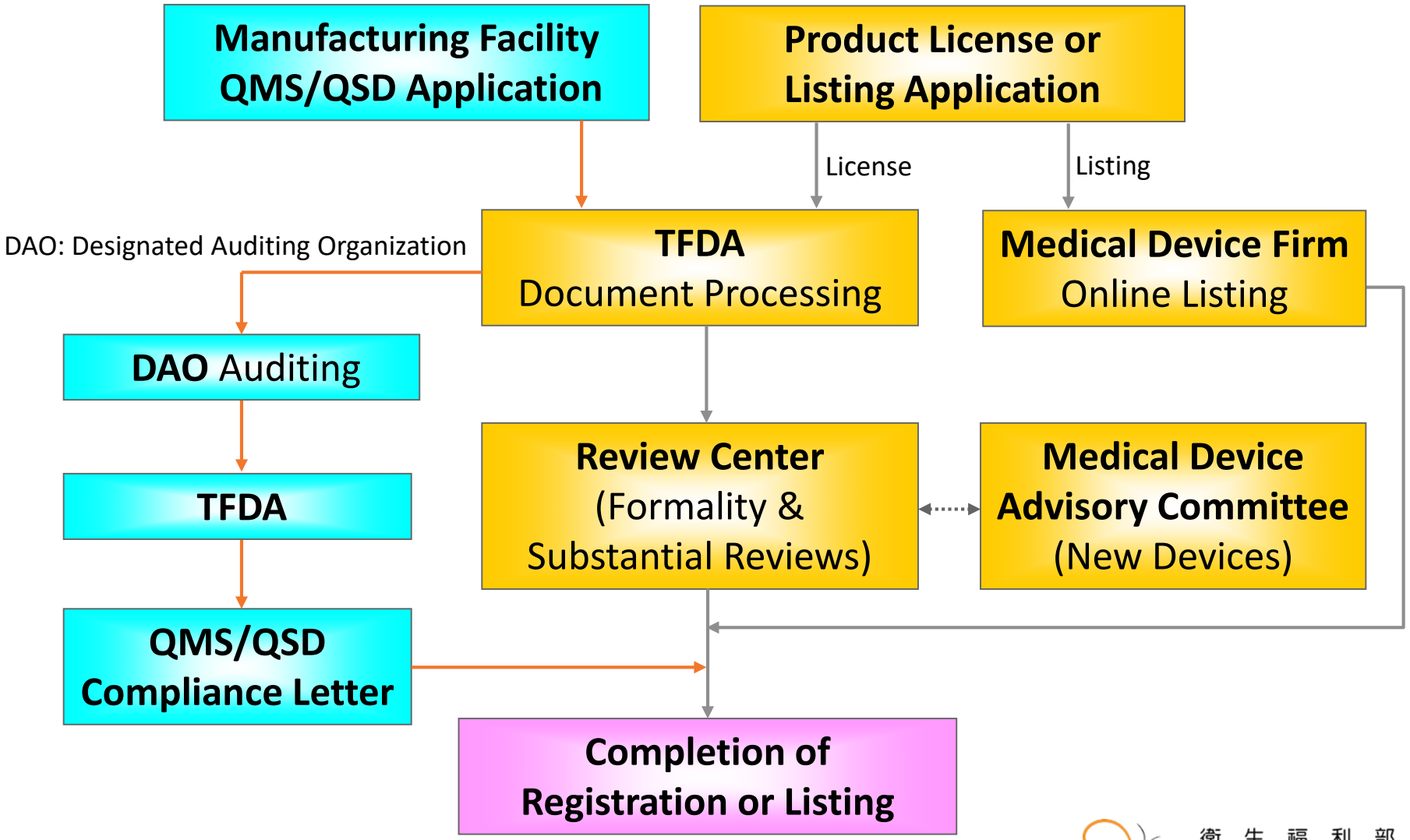
IVD

D. Anesthesiology Devices
E. Cardiovascular Devices
F. Dental Devices
G. Ear, Nose, and Throat Devices
H. Gastroenterology and Urology Devices
I. General, Plastic Surgery, and Dermatology Devices
J. General Hospital and Personal Use Devices
K. Neurological Devices
L. Obstetrical and Gynecological Devices
M. Ophthalmic Devices
N. Orthopedic Devices
O. Physical Medicine Devices
P. Radiology Devices

16 Categories

non-IVD

Premarket Pathways



Postmarket Surveillance

Manufacturer
- Adverse event / product defect
- Clinical trial adverse event
- Periodic Safety Update Report (PSUR)
- Voluntary recall notification

Asian Harmonization Working Party (AHWP)
Safety Alert Dissemination System (SADS)

Local Health Authority
- Investigation, seizure, and sampling of non-compliant product

Consumer & Medical Personnel
- Adverse device reaction (ADR)
- Product defect

Active surveillance of international postmarket safety information

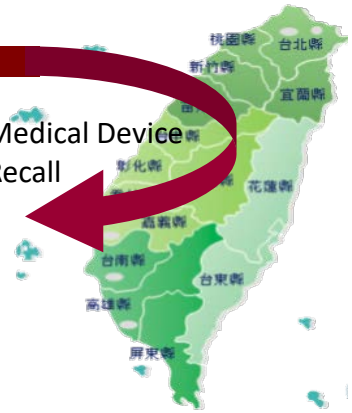
TFDA

Support

Analysis

National ADR Reporting Center

Medical Device Recall



Postmarket Reporting System

Account Information

Manuals & Documents

Contact Numbers

General Instructions

http://qms.fda.gov.tw

Hyperlink to obtain updated safety information

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Highlights of 2021

Announced Unique Device Identifier (UDI) Requirements on April 6, 2021

- Current UDI requirements for Class II and Class III medical devices
- Effective dates of UDI labeling:
  - Class III implantable devices: June 1, 2021
  - Class III devices: June 1, 2022
  - Class II devices: June 1, 2023
- Mandatory submission of device identifier information to TFDA's UDI database

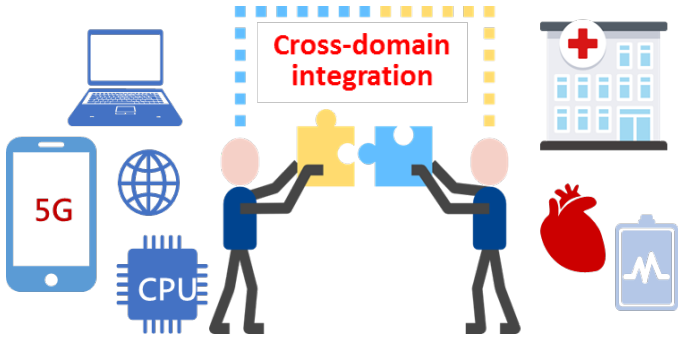
Highlights of 2021 (Cont'd)

Established & Inaugurated the AI Medical Device Center (AIMeC) on May 7, 2021

Implement consultation and assistance for domestic AI-based MD

Conduct training and promotion activities

Establish a single entry web portal of internet platform



Provide assistance in developing relevant policies and guidances

Establish a matching platform for ICT industries and medical institutions

AI: Artificial Intelligence
ICT: Information and Communication Technology

Key Points of Policy Administration

MDA Implementation

- Enforce 22 supporting subsidiary regulations & complete 16 announcements

Premarket Control

- Optimize review process & develop regulatory practices for emerging MDs

Clinical Trial

- Build a platform of eClinical trials management system

Postmarket Control

- Establish mechanisms to regulate the source and flow of implanted MD products

Distribution Management

- Promote Unique Device Identification (UDI) System

Industry Assistance

- Improve search of potential case sources & early-stage regulatory assistance

International Cooperation

- Participate actively in international organizations & establish bilateral agreements

Thank you for your attention!

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