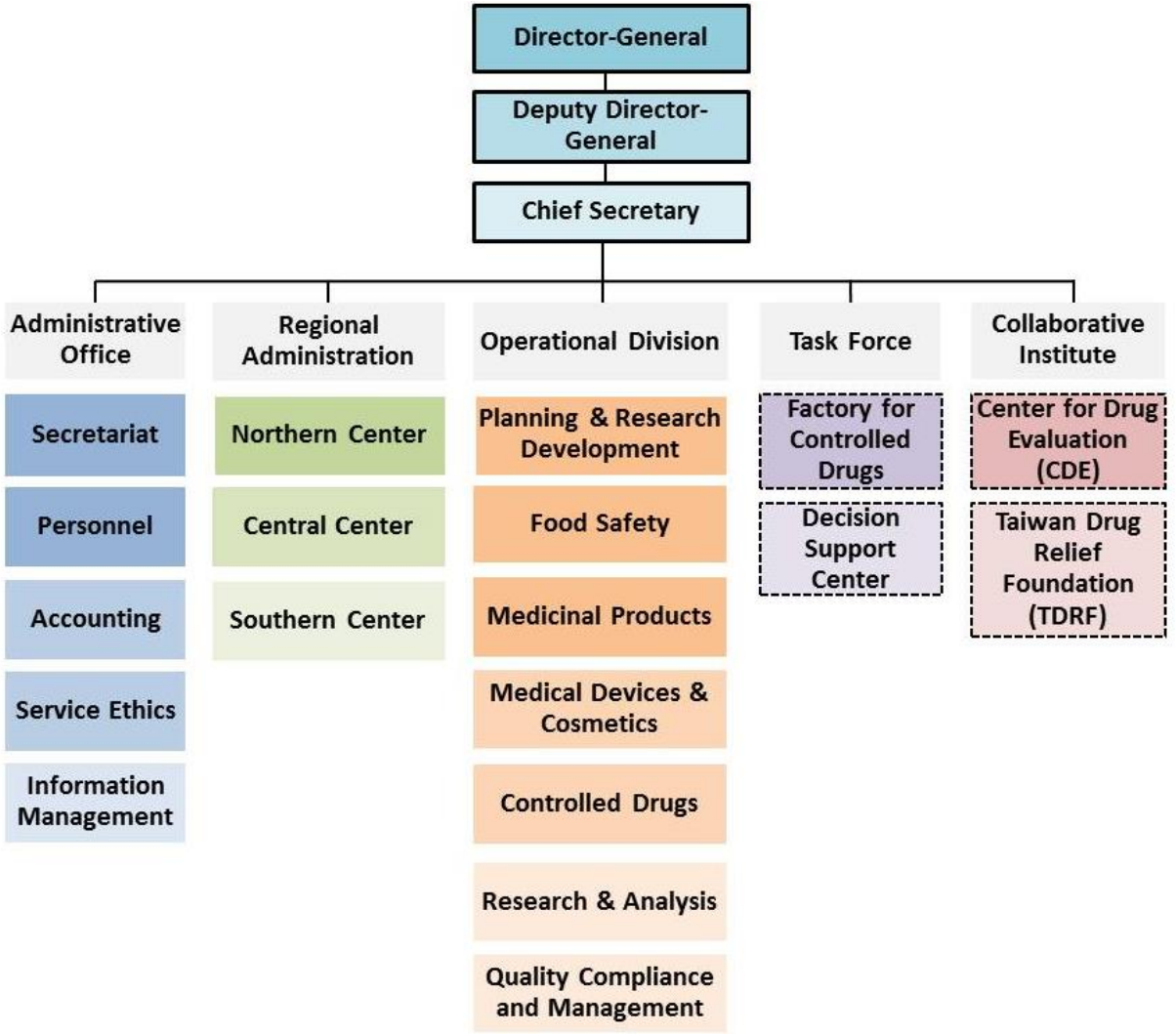
Chinese Taipei Regulatory Update

Division of Medical Devices and Cosmetics, TFDA

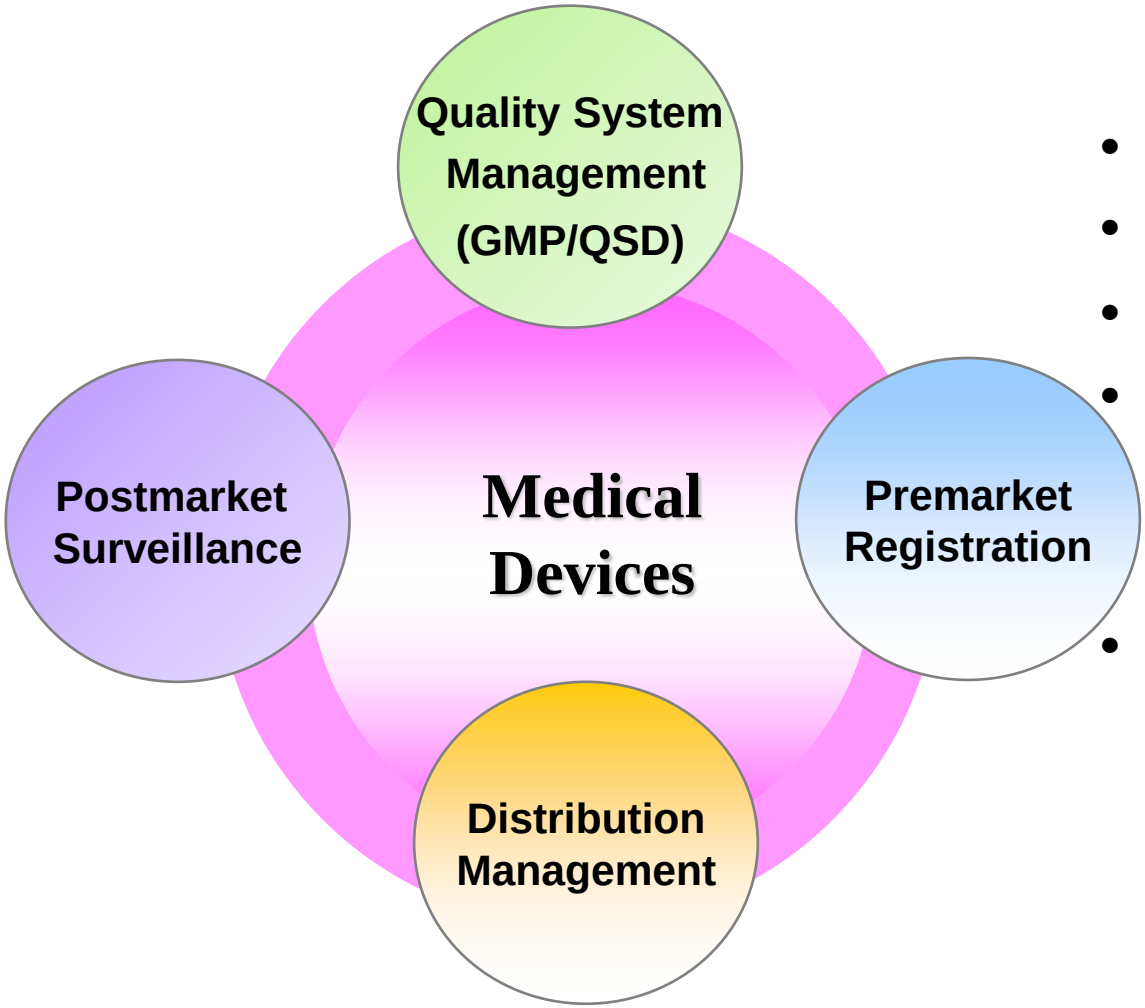
December 2020

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

TFDA Organization Chart



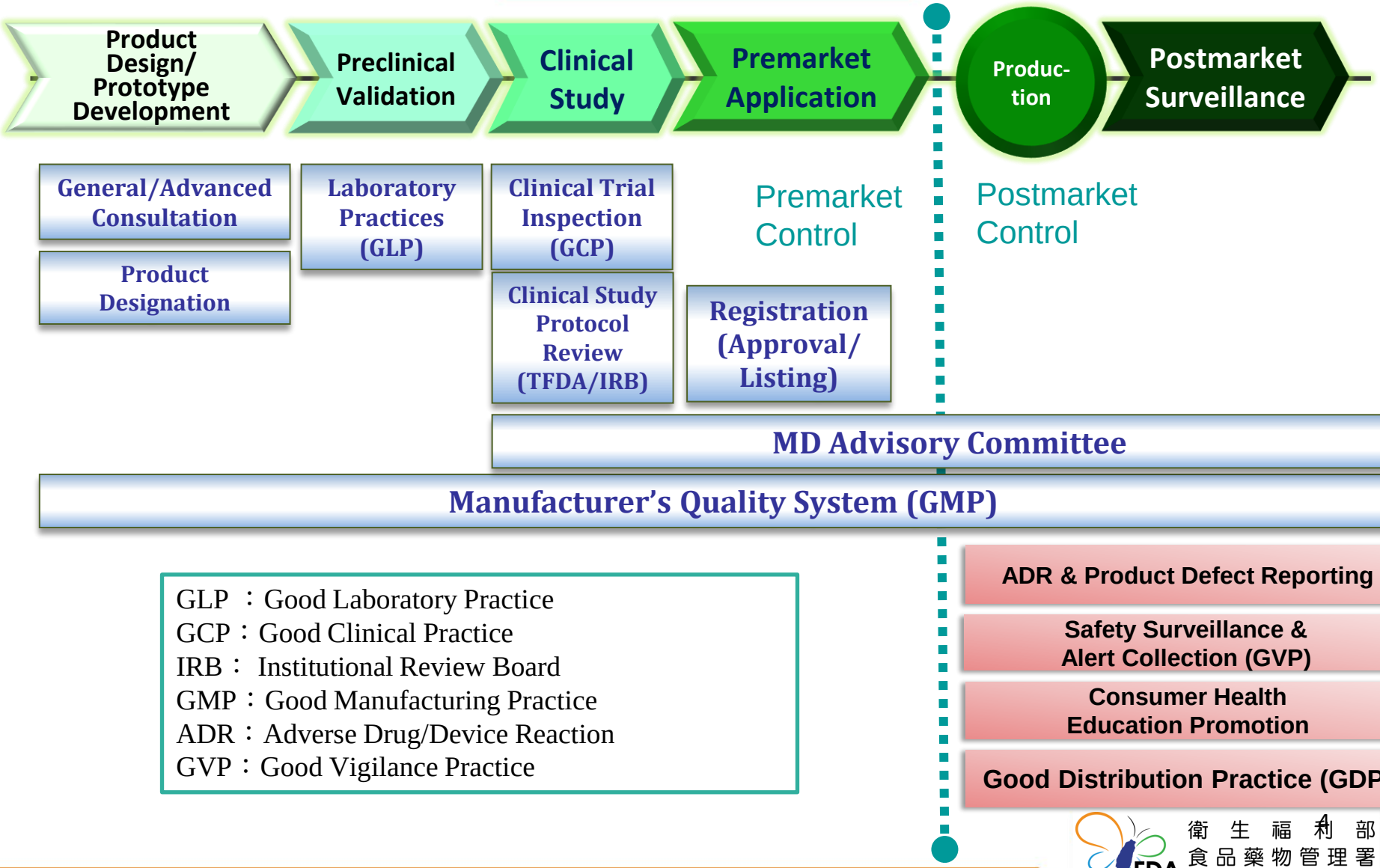
Medical Device Regulatory Framework



- Beginning of registration: 1973
- GMP* implementation: 1999
- Reclassification: 2000
- No. of registered MD licenses: 46,711 (as of 2020) (75% Imported; 25% Domestic)
- No. of registered MD manufacturers: 1,649 (as of 2019)

*ISO 13485 adopted

Medical Device Life Cycle Management



GLP ：Good Laboratory Practice
GCP：Good Clinical Practice
IRB： Institutional Review Board
GMP：Good Manufacturing Practice
ADR：Adverse Drug/Device Reaction
GVP：Good Vigilance Practice

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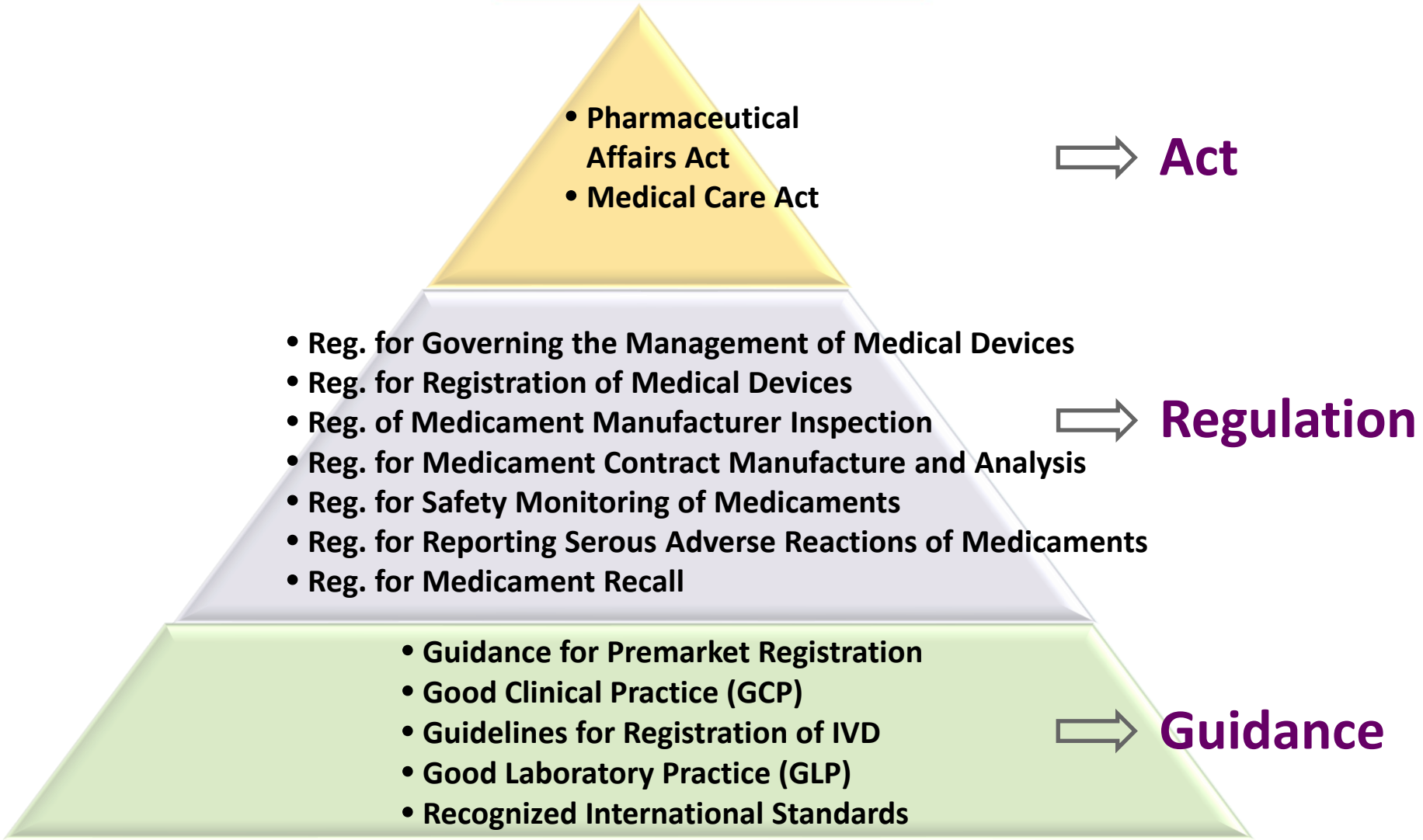
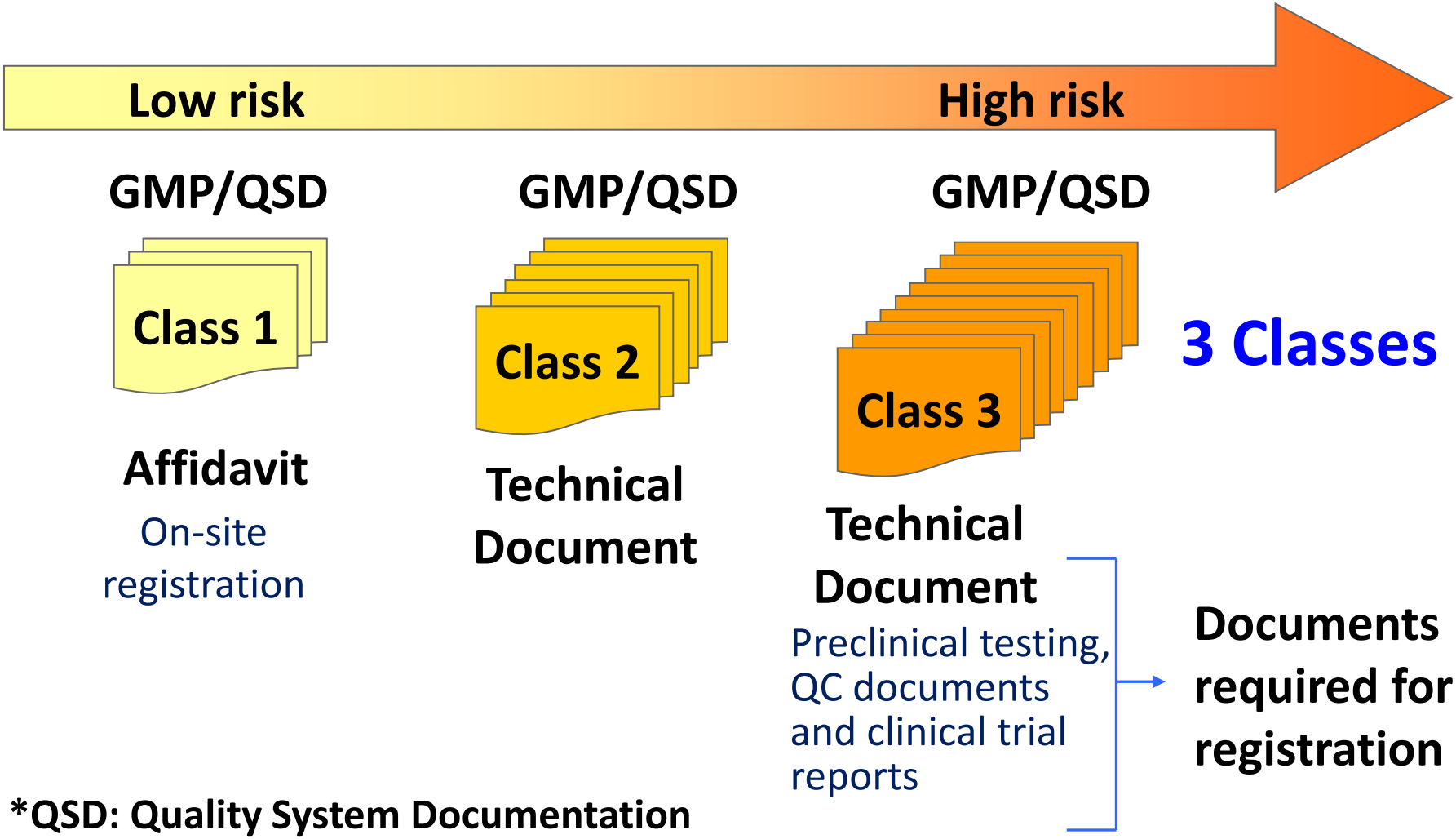
Basis of Medical Device Regulation



Risk Based Regulation



Medical Device Categories

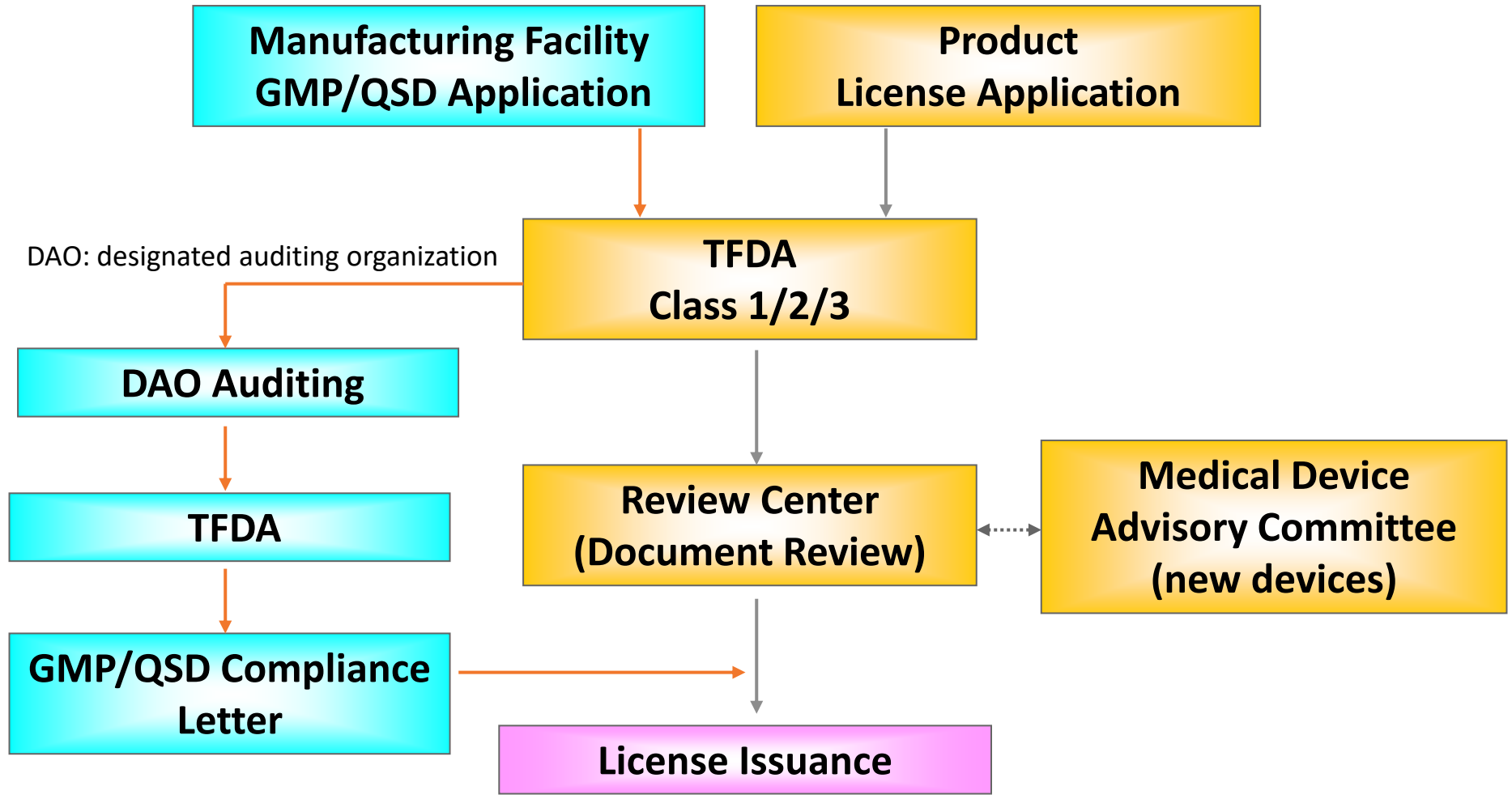
A. Clinical Chemistry and Clinical Toxicology Devices
B. Hematology and Pathology Devices
C. Immunology and Microbiology Devices
D. Anesthesiology Devices
E. Cardiovascular Devices
F. Dental Devices
G. Ear, Nose, and Throat Devices
H. Gastroenterology-Urology Devices
I. General and Plastic Surgery Devices
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

IVD

16 Categories

non-IVD

Premarket Registration



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

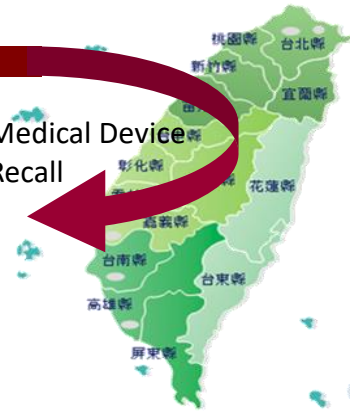
TFDA

Support

Analysis

National ADR Reporting Center

Medical Device Recall



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Medical Devices Act (MDA)

- 2020-01-15 promulgated by Presidential Order
- Establishing a separate act for a globally harmonized medical device regulation
- Perfecting the regulatory system of medical device total product life cycle

Key Points of Policy Administration

MDA Implementation

- Draft 22 supporting subsidiary regulations & promulgate 18 announcements

Premarket Control

- Optimize review process & develop regulatory practices for emerging MDs

Clinical Trial

- Build a platform of eClinical trials management system

Post-market 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