The 23rd AHWP Annual Meeting

Chinese Taipei Regulatory Update

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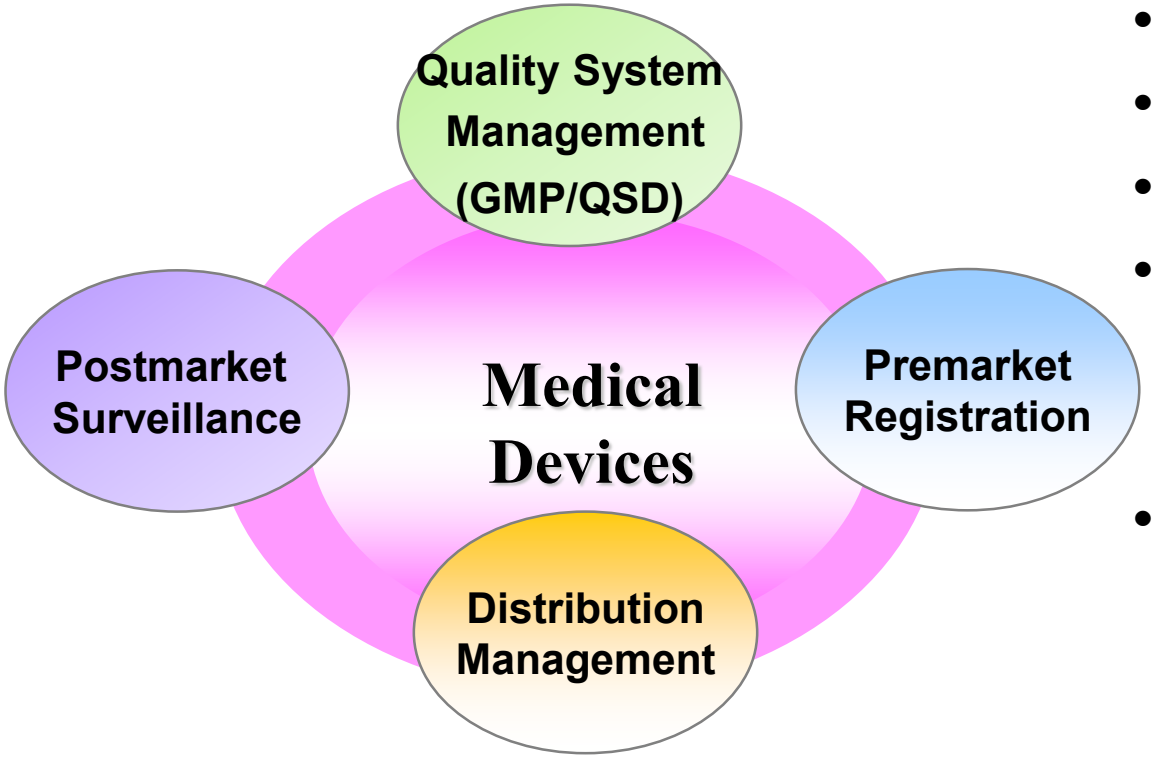
Kuala Lumpur, Malaysia

General Overview

Medical Device Regulatory Framework



- Beginning of registration: 1973
- GMP* implementation: 1999
- Reclassification: 2000
- No. of registered MD licenses: 44,694 (as of July 2018) (76% Imported; 24% Domestic)
- No. of registered MD manufac-turers: 1,516 (as of 2017)

*Adoption of ISO 13485

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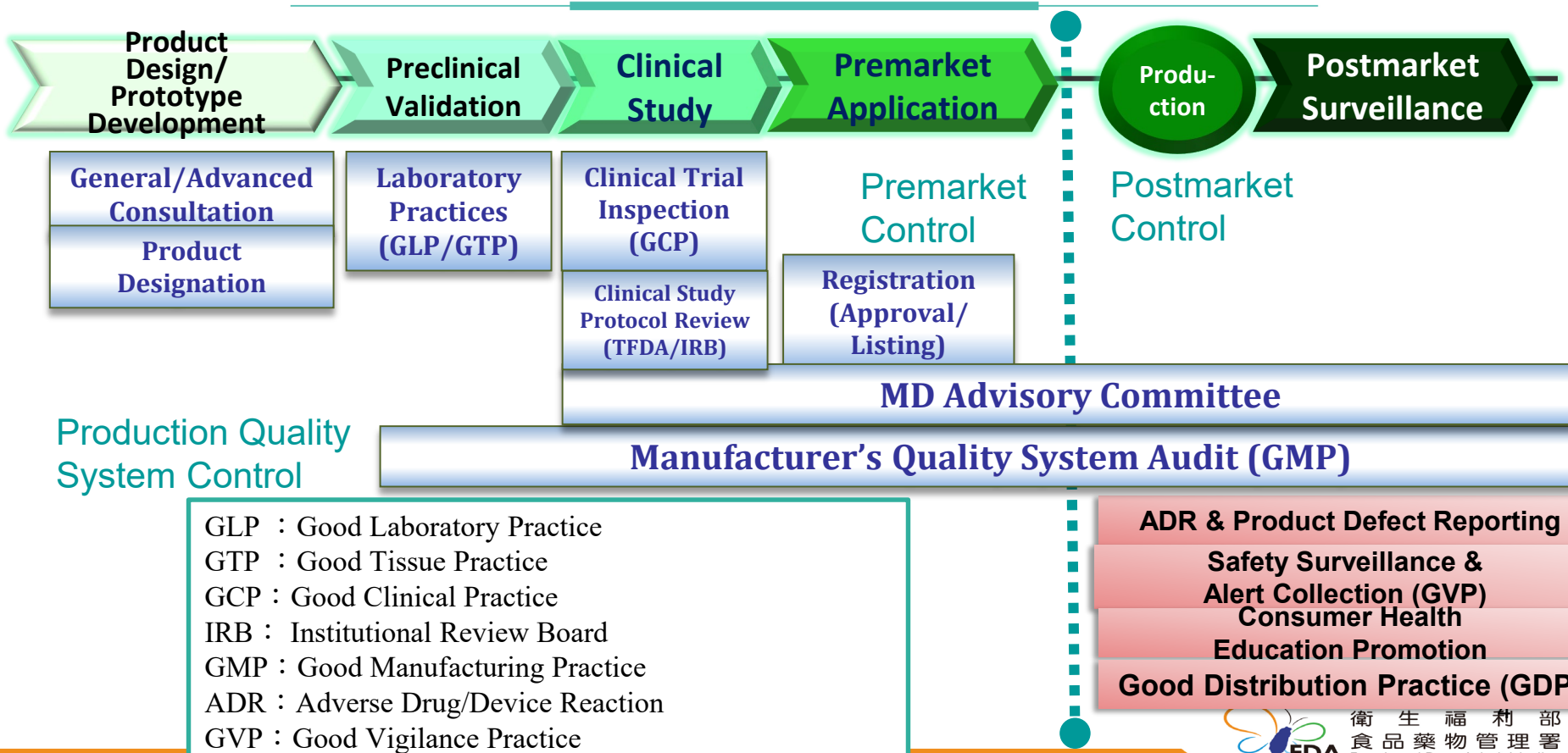
Medical Device Life Cycle Management



GLP ：Good Laboratory Practice
GTP ：Good Tissue 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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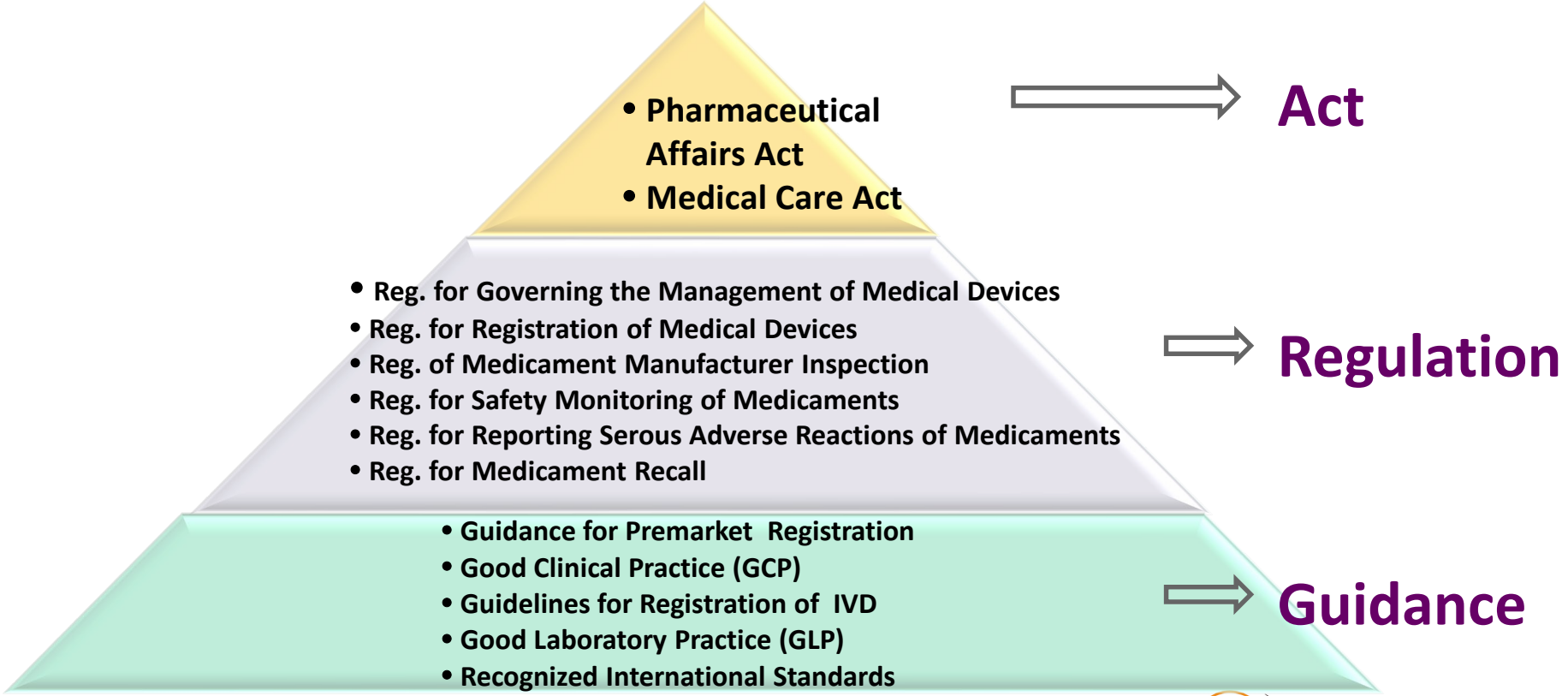
Basis of Medical Device Regulation



Premarket Regulation

Risk Based Regulation

Low risk

GMP/QSD

Class 1

Affidavit

On-site registration

GMP/QSD

Class 2

Technical Document

High risk

GMP/QSD

Class 3

Technical Document

Preclinical testing, QC documents and clinical trial reports

3 Classes

Documents required for registration

***QSD: Quality System Documentation**

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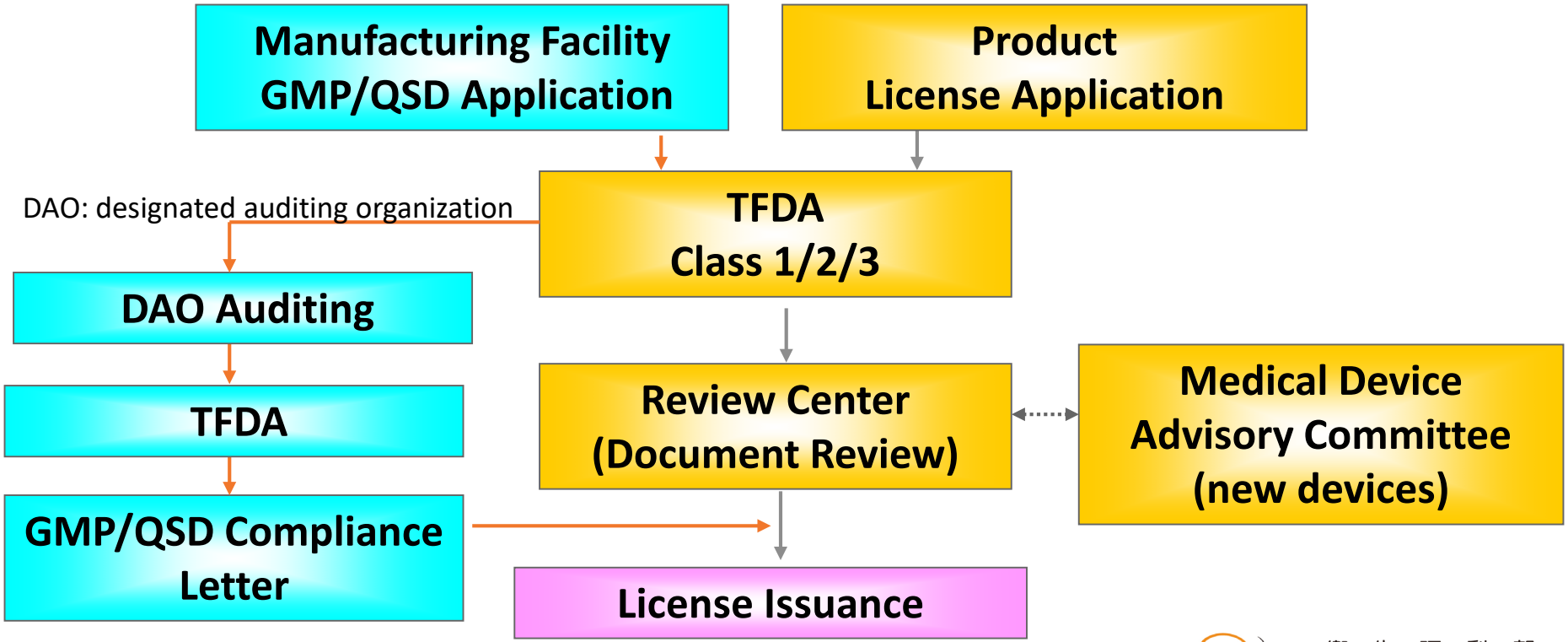
Premarket Registration



Medical Device License Database

http://www.fda.gov.tw/MLMS/H0001.aspx

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Postmarket Regulation

Postmarket Surveillance

Manufacturer

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

Local Health Authority

- Investigation, seizure, and sampling of non-compliant product

Consumer & Medical Personnel

- Adverse device reaction (ADR)
- Product defect

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

Active surveillance of international post-market safety information

TFDA

Support

Analysis

Medical Device Recall

National ADR Reporting Center

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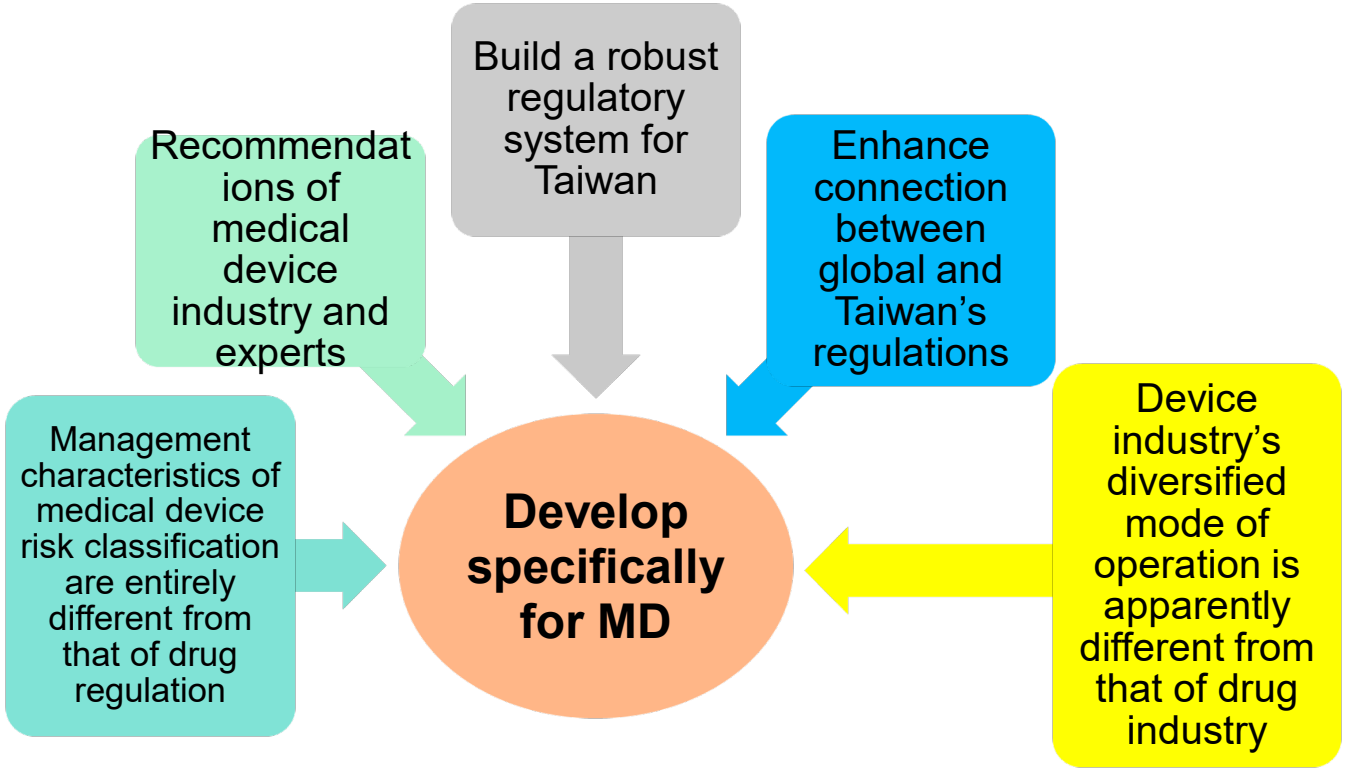
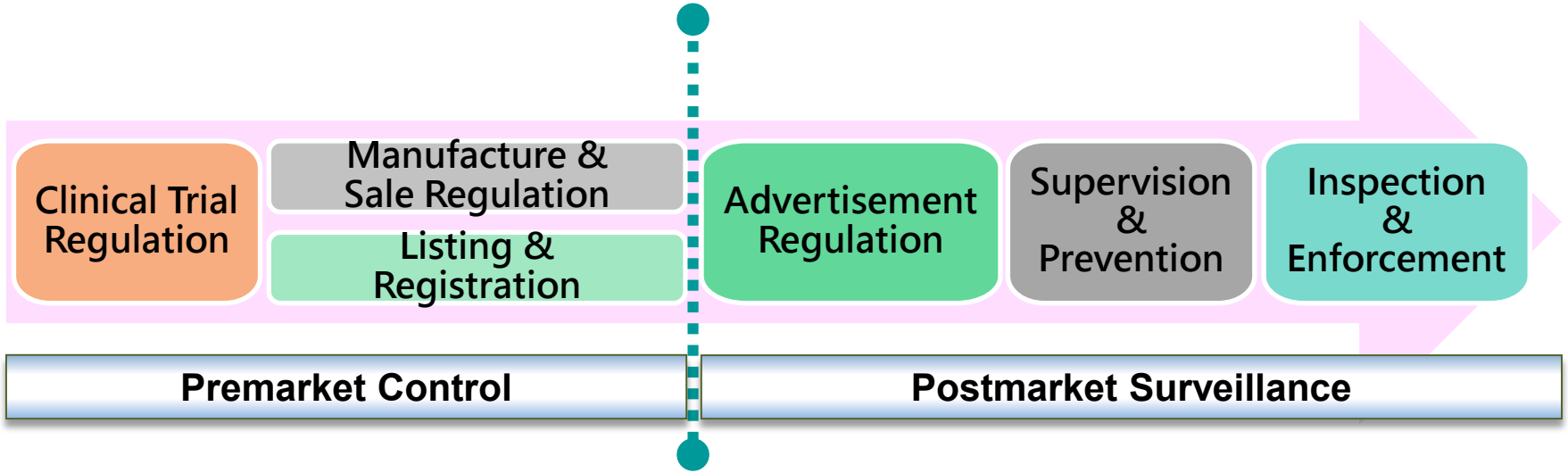
Medical Devices Act (draft)

Reasons for Promoting Medical Devices Act (MDA)



Regulatory Framework for Total Product Life Cycle in MDA



Main Points for Establishing MDA(1)

To advance industrial technology development and product innovation

- ✓ Incorporate manufacturers that engage in design and marketing of medical devices under their name
- ✓ Encourage industry development & product innovation, and in order to benefit patients, incorporate mechanisms of marketing acceleration and support for newly innovative medical devices

To enhance regulation of diversified technology industry of medical devices

- ✓ Incorporate regulation of business undertakings that perform maintenance and/or repair of medical devices
- ✓ Require technicians having professional background & experience with educational training to be employed according to different medical device categories in order to enhance professional management
- ✓ Further regulate the types of sale and supply for specific medical devices

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Main Points for Establishing MDA (2)

To strengthen management of product flow and distribution quality

- ✓ Assign responsibility to medical device firms and medical institutions for establishing and maintaining data on direct supply sources and flow of products
- ✓ Promote quality management of medical device distribution to ensure that product quality would not be impaired during distribution process

To fulfill regulation of medical devices by risk classification

- ✓ Registration system for a portion of the low risk medical devices would be changed to online listing and the validity of registration would be extended by filing annual report

Main Points for Establishing MDA (3)

To set up framework for regulating clinical trials

- ✓ Incorporate relevant practices of clinical trial
- ✓ Stipulate that medical device clinical trials which are conducted and have been announced as having no significant risks may be exempt from applying for competent authority's approval

To reinforce regulation of medical device postmarket safety surveillance

- ✓ Certain specific high risk medical devices must conduct postmaket surveillance and medical institutions should cooperate accordingly
- ✓ Firms would be tasked with conducting voluntary surveillance of marketed products' risk management and necessary corrective and preventive measures

Recent Achievements

Important Achievements in 2017 & 2018

I. Develop globally harmonized medical device regulations

1. Publicly announce guidances for emerging medical devices

- Announced “Guidance for the Management of Additive Manufactured (3D Printing) Medical Devices”
- Announced “Guidance for the Validation of Medical Device Software”
- Announced technical guidances for dengue virus serological reagents, RNA preanalytical systems, influenza virus nucleic acid detection assays, and quality control materials for in vitro diagnostics

2. Proactively address key regulatory issues

- Initiated the draft of regulatory guidance for Molecular Testing, Industrial Laboratory Testing, and Service Management of Precision Medicine (LDTs)
- Initiated the draft of medical device cybersecurity guidance
- Announced the list of recognized standards for 2018 and the list of withdrawn or revised standards that were previously recognized

Important Achievements in 2017 & 2018 (2)

II. Accelerate time to market for medical devices

3. Enhance review efficiency and quality

- Announced the pilot of "Priority Review Program for Medical Devices" to accelerate time to market for emerging medical devices:

  5 cases were received and out of which 3 obtained marketing approval

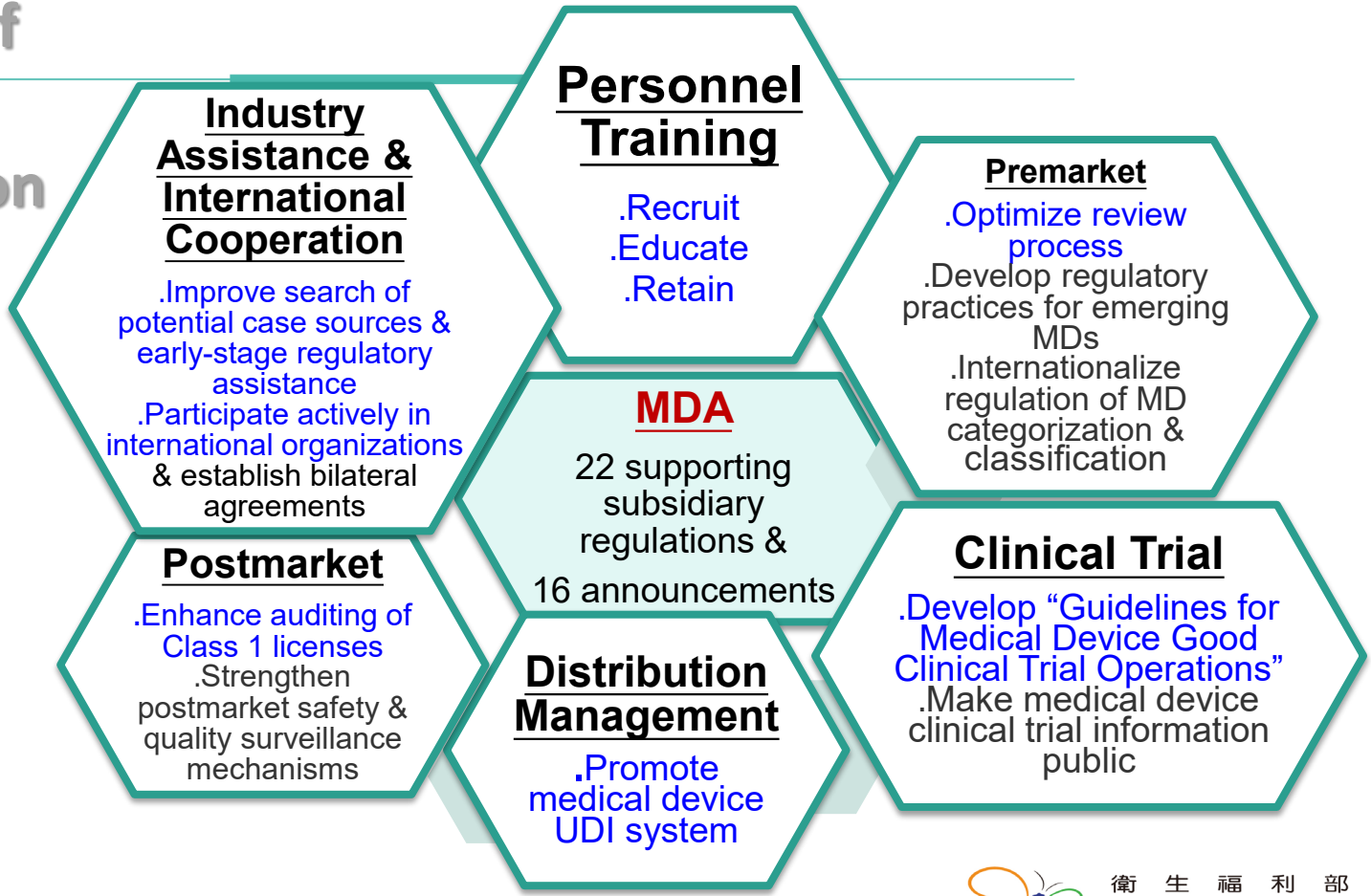
III. Establish a high quality environment for industry development

4. Optimize clinical trial environment

- Completed the recruit of 3 seeded hospitals for medical device clinical trials (Cathay General Hospital, Chung Shan Medical University Hospital, Tri-Service General Hospital) and conducted programs that improved clinical trial quality
- Elaborately designed basic and advanced medical device clinical trial courses for Taiwan, and produced a series of 36-hour digital high-quality learning materials on medical device clinical trials

Future Priorities

Key Points of Policy Administration



Thank you for your attention!

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