Current Status of Medical Device Administration in Taiwan

Li-Ling Liu, MS, RPh
Director, Division of Medical Devices and Cosmetics
Food and Drug Administration
Chinese Taipei, Taiwan

Dec. 5st, 2013

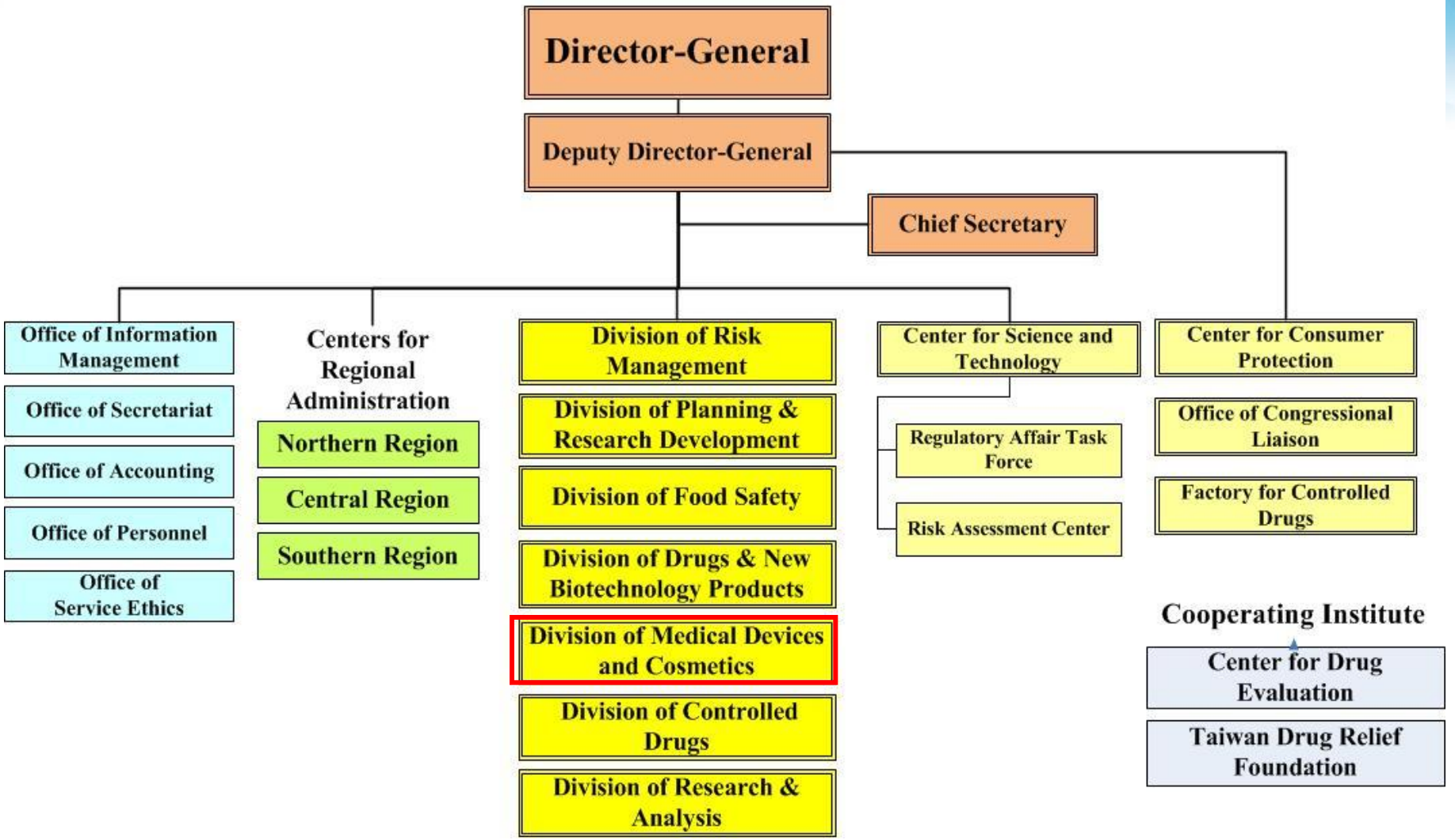
Outline

1. Medical Device Regulatory Framework
2. International Cooperation
3. Future Initiatives

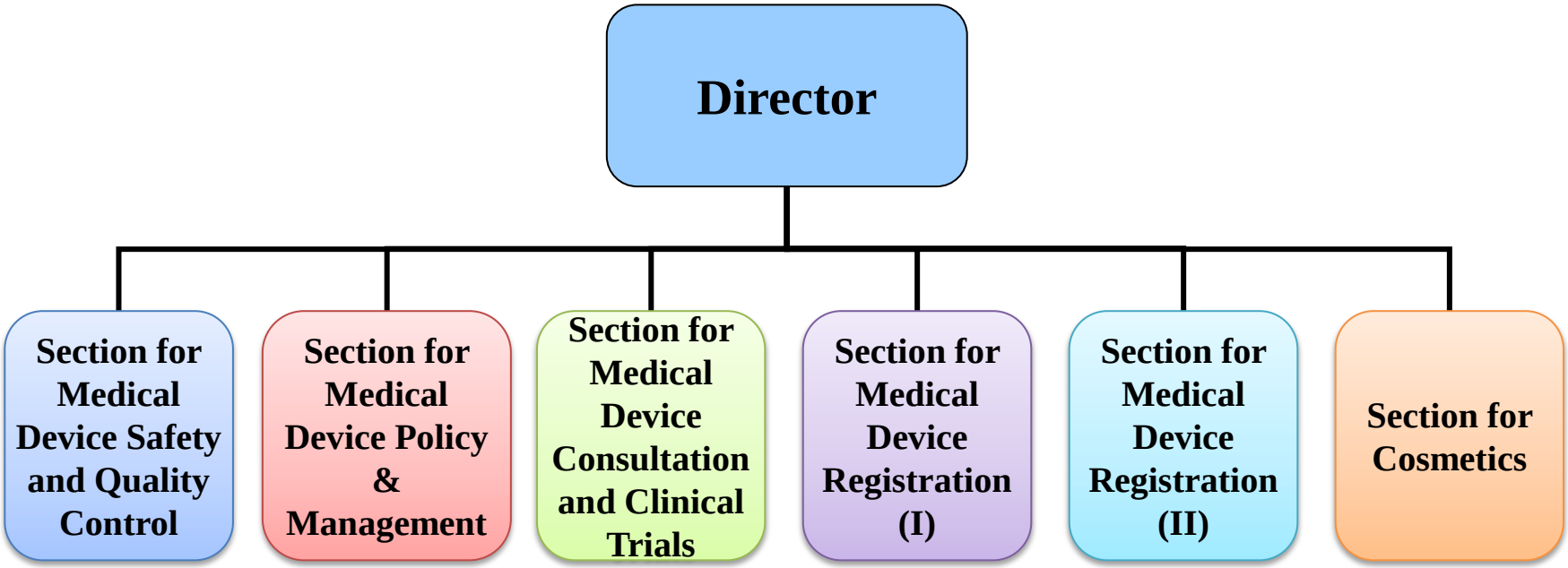
Taiwan Profile

- Area: 36,188 Km^2
- Population : 23.22 Millions
- Aging: 10.9% (2011)
- 99% Citizen Covered by NHI
- 17 Medical Centers, 917 Hospitals
- NHE/GDP: 6.6%
- Medical Device Sale Revenue:
  US$ 4 billion (2012)

Food and Drug Administration, Taiwan (TFDA)

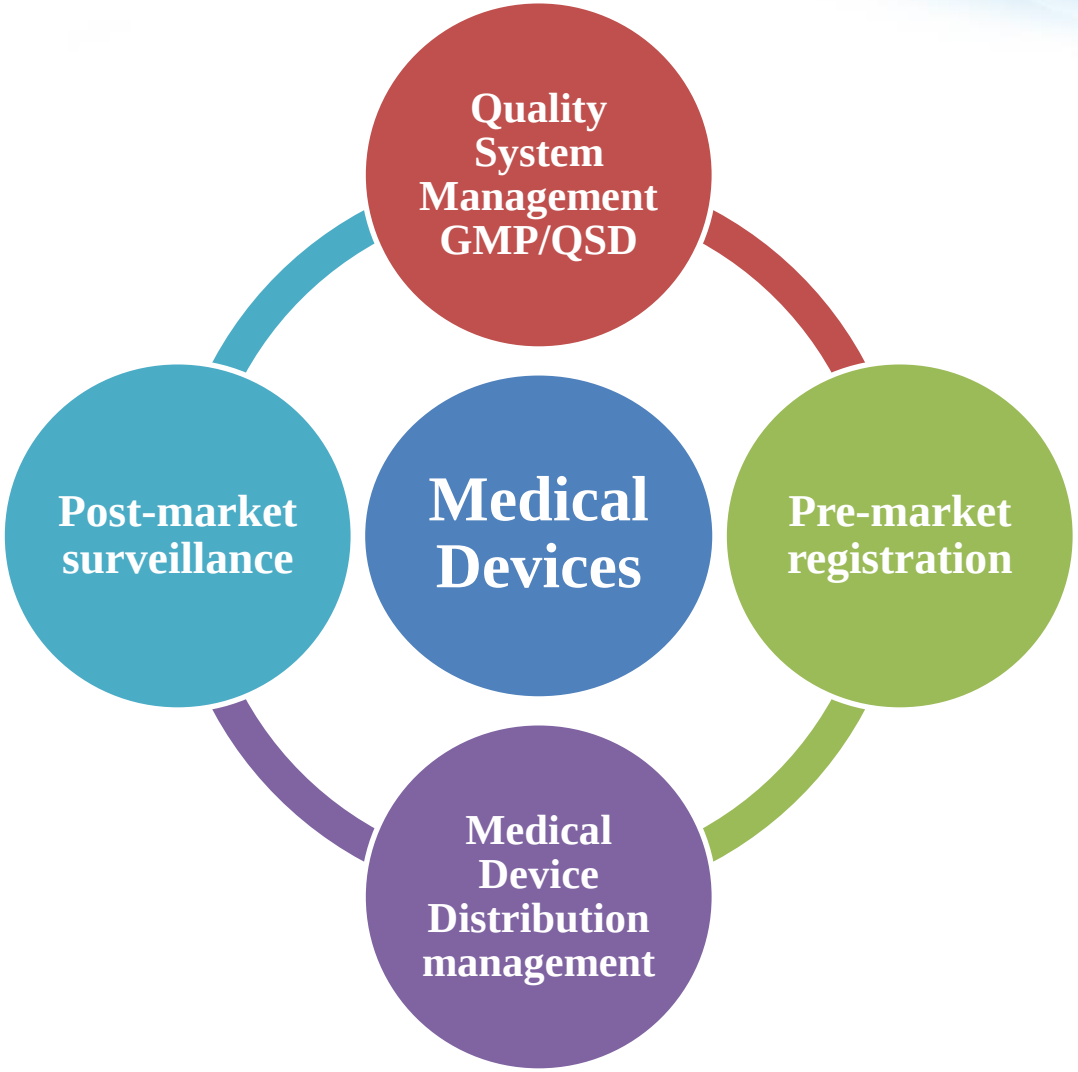


Organization Diagram of Division of Medical Device and Cosmetics



Medical Device Regulatory Framework

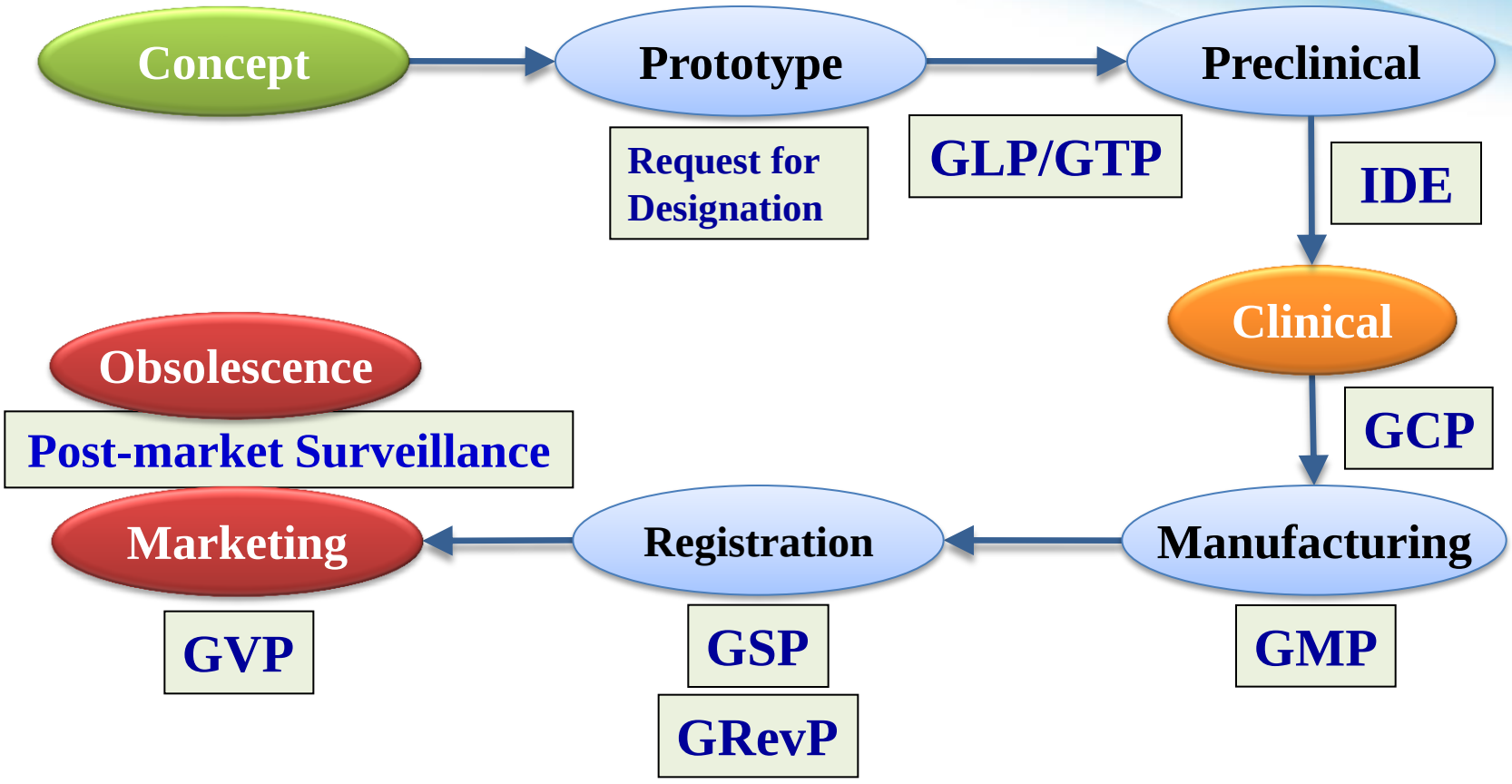
- GMP implementation: 1999



- Beginning of registration：1973
- Number of approved license：32,774

(around 80% imported)

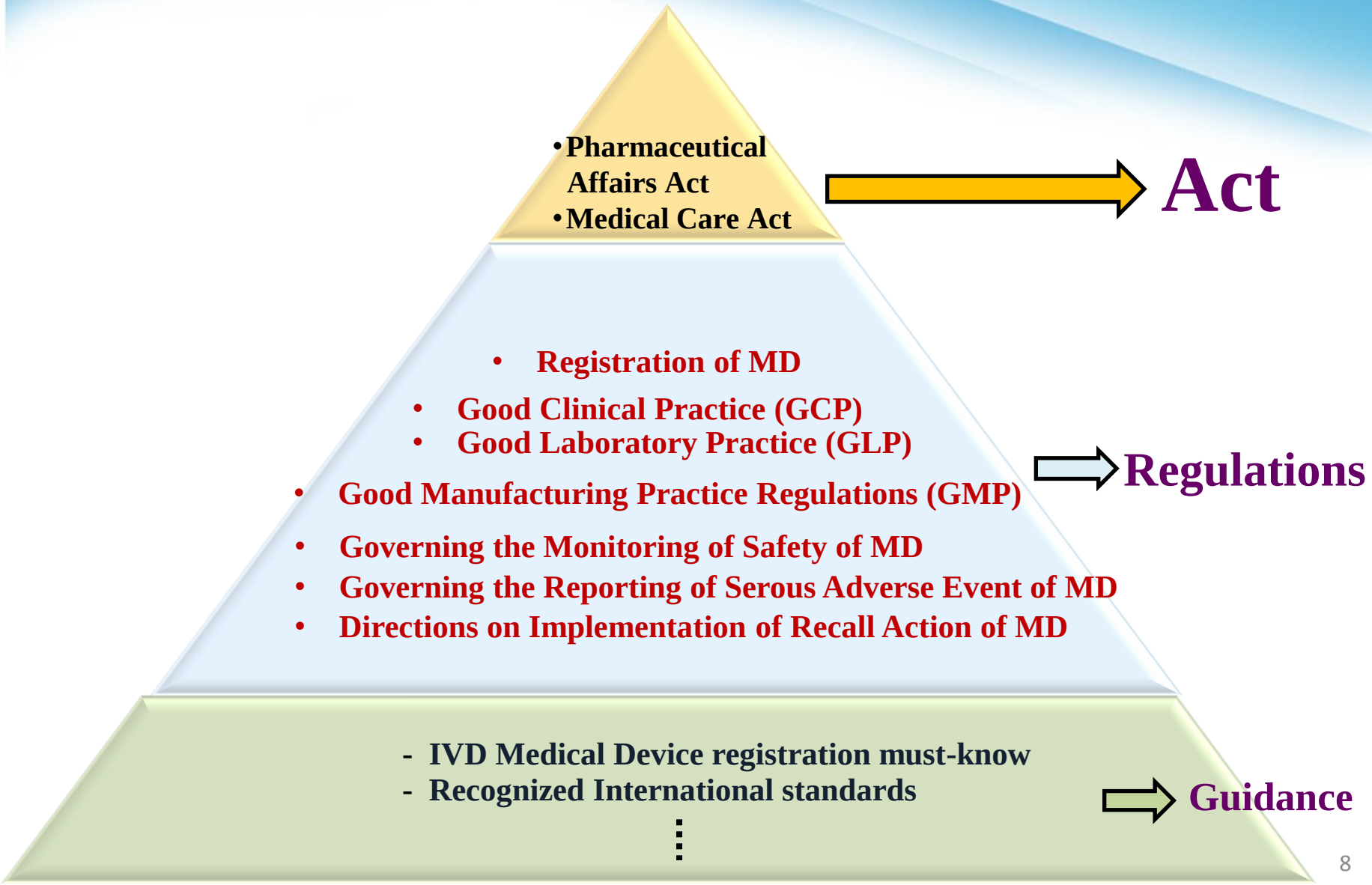
Medical Devices Life Cycle Management



GMP：Good Manufacturing Practice
GSP ：Good Submission Practice
GRevP ：Good Review Practice
GVP：Good Vigilance Practice

GLP ：Good Laboratory Practice
GTP ：Good Tissue Practice
IDE ：investigational device exemption
GCP：Good Clinical Practice

Basis of Medical Device Regulation



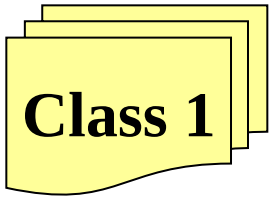
Amendment on Pharmaceutical Affairs Act

- Article 13 - Definition of Medical Devices
  - The term "medical device", as used in this Act, shall refer to any instruments, machines, apparatus, materials, **software, reagent for in vitro use**, and other similar or related articles, which is used in diagnosing, curing, alleviating, or directly preventing human diseases, **regulating fertility**, or which may affect the body structure or functions of human beings, and **do not achieve its primary intended function by pharmacological, immunological or metabolic means in or on the human body**.

Amended Date: May 8, 2013

Risk Based Regulation

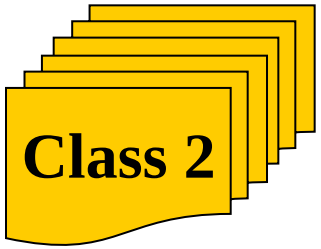
GMP/QSD



affidavit

On-site registration

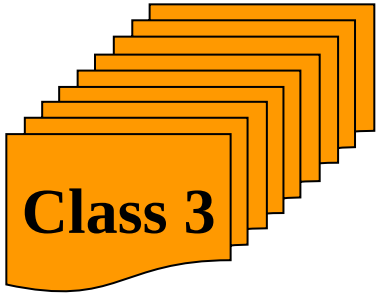
GMP/QSD



Technical Document

Preclinical testing and QC documents can be waived if with both EU and US marketing approval.

GMP/QSD



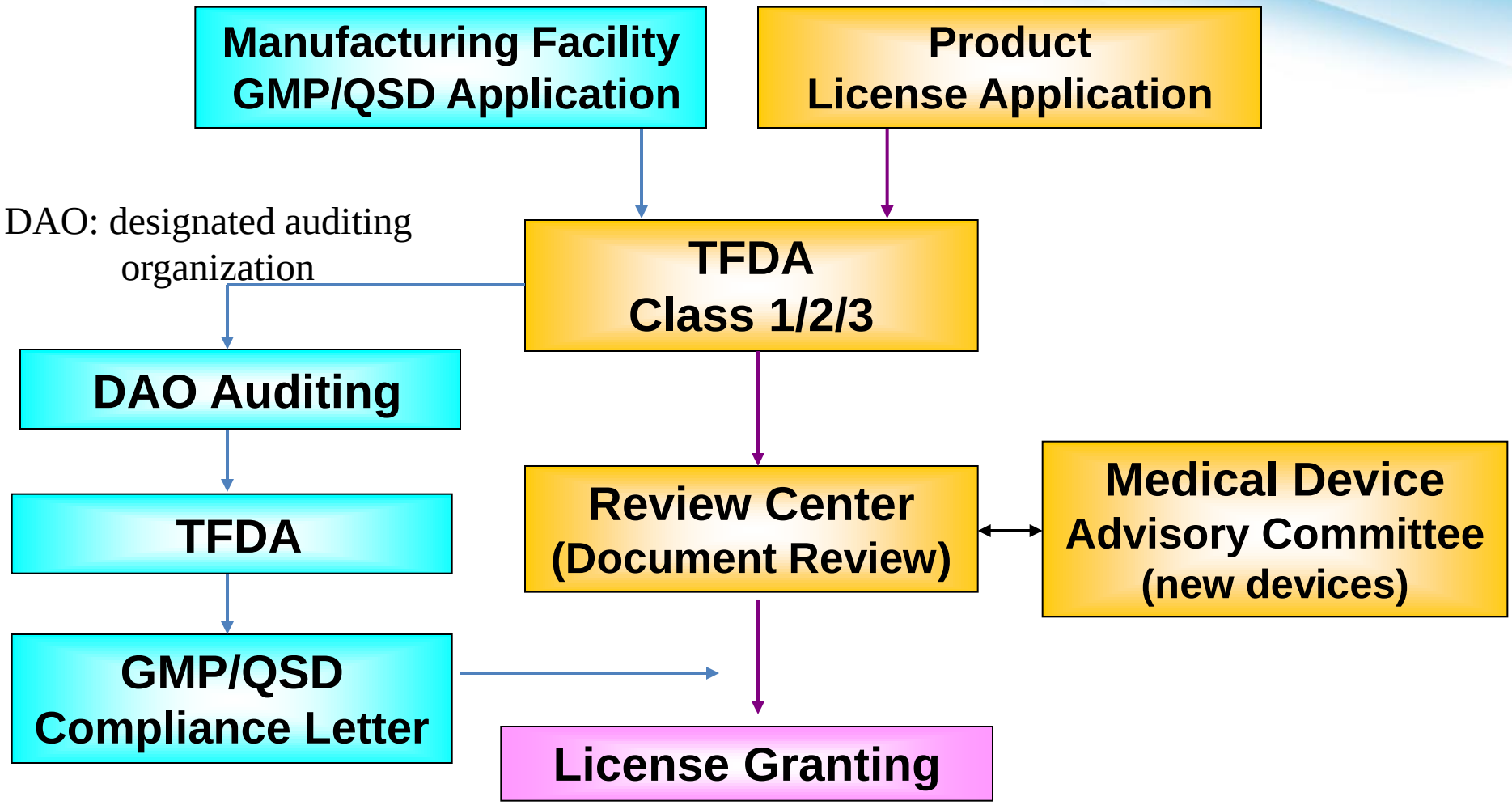
Technical Document

Clinical reports are required for most of the cases.

Documents required for Registration

QSD: Quality system document

Before Marketing a Medical Device Product in Taiwan



Review Time and Approval Rate for Medical Device Submissions in 2012

Submission	Proclamation review time (days)	Average review time (days)	Approval rate
New medical devices	220	200	67 %
Substantial Equivalence medical devices (Class 2 and 3)	140	107	79 %
Regular medical devices (Class 1)	On-site registration	–	–

Post-Market Surveillance

Domestic

Industry Device Companies & Consumer and Medical Personnel
- Adverse event reaction (ADR)
- Product defect

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

International

International Medical Device Regulators Forum (IMDRF)
National Competent Authority Reporting (NCAR) system

Actively monitor International post-market safety information

National ADR Reporting Center

Follow-up Actions

Analysis

TFDA

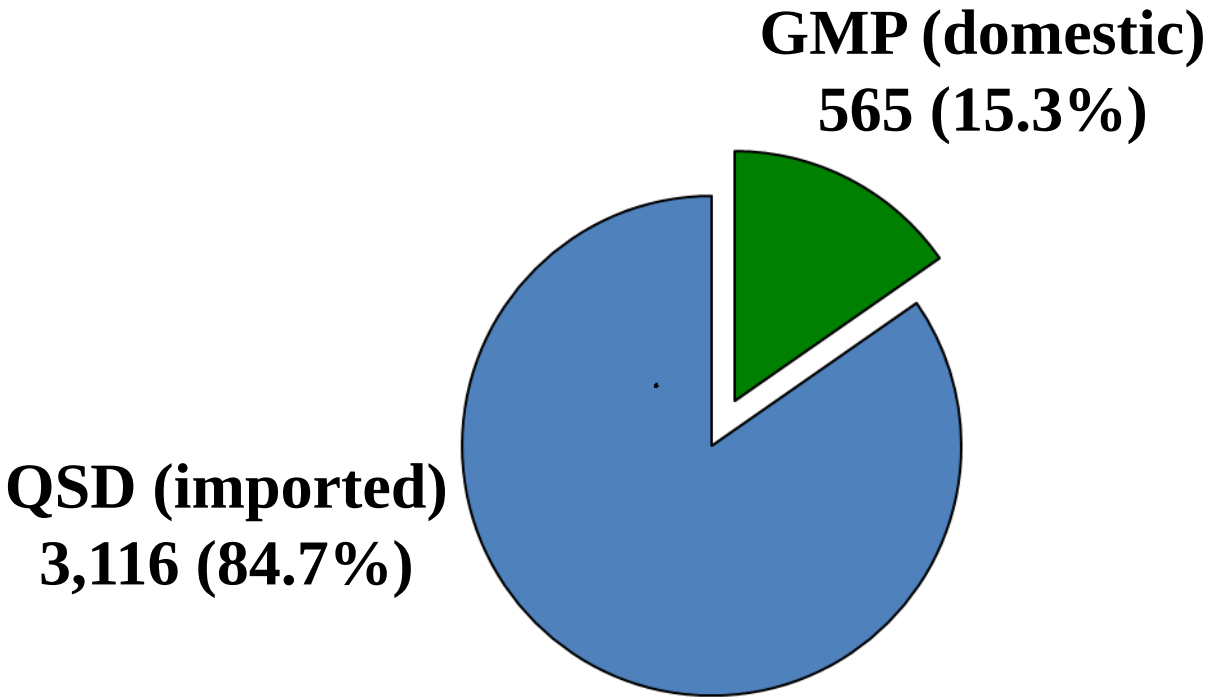
Medical Device Recall

Vigilance Reporting Webpage

- Provide updated safety information to the public
- On-line report an adverse event

http://medwatch.fda.gov.tw

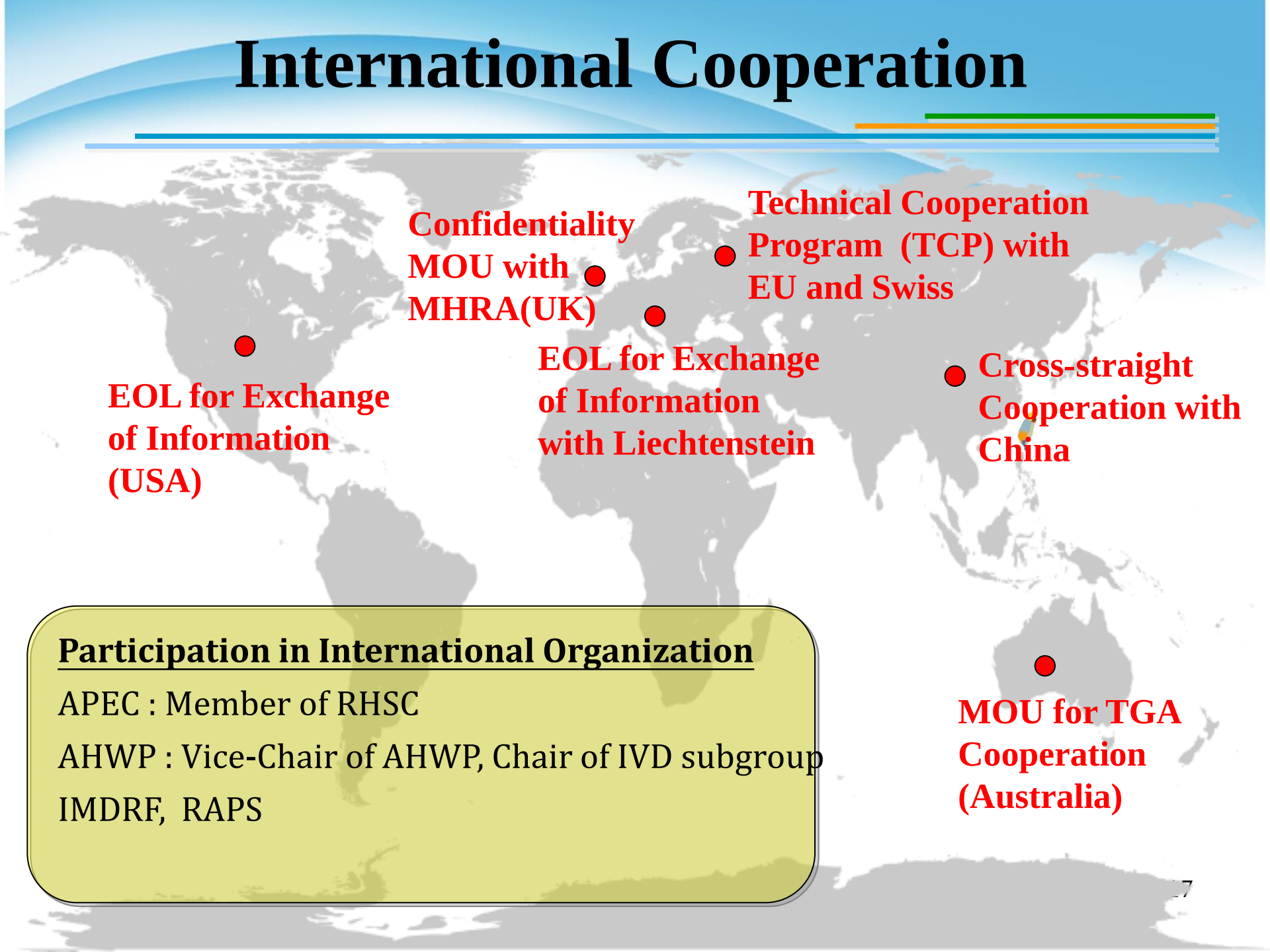
Statistics of GMP/QSD by Domestic and Imported Manufacturers



2013.08.data

International Cooperation

International Cooperation



Participation in International Organization

APEC : Member of RHSC

AHWP : Vice-Chair of AHWP, Chair of IVD subgroup

IMDRF, RAPS

Good Review Practices(GRevP) Roadmap

Goal

- To strengthen the performance, predictability and transparency of regulatory agencies through the implementation or enhancement of Good Review Practices (GRevP) stepwise in each interested APEC economy by 2020
- To enhance mutual trust for regulatory convergence among economies

Specific Activities and Timeframe

- Step 1 (2011-2012)： Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation
- Step 2 (2011-2014) ： Planned Solution to Address Gap
- Step 3 (2012-2015) ： Assessing the Impact of GRevP Training and Exchange of Regulatory Information
- Step 4 (2015-2020) ： Reaching the Goal for Achieving Common Regulatory Elements

Medical Device Combination Products Concept Note

- **Goal**
  - To promote regulatory convergence among member economies for combination products regulated as medical devices throughout the product life cycle
- **Activities Completed**
  - Concept Note: endorsed Aug. 2012
  - Workshop: "2012 APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products" held in Taipei Nov. 2012
  - Gap Analysis Survey among APEC member economies: Completed July 2013
- **Future Activities**
  - round-table discussion among interested APEC economies

TFDA's Achievements in 2012

- 3 GHTF Final Documents
- Recommendations on the use of recognized standards in safety and performance evaluation of IVD medical devices made
- 2 international conferences on IVD medical devices regulations held
  - May 17-18, 2012 "Conference for Convergence on IVD Medical Devices Regulations"
  - Nov 6, 2012 "Conference for Regulatory Convergence on New and Emerging IVD Medical Devices"

2013 Milestones

- Development of Regulatory Guidances on IVD Medical Devices
- Capacity Building and Training Activities for AHWP Member Economies and Other Developing Countries

2013 Milestones

6 IVD Regulatory Guidances

1 Training Workshop

- ***AHWP/WG1a/PD001-004 have been drafted and to be endorsed***
- ***3 draft documents subject to future work***

- ***AHWP WG1a Working Meeting***
- ***The 1st ARFMD & Pre-Forum Workshop***
- ***The AHWP WG1a-PAHWP-LSHTM Joint Conference***
- ***AHWP WG1a-PAHWP-LSHTM Joint Conference***

Development of Regulatory Guidances on IVD Medical Devices

Regular Regulatory Framework Doc.	Additional Guidance	AAIVD
AHWP/WG1a/PD001 AHWP Regulatory Model for IVD (To be endorsed in AHWP annual meeting)		AHWP/WG1a/PD001(AAIVD) Strategies for Implementing Regulatory Model for AAIVD **(Future work item)**
AHWP/WG1a/PD002 IVD EP (To be endorsed in AHWP annual meeting)	AHWP/WG1a/PD002(EPSTD) EP applicability and Recognized Std. Checklists **(Future work item)**	
AHWP/WG1a/PD003 IVD STED (To be endorsed in AHWP annual meeting)	AHWP/WG1a/PD004 Comparison btn STED and CSDT (To be endorsed in AHWP annual meeting)	Pilot program for Common Registration File **(Future work item)**

The AHWP WG1a-PAHWP-LSHTM Joint Conference on International IVD Medical Devices Regulations, Sep 16, 2013

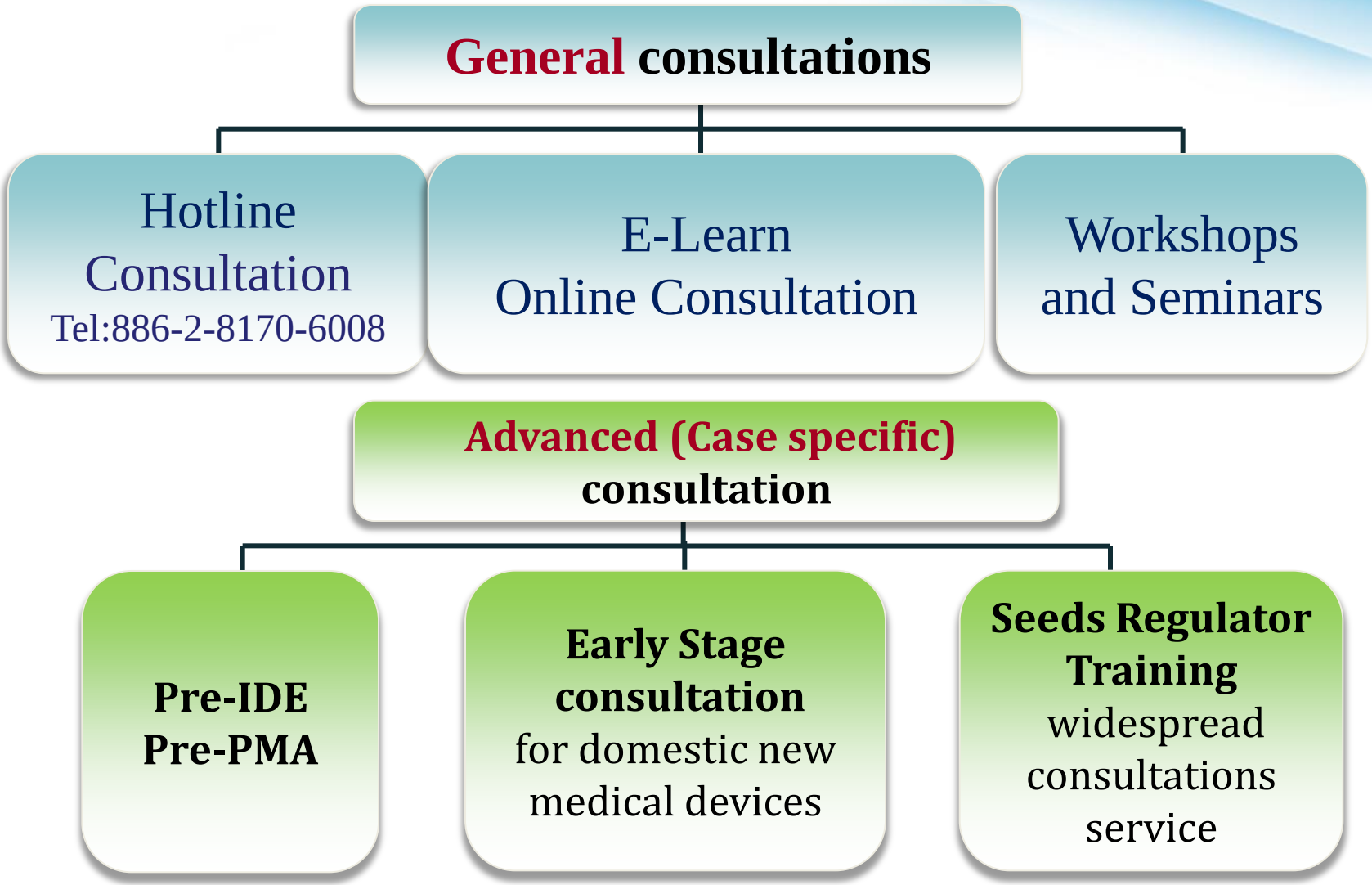
- **The Conference was held in Taipei and attended by 24 experts from AHWP, PAHWP, LSHTM, etc. and 200 people from local regulatory agencies and industry**
- **Main Topics:**
  - **Update on IVD Medical Devices Regulations**: USA, EU, Japan, Taiwan, Malaysia, Indonesia, Philippines, Thailand
  - **Common Registration File for IVD Medical Devices:** EP & STED
  - **Clinical Evidence for Infectious Diseases Diagnostics:** Clinical Evaluation and State-of-the-art Technology
  - **Quality Management System (QMS):** ISO13485, QC/QA & Process Validation
  - **Post Market Surveillance:** NCAR & SADS

Future Initiatives

- **Enhance quality and effeciency of review**
  Good Review Practice (GRevP)
  Good Submission Practice (GSP)

- **Enhance Post-Marketing Control**
  Unique Device Identification (UDI)
  Good Distribution Practice (GDP)

Comprehensive Consultation for Medical Device Industry



Key Drafting Amendments for the Pharmaceutical Affairs Act

Listing	Annual Report	Good Distribution Practice
Adoption of electronic listing for low-risk medical devices	Waive preapproval of minor changes and renew license	Medical Device storage, distribution, service
Improve efficiency in management	Enhance firm's self-management	Enhance firm's ability to control and manage medical device distribution

Key Amendments for the Pharmaceutical Affairs Act

"Manufacturers" to include Repairer

- Definition of Manufacturers to include Repairer
- Maintain post-market product quality and safeguard consumer health

Deregulation of Advertisement Review

- Waive advertisement preapproval for low-risk medical devices
- Enhance manufacturer self-management

Capacity building for Clinical Trails

Innovative Organization

Increase administrative efficiency

THANK YOU FOR YOUR ATTENTION