Overview of Medical Device Regulation System - Chinese Taipei

12th AHWP in CHENGDU, PRC.

Chiou, Chi-Ming, Ph.D.
Audit Manager

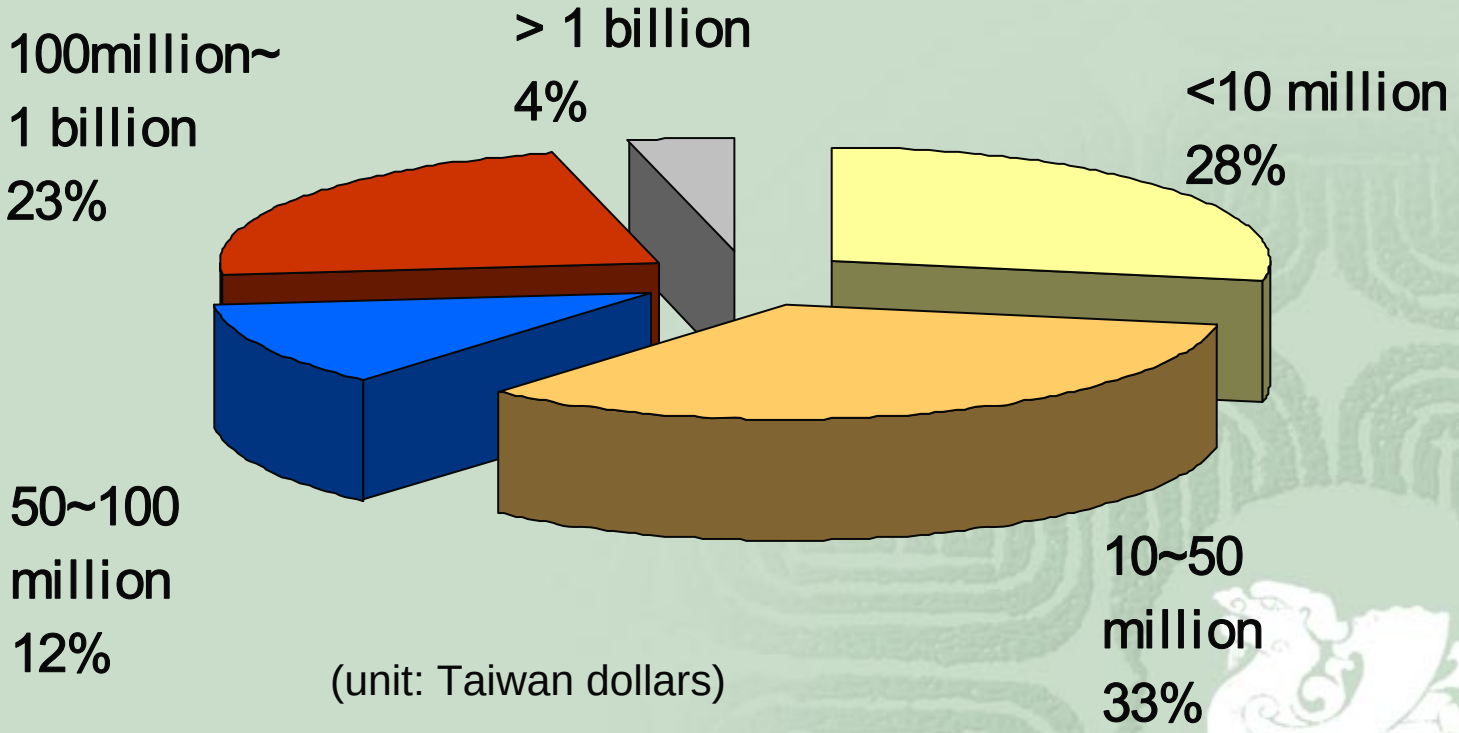
財團法人醫藥工業技術發展中心
Medical and Pharmaceutical Industry Technology and Development Center (PITDC)

Medical Device Import vs Domestic

Year	Production value *	Export value *	Import value (I)*	Domestic* Requirements (D)	I/D ratio (%)
2002	30.4	20.1	29.9	40.2	74
2003	37.0	25.0	31.6	43.6	72
2004	38.9	22.0	34.4	51.2	67
2005	43.3	24.6	35.8	54.5	66
2006	48.6	26.8	37.5	59.3	63
2007 (e)	54.3	29.5	39.4	64.2	61

* unit-1billion Taiwan Dollars (1RMB≒4.3 Taiwan dollars)

Device Industries – Capital Scale Analysis



Top 5 Import Medical Device

Rank	2004		2005		2006	
		value		value		value
1	USA	11,483,928	USA	11,980,520	USA	12,642,104
2	Japan	6,451,040	Japan	6,346,761	Japan	5,903,284
3	German	4,393,633	German	4,132,827	German	4,143,478
4	China	1,436,948	China	2,294,057	China	2,574,904
5	Ireland	1,349,475	Ireland	1,575,169	Ireland	2,085,934
Subtotal	-	25,115,025	-	26,329,335	-	27,349,704
Total import value	-	34,061,158	-	39,837,232	-	39,275,012

Unit: thousand Taiwan dollars

Domestic Medical Device Industry

Categories	Items	Manufacturers
Health care and mobility assistant devices	**Electric walkers, wheel chairs, air mattress, Medical bed, Contact lenses,**	**KYMCO, Merits, PIHSIANG, Chien Ti, EUROTAI, ST Shine Optical, etc.**
Medical electronics &diagnostic devices	**Digital blood pressure gauges, electronic clinical thermometers, respirators, physical therapy equipment, medical laser devices, blood glucosemeter,etc.**	**Microlife, Rossmax, Health&Life, Apex Biotech., Apex Medical. Tyson bioresearch Inc., SHL groups, etc.**
Medical disposable products	**Medical use plastics, safety syringes, mask,etc.**	**PM gloves, Pacific Hospital Supply, DEFEN, BIOTEQ, etc.**

Top 5 Export Medical Device

Rank	2004		2005		2006	
		value		value		value
1	USA	8,187,130	USA	9,077,190	USA	8,911,014
2	Japan	2,846,160	Japan	2,873,974	Japan	3,129,482
3	UK	1,722,440	UK	1,857,044	UK	1,850,470
4	China	927,187	China	962,639	China	1,280,223
5	HK	779,782	HK	777,164	Holland	1,280,223
Sub-total	-	14,462,698	-	15,548,010	-	15,989,766
Total export value	-	21,979,797	-	24,551,558	-	26,780,710

Unit: thousand Taiwan dollars

Risk Management

	Class I	Class II	Class III
GMP	Some required	All required	All required
Premarket Registration	All required	All required	All required (Clinical data)

Medical Device Categories

1. CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES
2. HEMATOLOGY AND PATHOLOGY DEVICES
3. IMMUNOLOGY AND MICROBIOLOGY DEVICES
4. ANESTHESIOLOGY DEVICES
5. CARDIOVASCULAR DEVICES
6. DENTAL DEVICES
7. EAR,NOSE,AND THORAT DEVICES
8. GASTROENTROLOGY-UROLOGY DEVICES

9. GENERAL AND PLASTIC SURGERY DEVICES
10. GENERAL HOSPITAL AND PERSONAL USE DEVICES
11. NEUROLOGICAL DEVICES
12. OBSTETRICAL AND GYNECOLOGICAL DEVICES
13. OPHTHALMIC DEVICES
14. ORTHOPEDIC DEVICES
15. PHYSICAL MEDICINE DEVICES
16. RADIOLOGY DEVICES
17. OTHER CATEGORIES SPECIFIED BY THE CENTRAL COMPETENT HEALTH AUTHORITY.

(modified from FDA/CDRH categories)

Class I Device Submission

1. Application form
2. Copy of pharmaceutical distributor/manufacturer license
3. Truth and Accuracy Statement to fulfill the class I device identification (made by applicant)
4. Registration fee (US$310)
5. Over the counter registration

Class II/III Submission

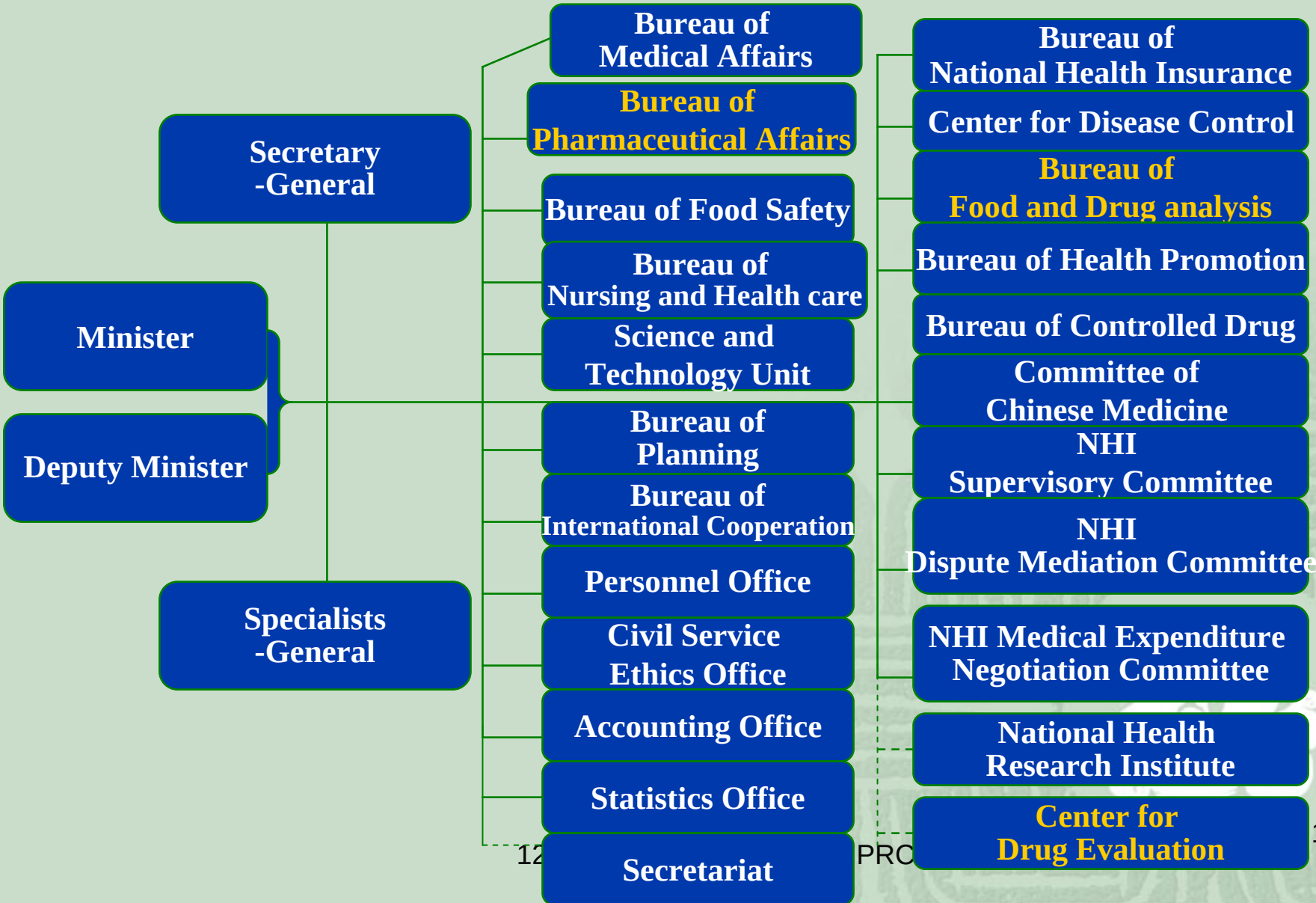
1. Application form
2. Packaging insert, labeling, and instruction for use
3. Copy of pharmaceutical distributor/manufacturer license
4. Truth and Accuracy statement (made by applicant)
5. Registration fee (US$310 or $620 for new device)
6. Photo or sample
7. Technical documents: construction, material, specification, intended use and drawing.
8. Radiological safety information (if applicable)
9. Import device- certificate for foreign government/free sale certificate and letter of authorization.
10. Medical device GMP/QSD Compliance letter
11. For device with no similar product been registered in Taiwan: need scientific theory, research report, safety evaluation and clinical investigation report.

Abbreviated Class II device Premarket Submssion

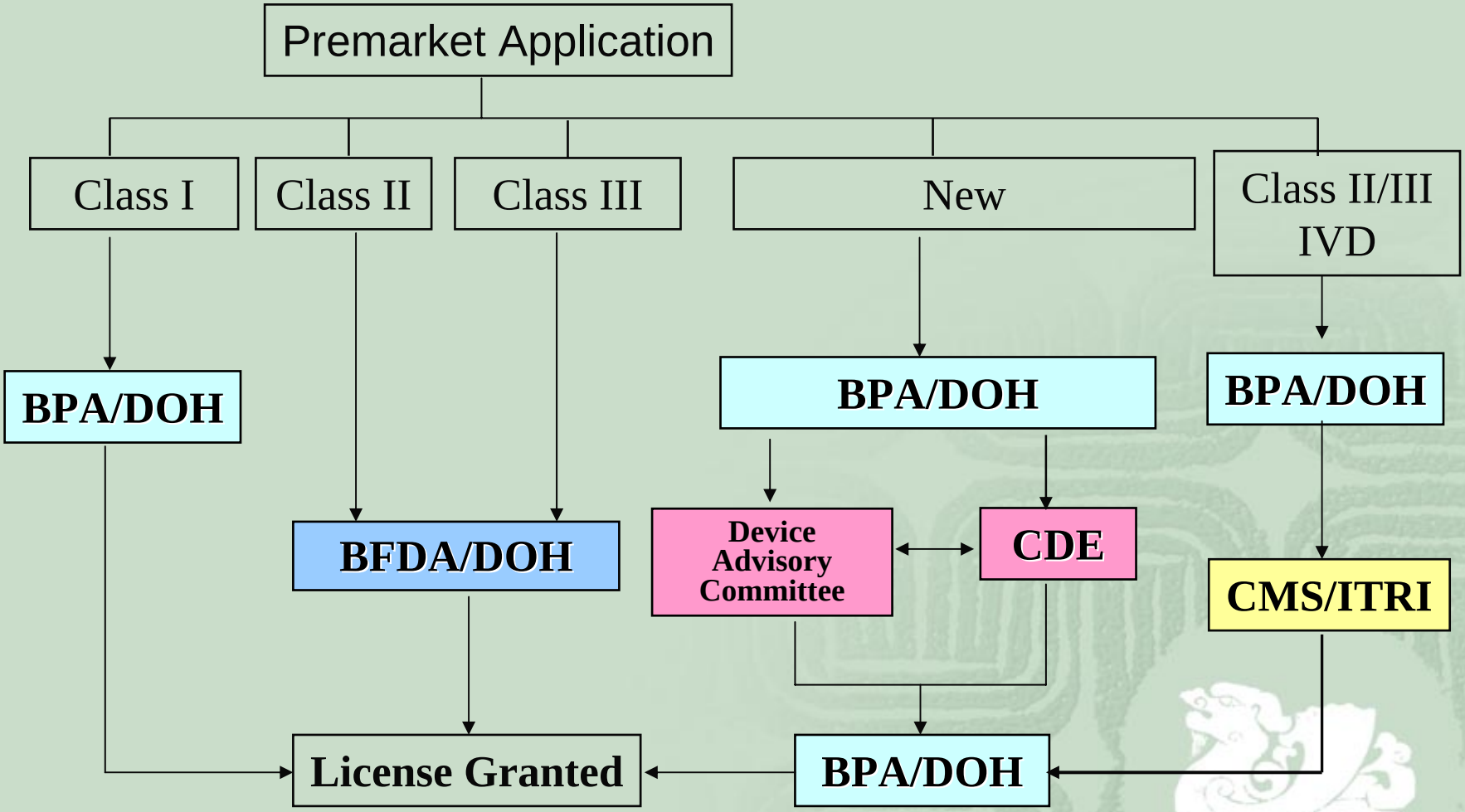
- Preclinical testing, QC records are exempted if the following information is available:
  - FDA CFG/510(k) Clearance letter plus

    EU free sale certificate/EC certificate

Department of Health Organization

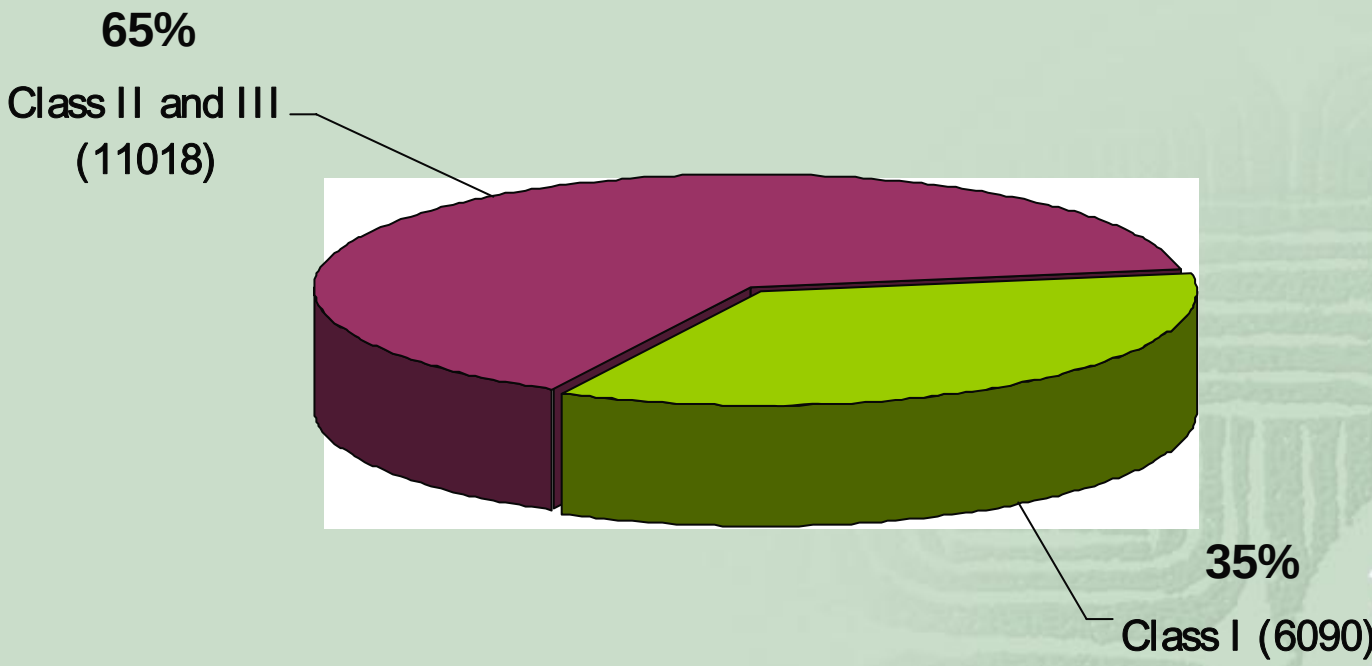


Premarket Registration Process



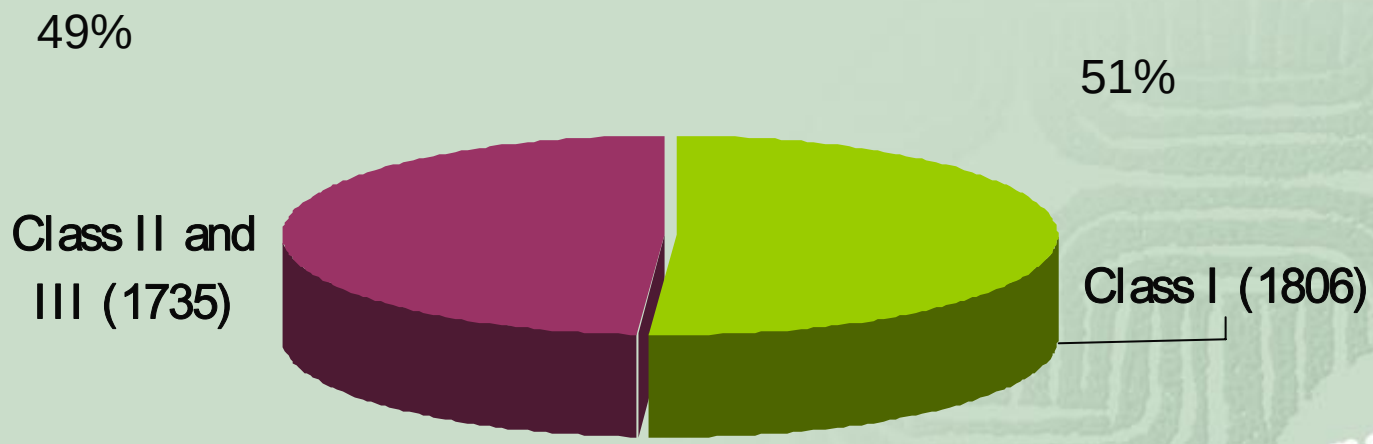
Import Device Licenses

- Import Device Licenses 17108

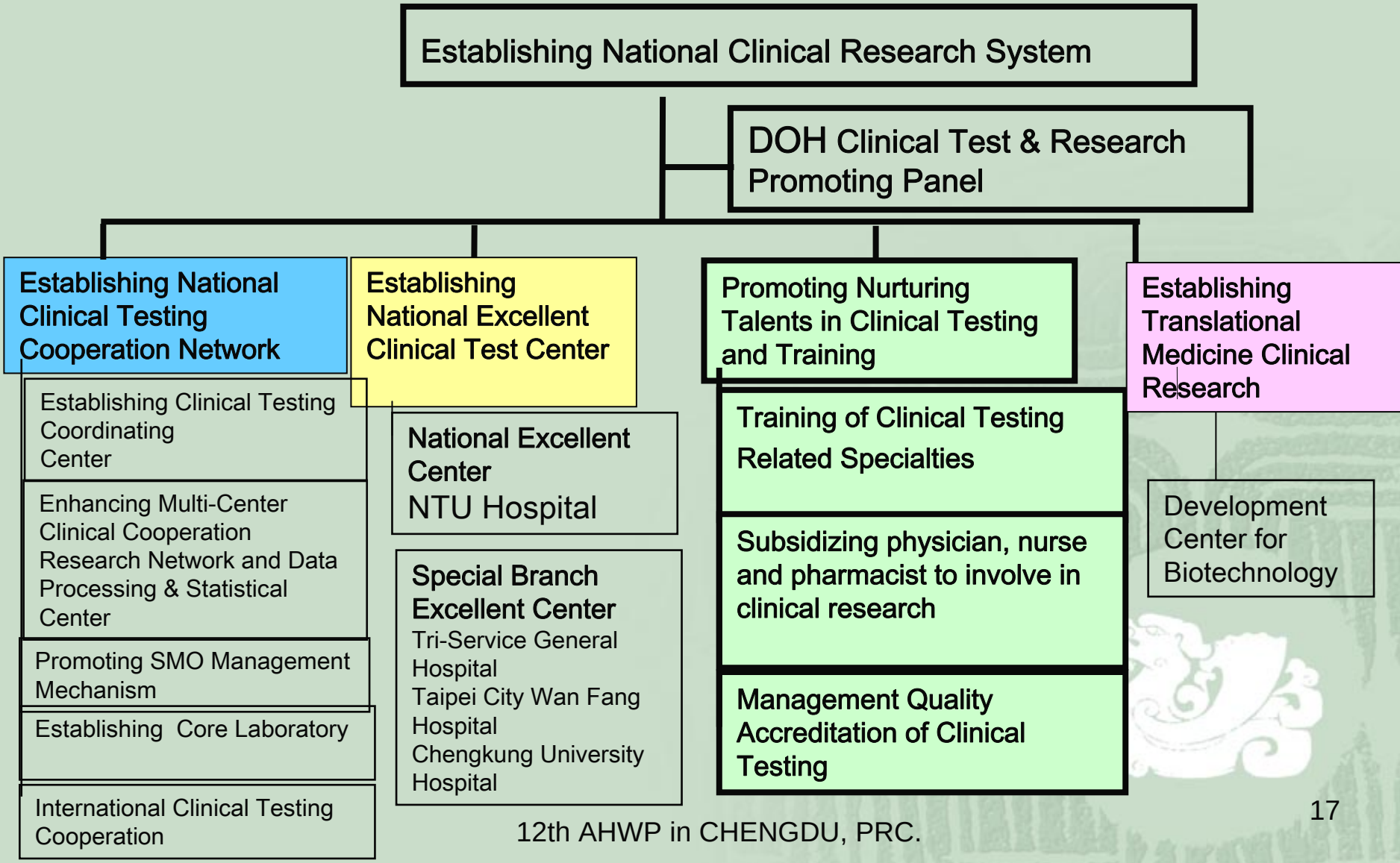


Domestic Device Licenses

- Domestic Device Licenses 3541



Establishing National Clinical Research System
(2005-2009)



14 Government Funded General Clinical Research Center

- Chang Gung Memorial Hospital Linkou Branch　長庚紀念醫院林口總院
- Buddhist Tzu Chi General Hospital　佛教慈濟綜合醫院
- Koo Foundation Sun Yat-Sen Cancer Center　辜公亮基金會和信治癌中心
- Taichung Veterans General Hospital　台中榮民總醫院
- Mackay Memorial Hospital　馬偕紀念醫院
- Changhua Christian Hospital　彰化基督教醫院
- Jianan Mental Hospital　衛生署嘉南療養院
- Yuli Hospital　衛生署玉里醫院
- Bali Psychiatric Center　衛生署八里療養院
- Taipei Medical University Hospital　臺北醫學大學附設醫院
- Chung Shan Medical University Hospital　中山醫學大學附設醫院
- China Medical University Hospital　中國醫藥大學附設醫院
- Chung-Ho Memorial Hospital, Kaohsiung Medical University 高醫中和醫院
- Chi Mei Medical Center　奇美醫院

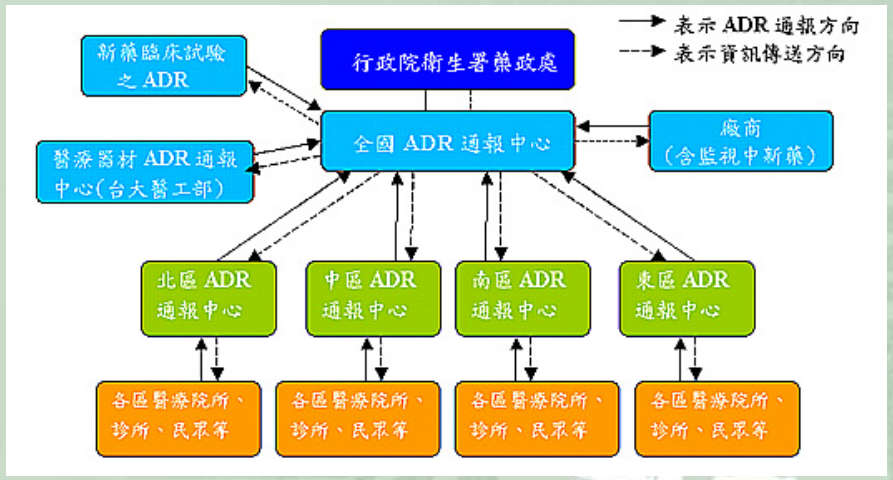
行政院衛生署醫材不良反應通報系統

National Reporting System of Adverse Medical Device Reactions in Taiwan

藥品不良反應通報

National Reporting System of Adverse Drug Reactions in Taiwan

- 藥物安全簡訊
- 醫療器材查詢
- ADR資料統計
- 下載通報表格



http://adr.doh.gov.tw/adr-med/

Postmarket Surveillance

- GMP compliance is valid for 3 years.
- Device license is valid for 5 years.
- Reporting of Adverse Events
- Recall
- Postmarket inspection and product testing

Postmarket Surveillance

- 1998-National Reporting System of adverse events in Taiwan was established.
- 2002-Adverse Medical Device Reactions was added to this system.
- For Fatal or life-threatening Serious Adverse Reactions-
  - Report to DOH or the national ADR reporting center ASAP but no later than 7 calendar days. A complete follow-up report should be submitted within 8 additional calendar days.
- For All other Serious Adverse Reactions-
  - ASAP but no later than 15 calendar days
- For Non-serious Adverse Reactions-
  - Encourage report all suspected adverse reactions any time.

Postmarket Surveillance

- Pharmacovigilance in Taiwan：

http://adr.doh.gov.tw/ADR-eng/index.htm

- Procedure for Reporting Severe Adverse Reactions to Medicines ：

http://www.doh.gov.tw/ufile/doc/200503_Procedure%20for%20Reporting%20Severe%20Adverse%20Reactions%20to%20Medicines.doc

- Drug Safety Monitoring Procedure：

http://www.doh.gov.tw/ufile/doc/200503_Drug%20Safety%20Monitoring%20Procedure.doc

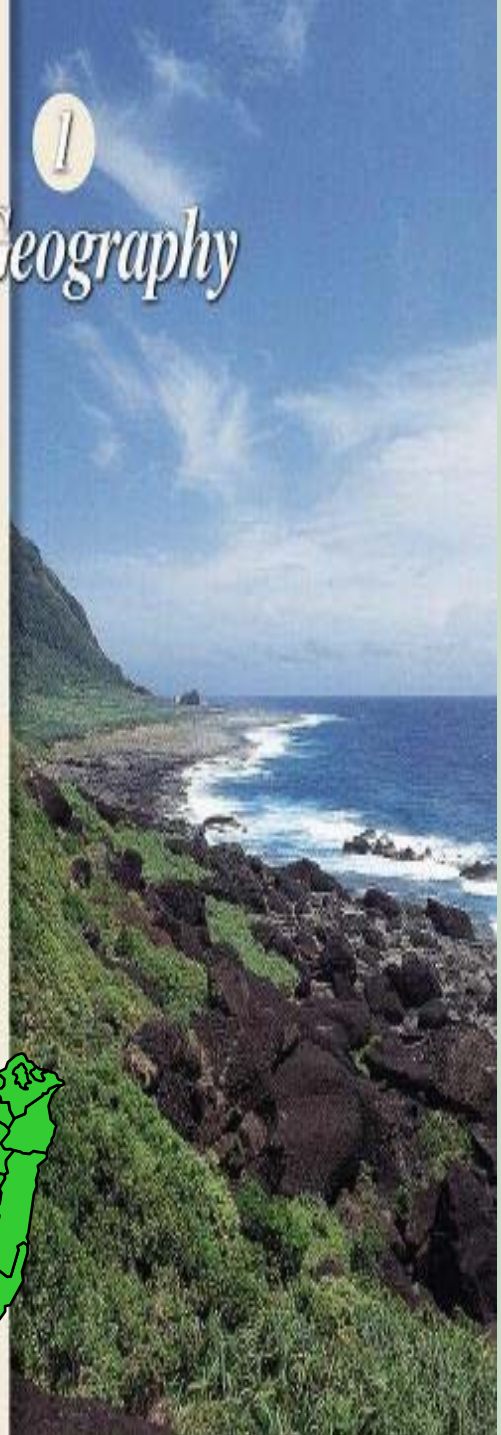
Harmonization

- 1999 DOH announcement:
  - ISO 13485 requirement for manufacturer
- Exchange of Letter:
  - USA-FDA
  - European Commission
  - Switzerland-Swissmedic

EU NB – Taiwan DOH DAO Cooperation

- Technical Cooperation Program between EU NB and DOH designated GMP auditing organizations (CMS/ITRI, MIRDC, ETC) since 2002.

- Exchange of GMP/ISO 13485 audit report to eliminate duplicate inspection.
  - 2004-TUVPS, NSAI, G-MED, MDC, BSI PS, TUV Rheinland.
  - 2006-KEMA, SGS UK, AMTAC, MEDCERT, DGM, UL UK.
  - Audit report can be used as part of the QSD requirement.



TAIWAN

- **Population**

  23 million

- **Area**

  36,006 m^2

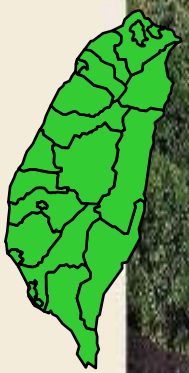
- **GNP per capita**

  US$16,309

- **Medical Cluster**

  19 Medical Center

  114 Regional Hospital



Thanks for your attention!

邱繼明 (CHIOU, Chi-Ming)

cmchiou@pitdc.org.tw

財團法人醫藥工業技術發展中心

Medical and Pharmaceutical Industry Technology and Development Center

www.pitdc.org.tw

www.mdic.org.tw