Medical Device Regulation System in Taiwan

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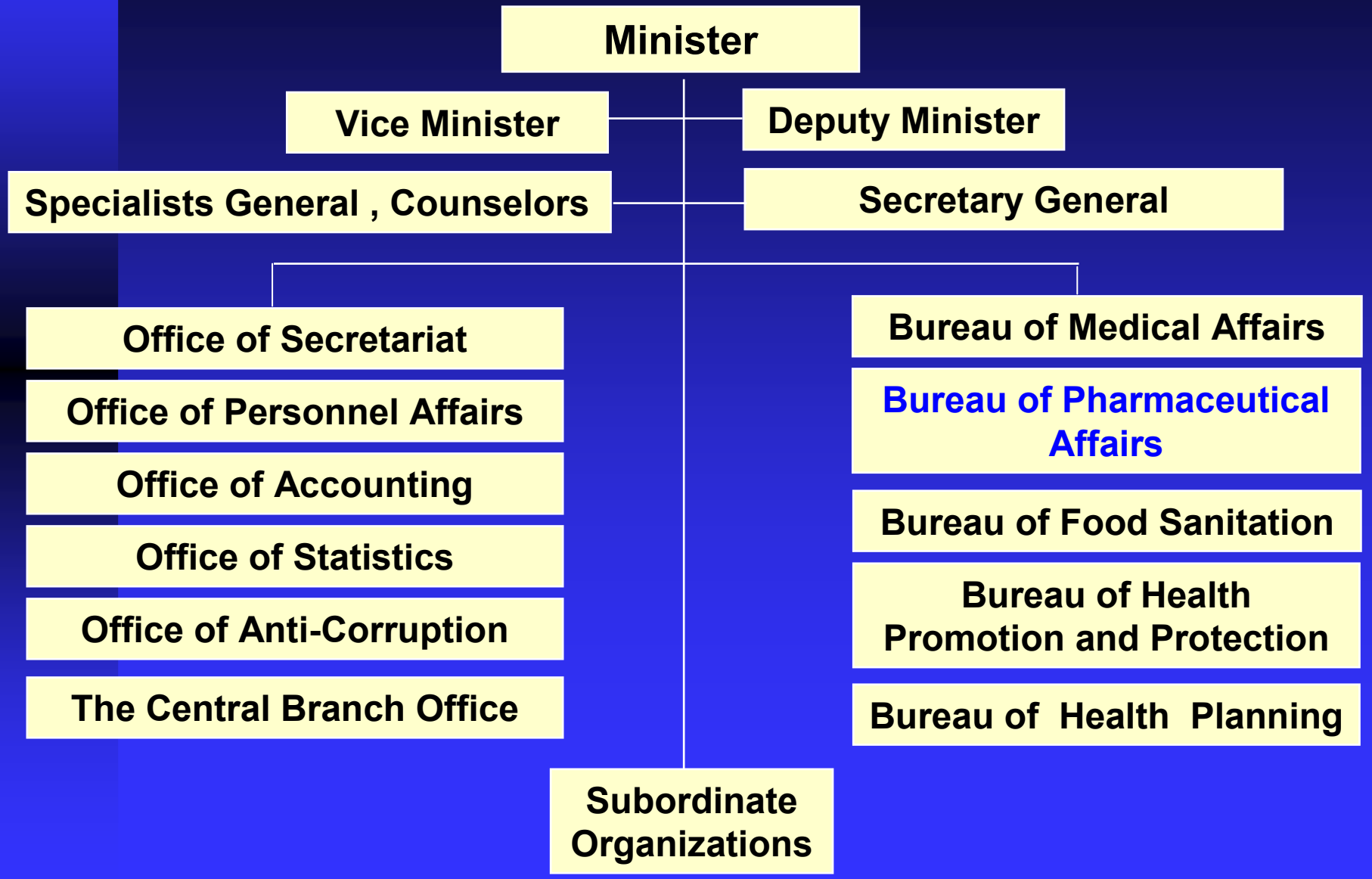
Topics

- DOH Organization
- Pharmaceutical Affairs Law
- Medical Device Regulation

  Classification, Premarket Requirement, Quality System, and Postmarket Surveillance
- Combination Product
- International Cooperation

Organization of DOH, ROC

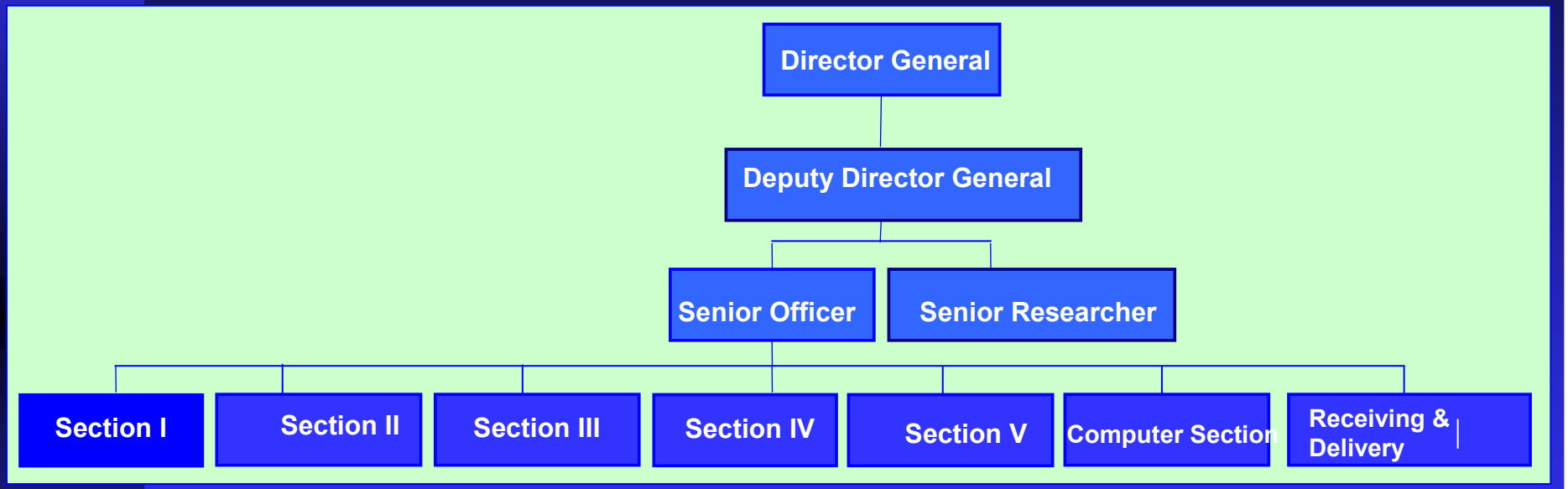


Subordinate Organizations of DOH

Department of Health

- Bureau of National Health Insurance
  - NHI Supervisory Committee
  - NHI Dispute Review and Settlement Committee
  - NHI Committee for the Arbitration of Medical Costs
- Center for Disease Control
- National Bureau of Controlled Drugs
- Bureau of Food and Drug Analysis
- Committee on Chinese Medicine and Pharmacy
- Hospitals and Branch Hospitals (27)
- Bureau of Chronic Disease Control and Branch Bureaus
- Sanitariums (5)
- Institute of Maternal and Child Health
- Institute of Family Planning
- Institute of Public Health
- National Health Research Institute
- Center for Drug Evaluation

Organization Chart
Bureau of Pharmaceutical Affairs



I
- Compliance

II
- Medical device
- Quality system

III
- New drug
- Clinical trial
- Post marketing surveillance

IV
- Generic drug
- GMP
- Bioequiva-lence

V
- Genetic engineering product
- Plasma product
- Radiopharmaceutical
- IVD
- Cosmetics

Pharmaceutical Affairs Law

Promulgation :1970

Revised : 4. 21. 2004

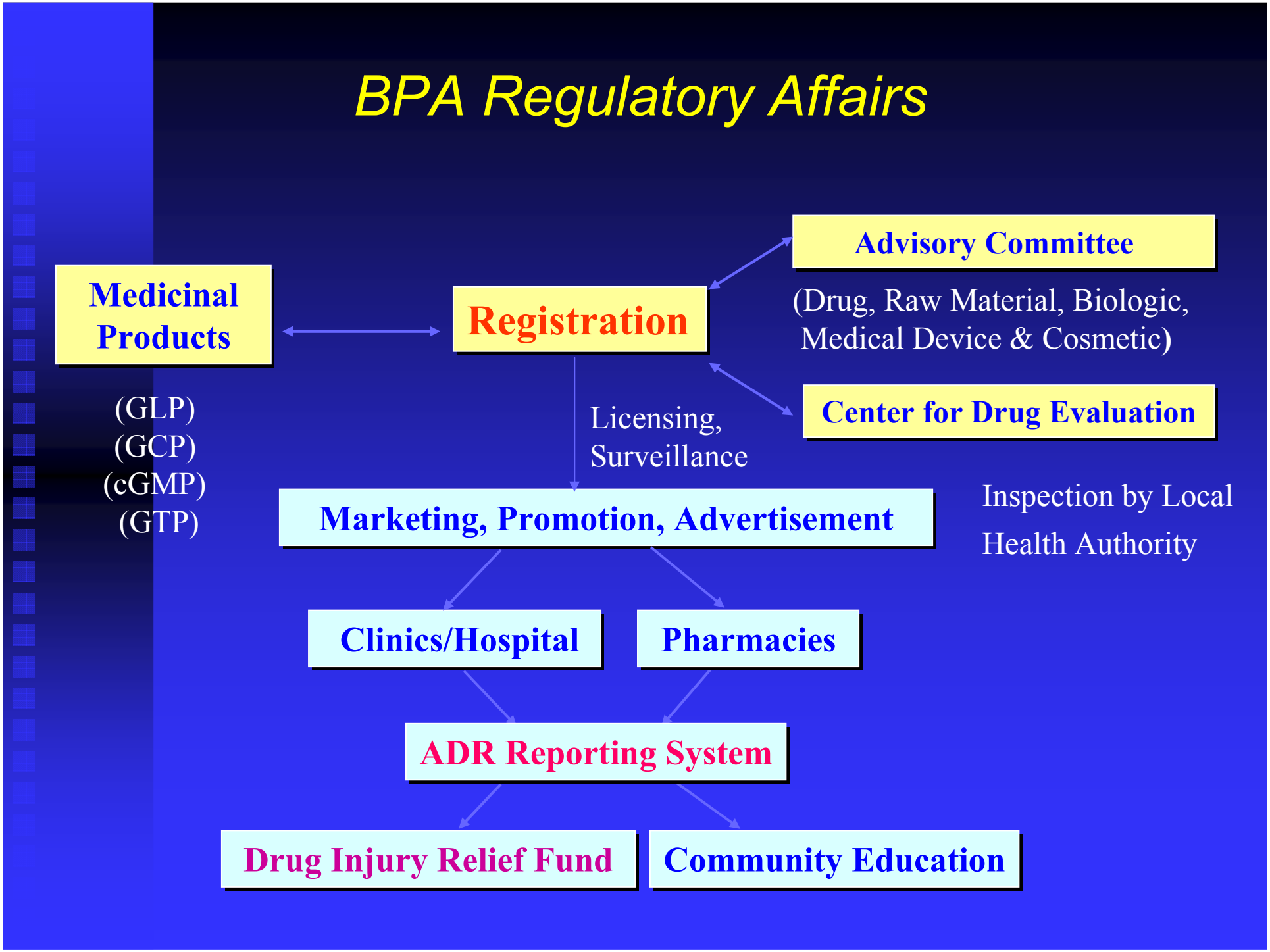
Regulation under authorization

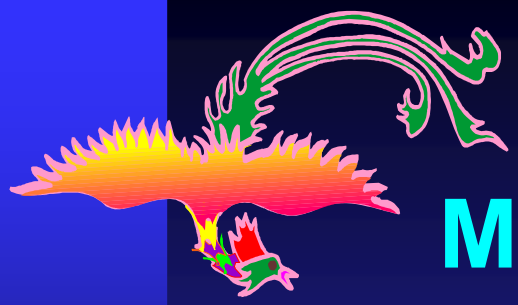
GOAL

- *Safety*
- *Effectiveness*
- *Quality*
- *Global Harmonization*

  ICH, GHTF, US FDA, EC, MHLW
- *Protect and Promote the Public Health Through the Product Life Cycle*

BPA Regulatory Affairs



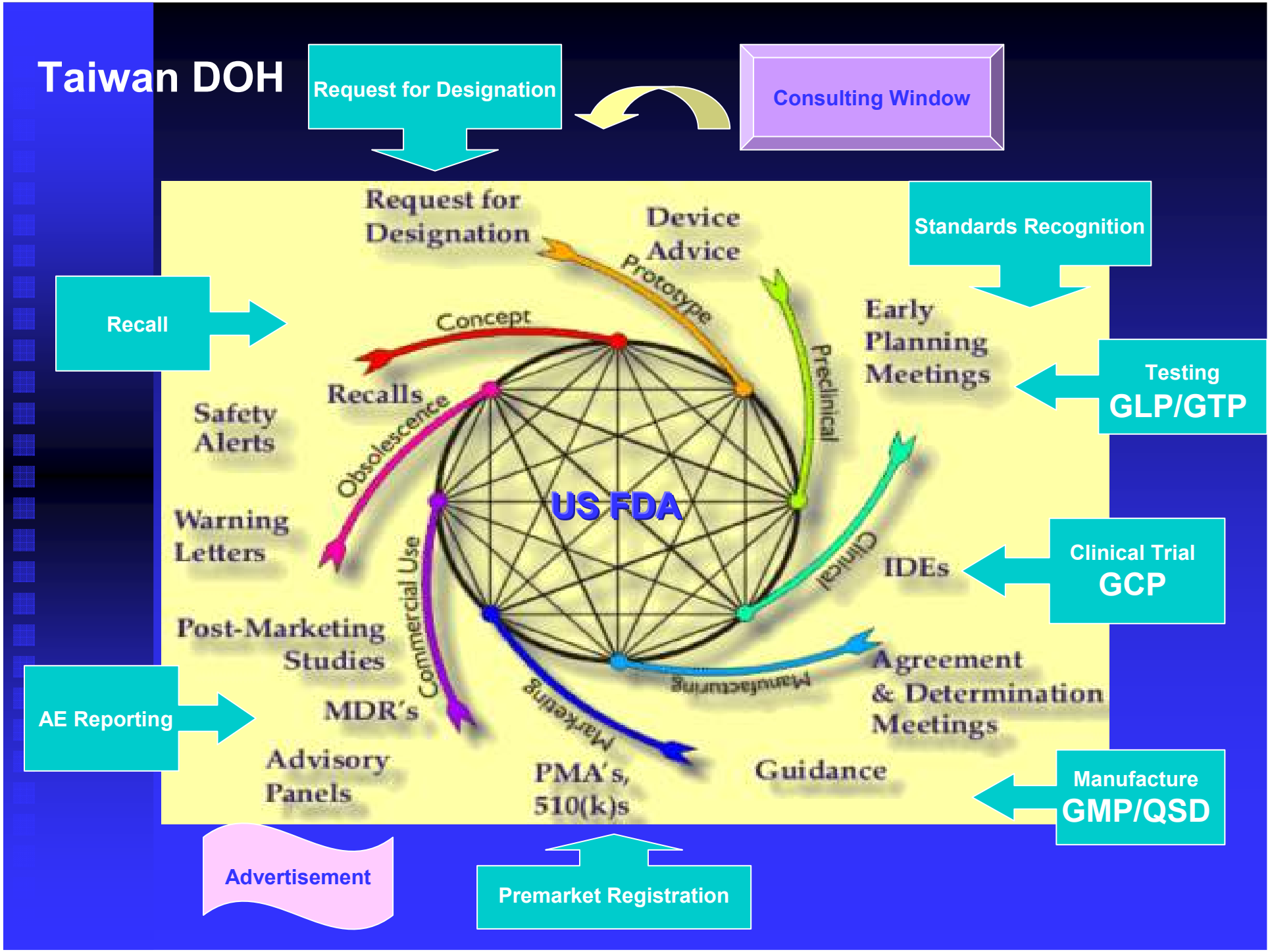


Medical Device Regulation

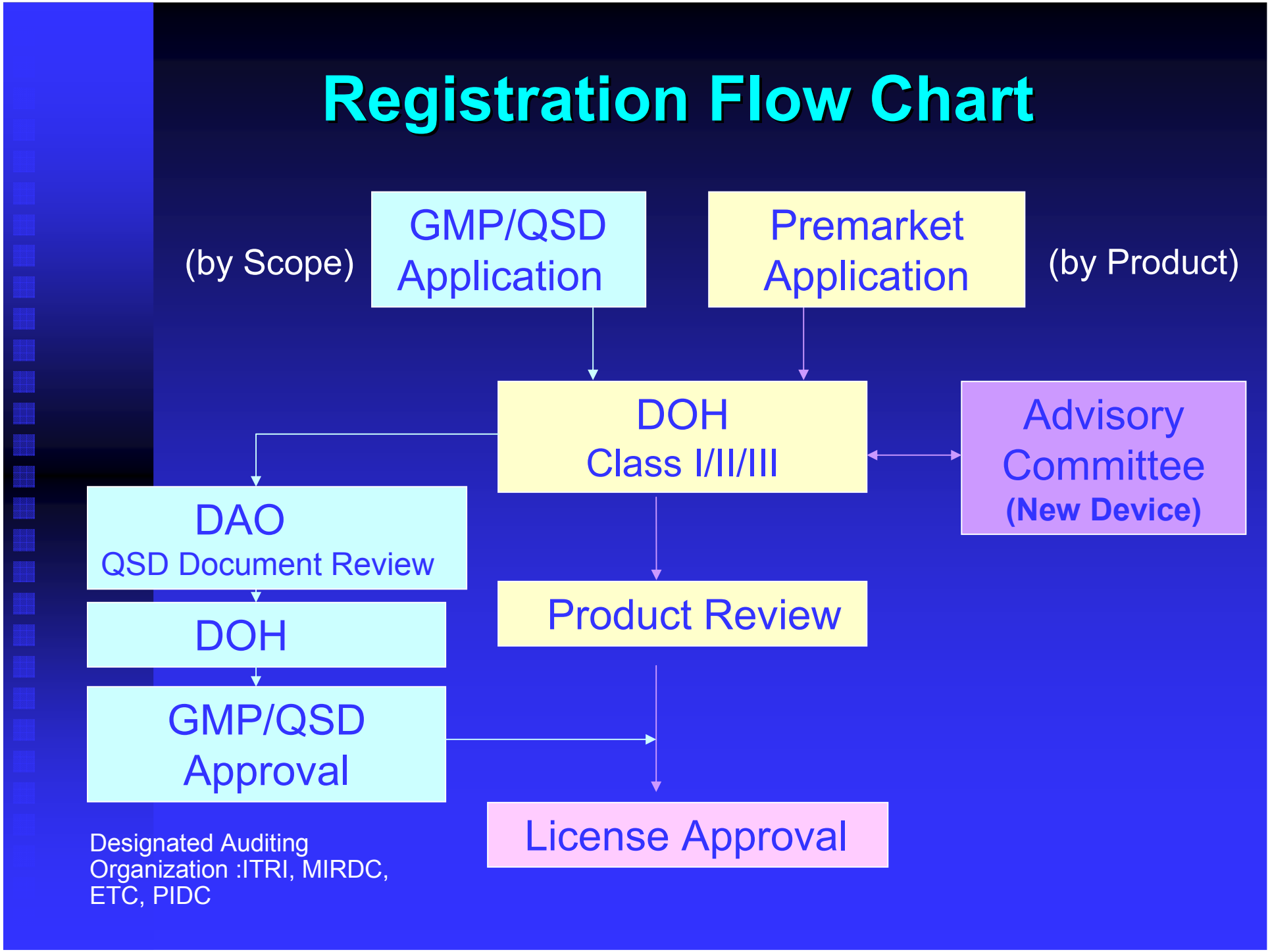
Definition of medical devices – include the instruments, equipment, apparatus, and their accessories and spare parts which are used for diagnosing, curing, alleviating and directly preventing the human diseases, or changing the structure and function of human body.

Revolution of Regulation

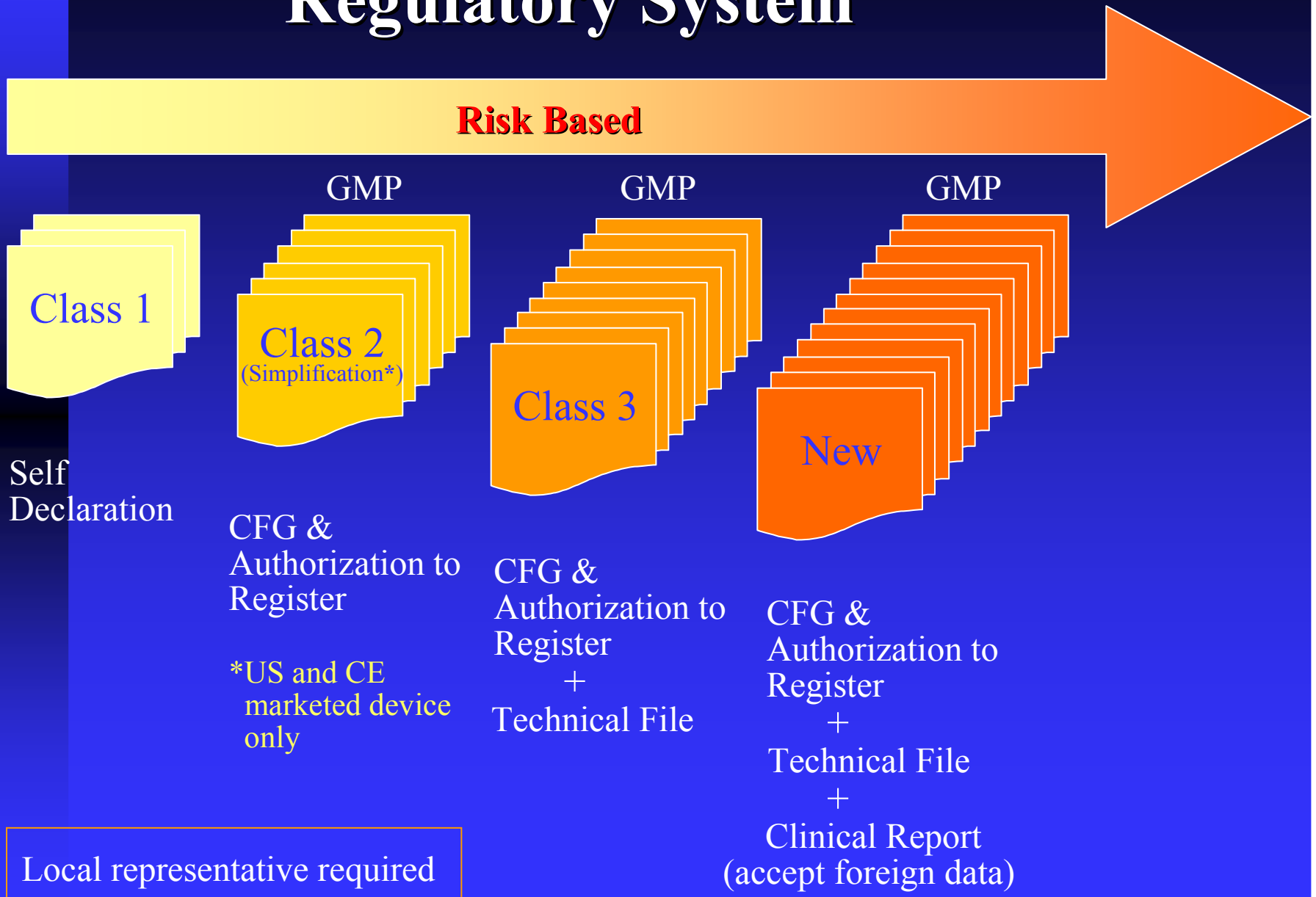
1999	GMP/QSD Implementation	ISO 13485
2000	Adverse Event Reporting	
2000	Reclassification	Risk based FDA template
2002	IVD Regulation	
2002	GTP	
2003	BSE Control	
2004	Standards Recognition	EC, FDA, CNS(Taiwan)
2004	PAL Revision	Class I/II/III premarket approval required
2005	Completion of Transition	
2006	GLP	
2007	GCP	


Taiwan DOH
Request for Designation
Consulting Window
Request for Designation
Device Advice
Prototype
Concept
Recalls
Obsolescence
Safety Alerts
Warning Letters
Post-Marketing Studies
MDR's
Advisory Panels
PMA's, 510(k)s
Guidance
Agreement & Determination Meetings
IDEs
Early Planning Meetings
Preclinical
Clinical
Commercial Use
Marketing
Manufacturing
US FDA
Standards Recognition
Recall
Testing GLP/GTP
Clinical Trial GCP
AE Reporting
Manufacture GMP/QSD
Advertisement
Premarket Registration

Registration Flow Chart



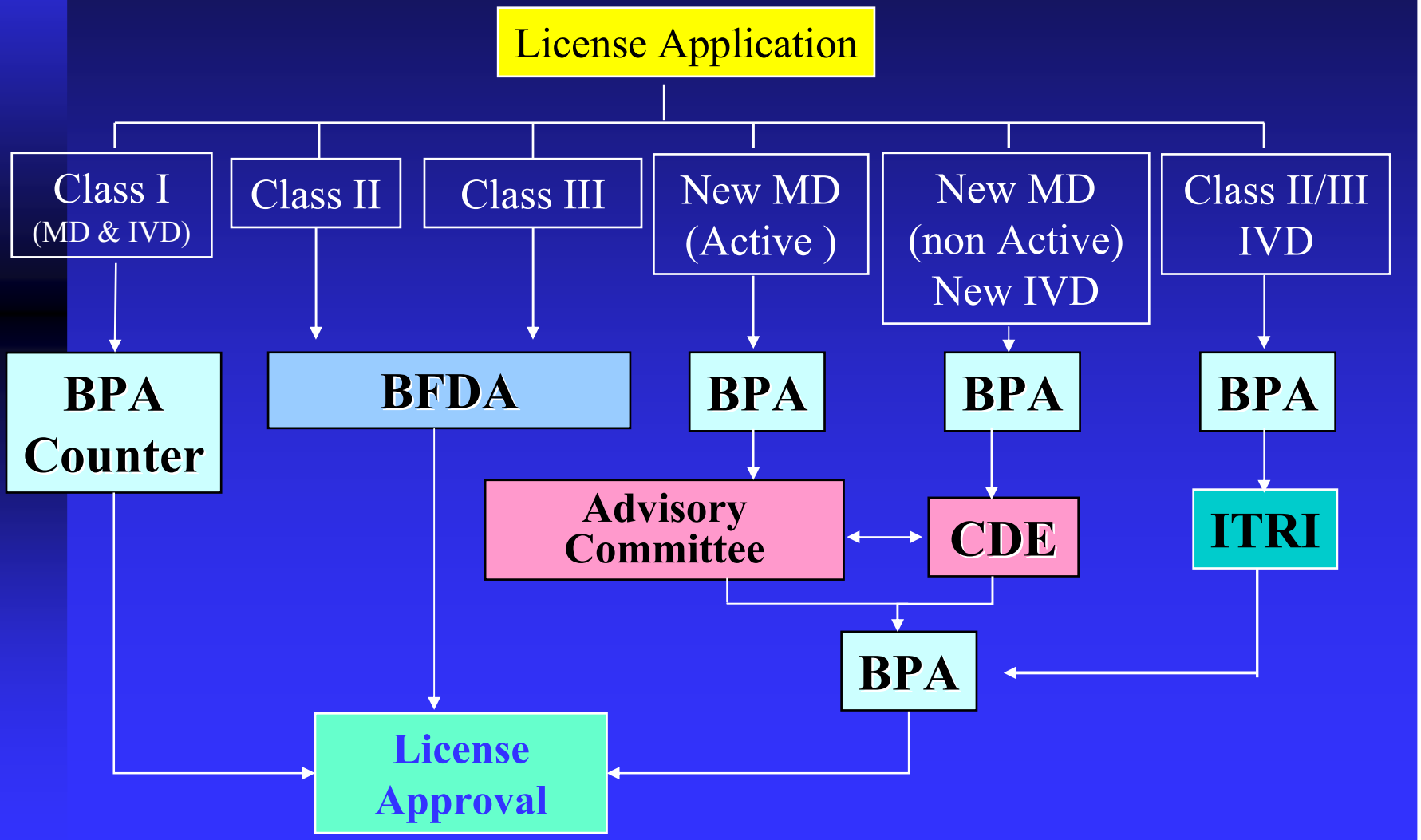
Regulatory System



Classification
17 Categories

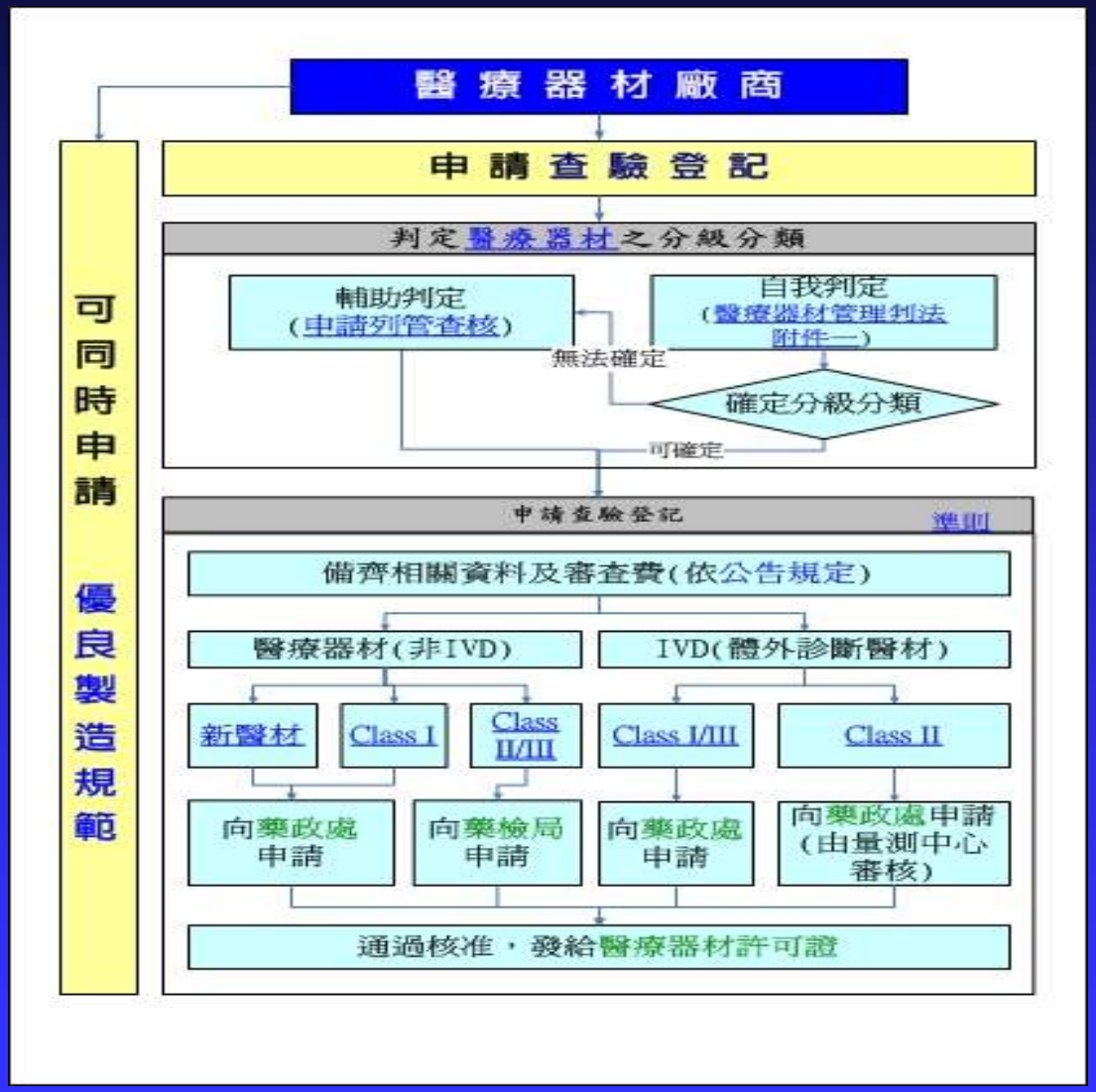
A. Clinical Chemistry and Clinical Toxicology Devices
B. Hematology and Pathology Devices
C. Immunology and Microbiology Devices
D. Anesthesiology Devices
E. Cardiovascular Devices
F. Dental Devices
G. Ear, Nose, and Throat Devices
H. Gastroenterology-Urology Devices
I. General and Plastic Surgery Devices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

Filing and Reviewing



For New Comer

06.28.2006



http://www.doh.gov.tw/cht/list.aspx?dept=R&now_fod_list_no=4079&class_no=2&level_no=1&divNo=2&divCount=5

Global Outsourcing

CFG from original Regulatory Authority
Manufacture & Sale legally

Standard Format

CFG from original RA

Manufacture

+

CFG from other RA

Sale

CFG from RA (country P)

Manufactured by P (production site) for L (legal manufacturer/head quarter)

Manufacture & Sale Legally

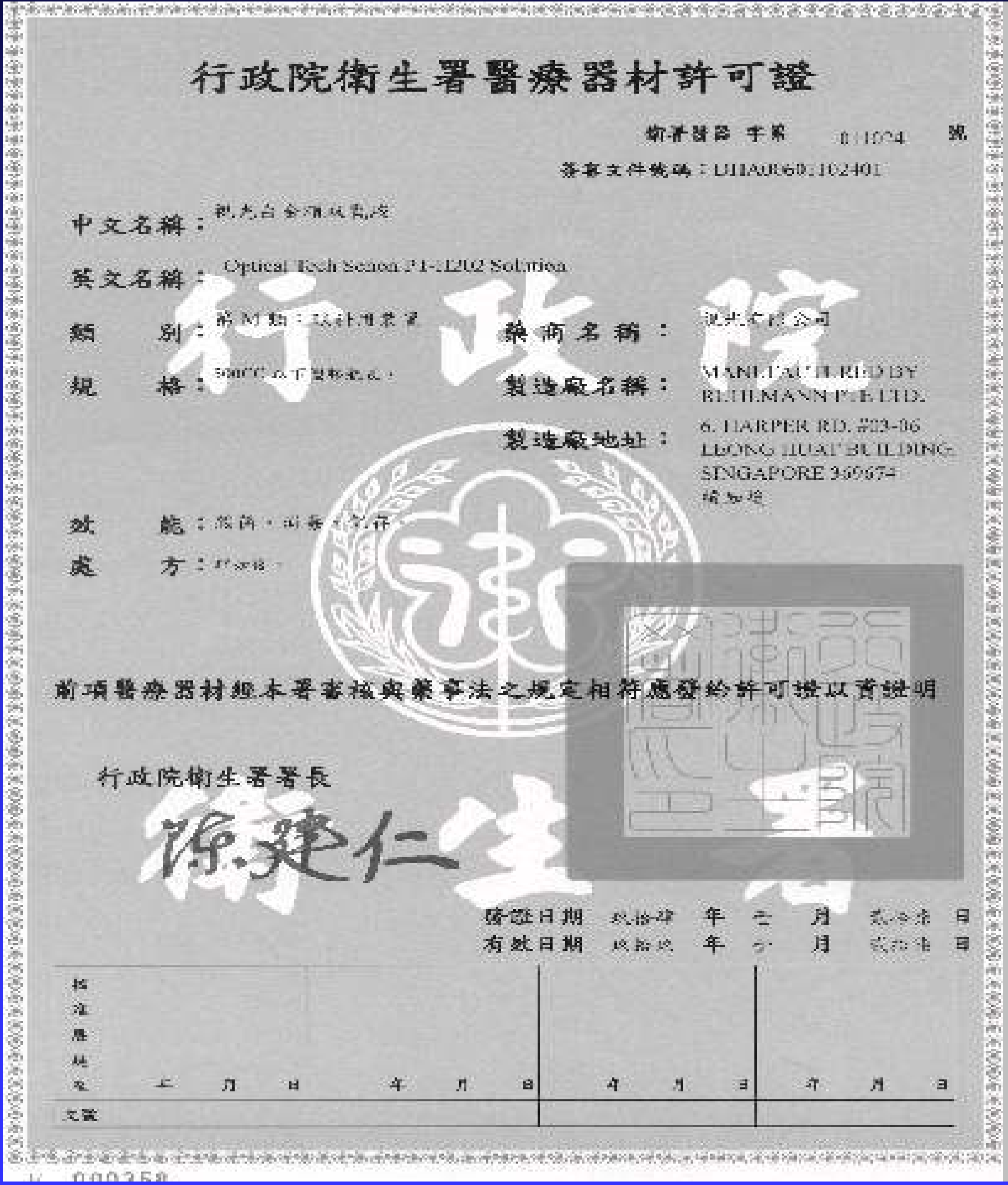
Review Efficiency (2006.1.1~2007.3.31)

Category	Number of Application	Review Time (Month)
New Drug	241	4.0
Generic Drug	668	2.7
Clinical Trial	242	1.1
BA/BE	112	2.5
Medical Device	2687	3.6
New Medical Device	129	4.5
IVD	764	4.0

Appeal case not included

Review Time: BPA/CDE time only

License Renew Every 5 Years



行政院衛生署醫療器材許可證

衛署醫器 [illegible] 字第 [illegible] 號

查驗文件號碼：[illegible]

中文名稱：[illegible]

英文名稱：Optical Tech [illegible] Solution

類　　別：[illegible]

規　　格：[illegible]

藥商名稱：[illegible]

製造廠名稱：MANUFACTURED BY [illegible] PTE LTD.

製造廠地址：6, HARPER RD. #03-06 LEONG HUAT BUILDING SINGAPORE 369674 新加坡

效　　能：[illegible]

處　　方：[illegible]

前項醫療器材經本署審核與藥事法之規定相符應發給許可證以資證明

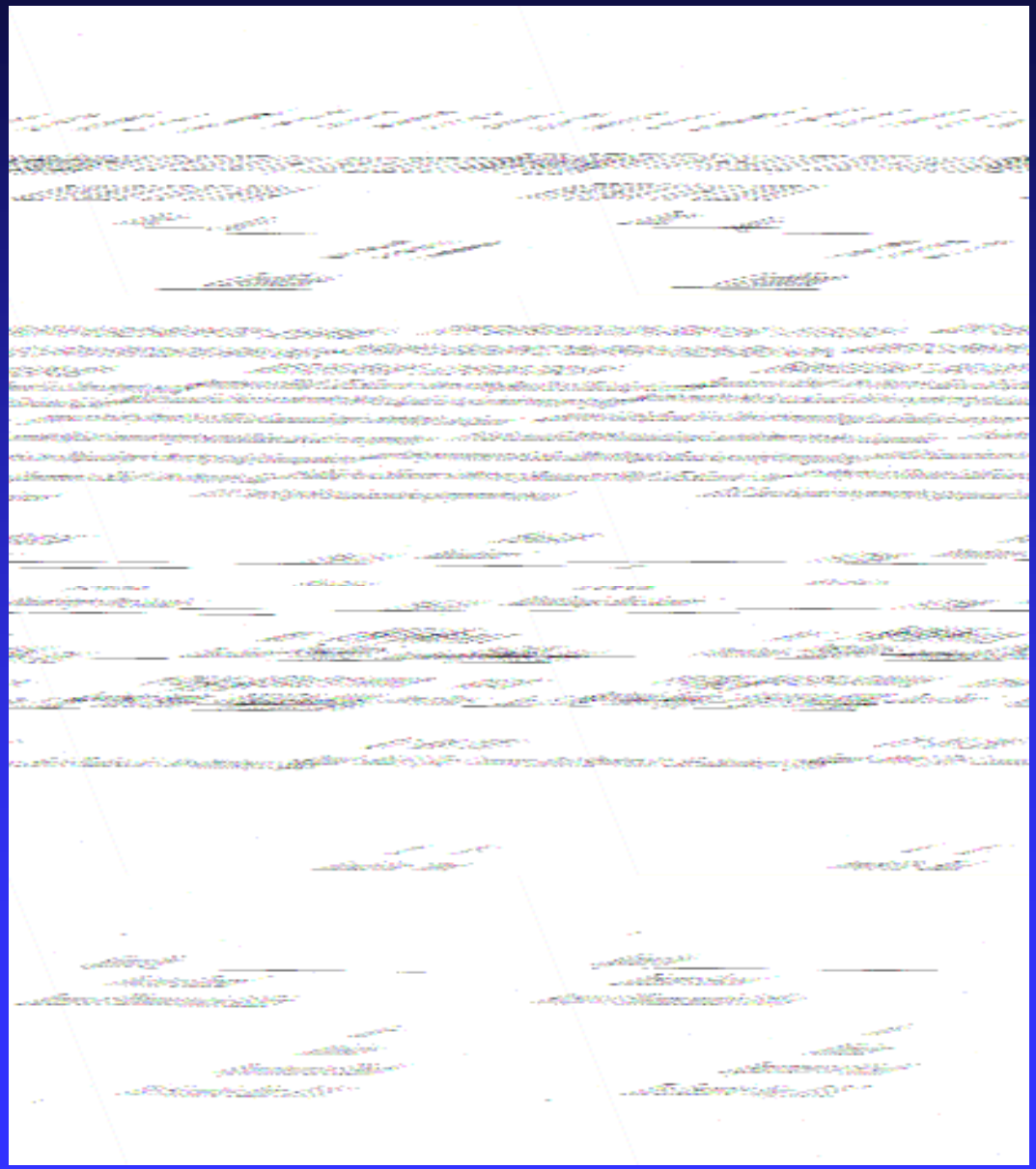
行政院衛生署署長

發證日期 [illegible] 年 [illegible] 月 [illegible] 日

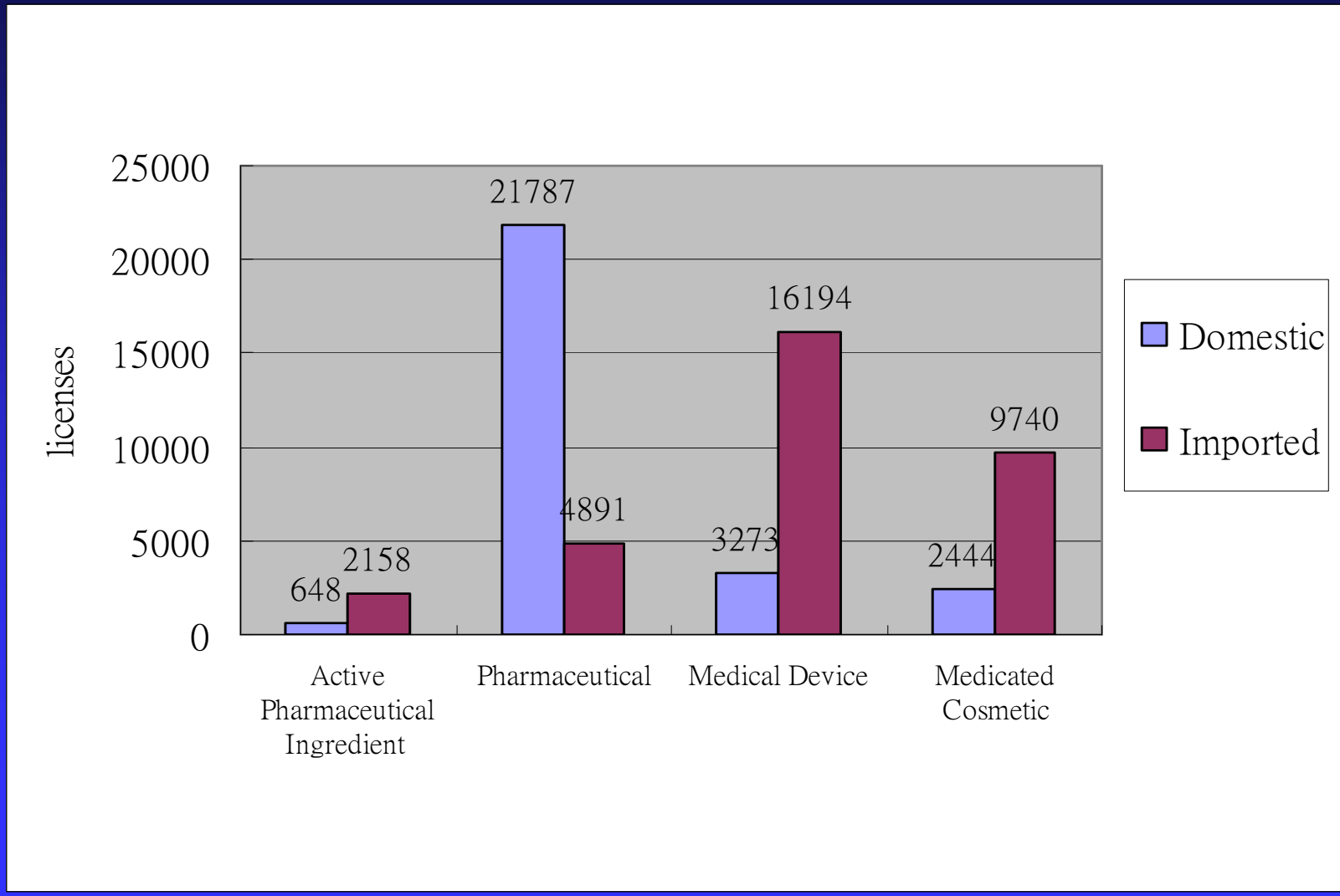
有效日期 [illegible] 年 [illegible] 月 [illegible] 日

核准展延至	年	月	日	年	月	日	年	月	日	年	月	日
文號												

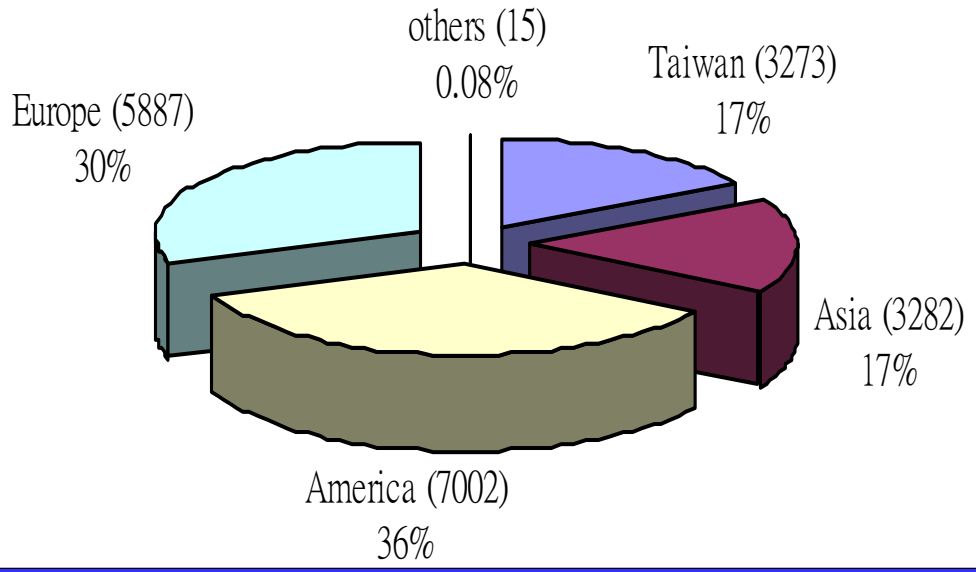
Certificate to Foreign Government



Statistics of licenses (2007.01.19)



Origin of Medical Devices (2007.01.01)



Top 16 Licensed Countries

2006

No. of product licenses in Taiwan

U.S.A.	4661	China	213
Taiwan	2204	Puerto Rico	187
Germany	1655	Sweden	138
Japan	1222	Korea	129
Ireland	525	Netherlands	124
U.K.	419	Italy	117
France	325	Denmark	108
Switzerland	241	Singapore	105

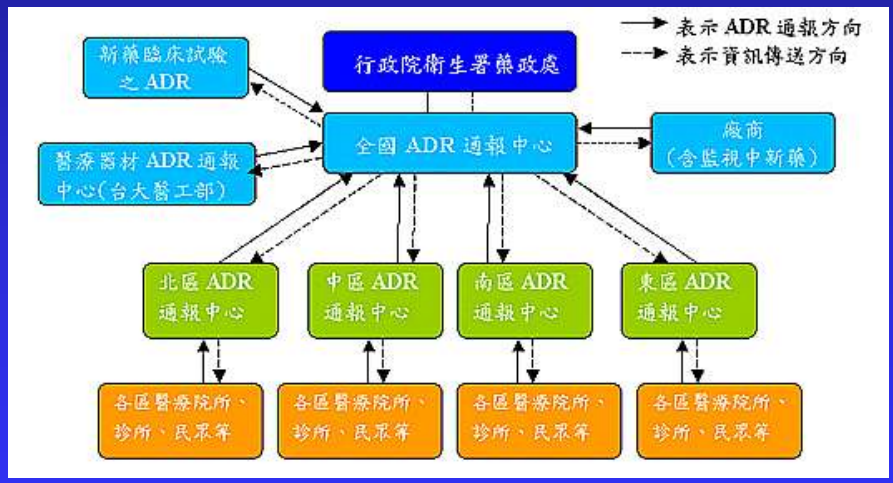
行政院衛生署醫材不良反應通報系統

National Reporting System of Adverse Medical Device Reactions in Taiwan

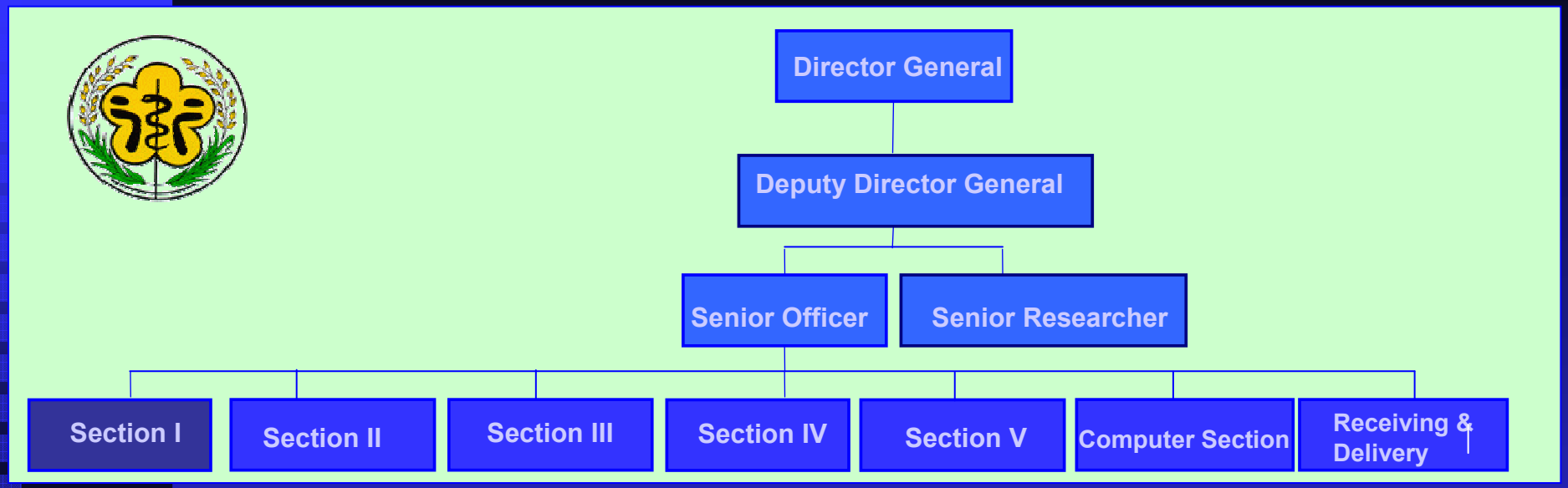
藥品不良反應通報

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/



I	II	III	IV	V
•Compliance	•Medical device	•New drug	•Generic drug	•Biologic
	•Quality system	•Clinical trial	•GMP	•Radiopharmaceutical
		•Post marketing surveillance	•BA/BE	•IVD
				•Cosmetics

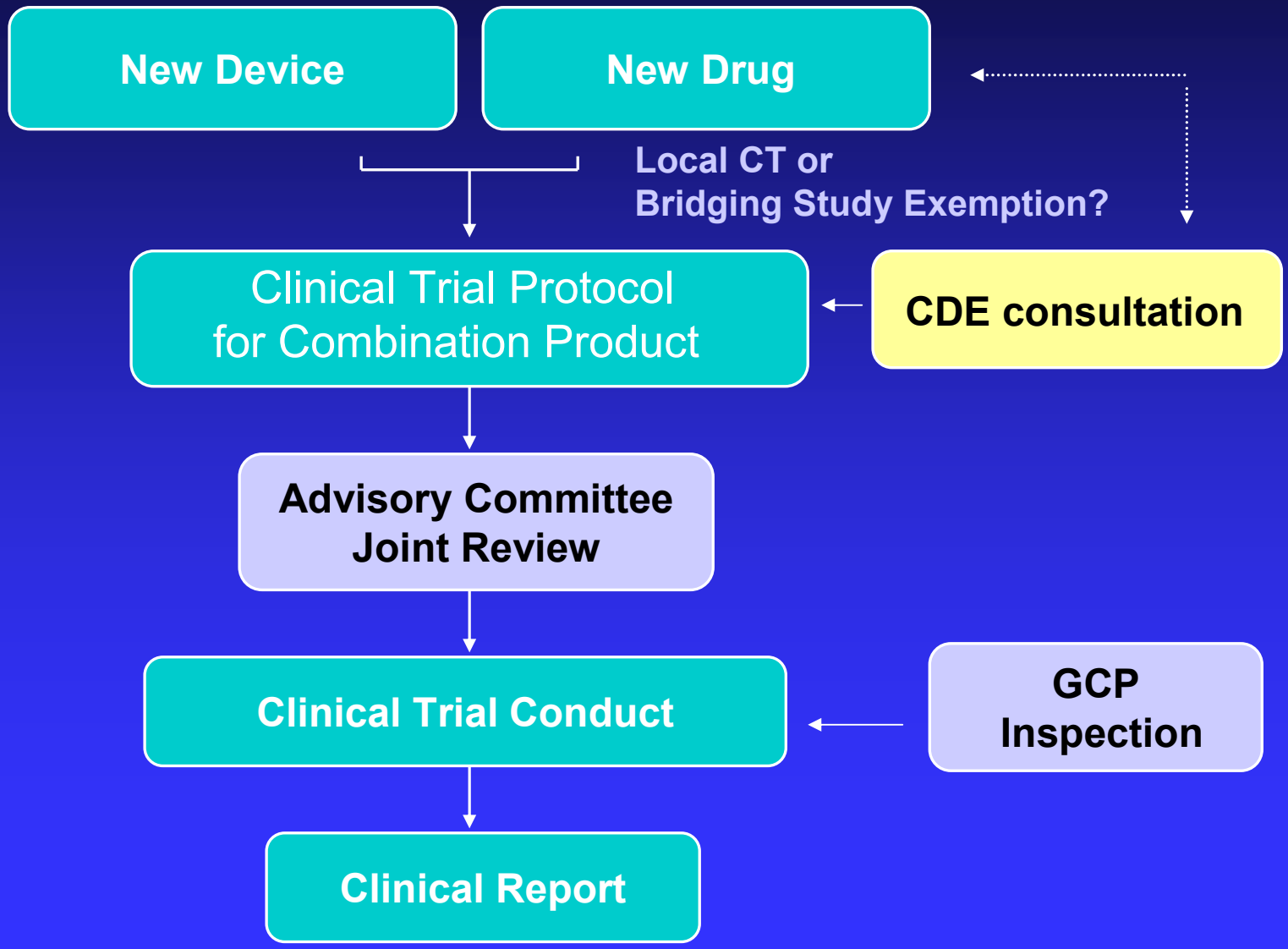
?

Combination product

Inquiry of Regulatory Status

- Intended use
- Mode of action
- Instruction for use
- Product name
- Manufacturer
- Sponsor

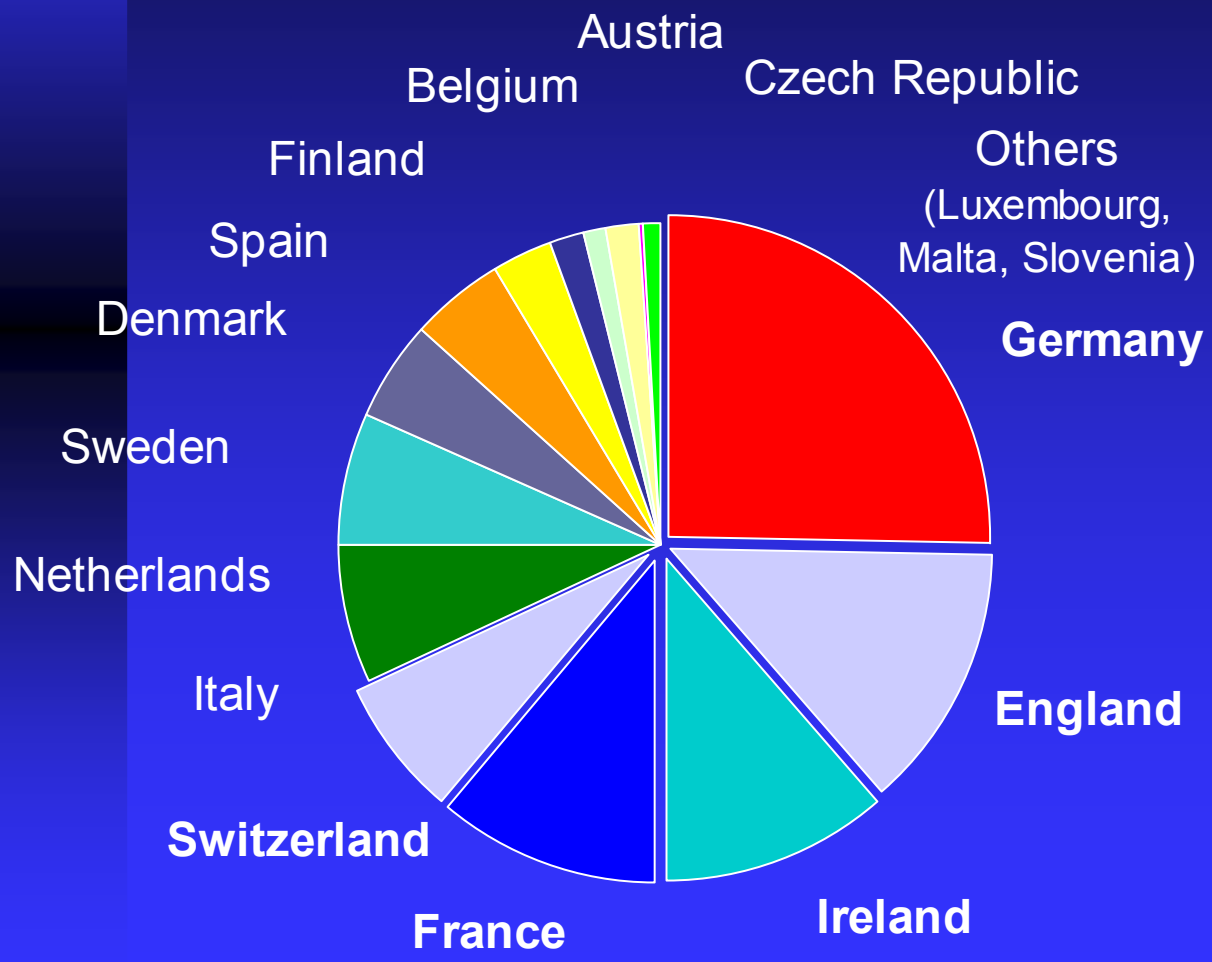
One Stop for Combination Product Clinical Trial



Global Harmonization

Waive document requirements based on data sharing through Exchange of Letter (EOL)

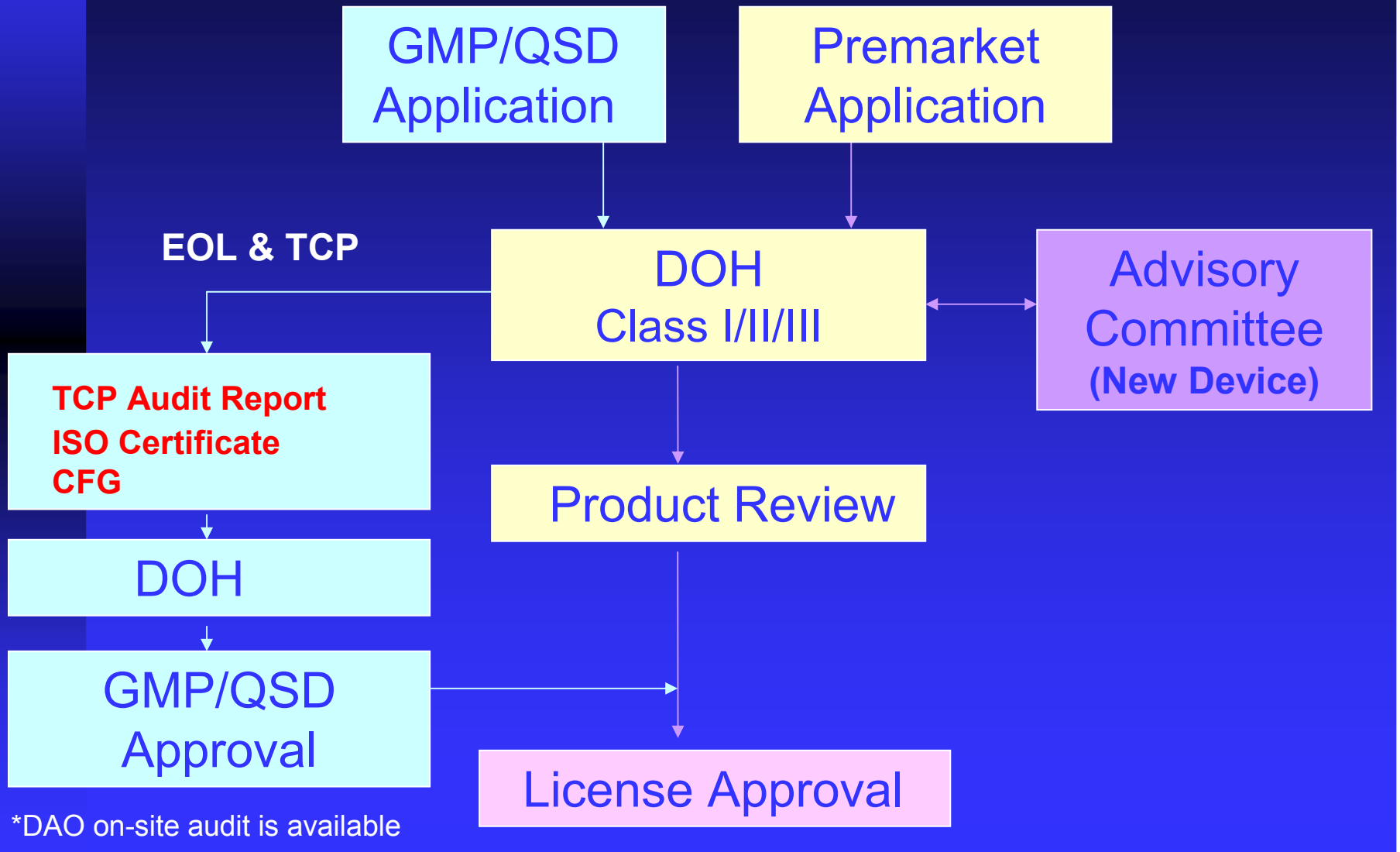
EOL with European Commission



DSD approval

- Germany (25%)
- England (13%)
- Ireland (11%)
- France (11%)
- Switzerland (7%)
- Italy (7%)
- Netherlands (7%)
- Sweden (5%)
- Denmark (5%)
- Spain (3%)
- Finland (2%)
- Belgium (1%)
- Austria (1%)
- Czech Republic (0.5%)
- Others (0.7%)

Simplification Mode via EOL



EU NB/DOH DAO Cooperation

- Technical Cooperation Programme between EU NB and DOH designated GMP auditing organizations (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,AMTAC,MEDCERT, DGM,UL
  - Audit report can be used as part of the QSD requirement