

# Infrastructure of Clinical Trial in Taiwan

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1  
*Geography*



# Background Information

- **Population**  
**23 million**
- **Area**  
**36,006 m<sup>2</sup>**
- **GNP**  
**US\$16,309**
- **Medical Cluster**  
**19 Medical Center**  
**114 Regional Hospital**

## Current Status of Biotechnology Development in Taiwan

Industry	Biotechnology	Pharmaceutical	Medical Device	Total
Revenue*	1.21	1.95	1.84	5
Number of manufacturers	253	419	484	1,156
Size of work force (number)	8,090	14,995	15,000	38,085
Export value*	0.48	0.36	0.84	1.68
Import value*	0.50	1.80	1.23	3.54
Domestic sales vs. export	60:40	82:18	54:46	66:34
Domestic market Demand*	1.23	3.39	2.23	6.86

\*Units: US \$ billion

Biotechnology and Pharmaceutical Industries Program Office (BPIPO), MOEA, Taiwan, 2006

# Topics

- Commitment and Strategy to Promote and Protect the Public Health
- GCRC and Center of Excellence
- International Harmonization

# Top Down Policy Making

## Strategy to Promote the Biotech Industry 1995

R&D, IP Protection, Technology Transfer, Regulation for  
Pre-market Review, Tax Incentive



## Strategic Review Board Annual Meeting Since 1997

Investment Environment, CRO, SMO, National Research  
Funding Program for Medical Product (Drug, Device,  
Biologics, Chinese Herbal Medicine)

# Establishment of New Institution

## JIRB

- Authorized by hospital IRBs to review clinical protocols
- One stop for all (multi-center trials)
- Average review time calendar 32 days

# Establishment of New Institution

## CDE

- Full time professionals
- Based on regulatory science
- Consultation
- Critical Path Program

# Regulatory Environment

- **Implement ICH E6 for Conducting Clinical Trial**

**ICH : The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use**

- **Data Exclusivity Protection for New Chemical Entity**



# 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

# Biomedical Technology Island Program 2005-2009

## Infrastructure for Clinical Trial



# FERCAP Recognition

(The Forum for Ethical Review Committees in Asia and the Western Pacific Region)

## 2005

- Changhua Christian Hospital 彰化基督教醫院
- Joint Institutional Review Board (JIRB)

## 2006

- Chang Gung Memorial Hospital Linkou Branch 長庚紀念醫院林口總院
- National Taiwan University Hospital 台灣大學附設醫院
- Taipei Veterans General Hospital 台北榮民總醫院
- Tri-Service General Hospital 三軍總醫院

## 2007 Under Preparation

- National Cheng Kung University Hospital 成功大學附設醫院
- Chi Mei Medical Center 奇美醫院
- Chung-Ho Memorial Hospital, Kaohsiung Medical University 高醫中和醫院



Translational Research  
Core Laboratory



CRO/SMO  
GCRC/Center of Excellence  
JIRB/FERCAP Recognition



CDE/DOH  
ICH E6  
GCP Inspection



Network of Clinical Trial  
CT Training Program  
Professional Scholarship



# Harmonization Activities of DOH

- ❖ Host APEC Network of Pharmaceutical Regulatory Science: every 2 years
- ❖ Participate ICH for drug regulation
- ❖ Participate GHTF and AHWP meetings for medical devices regulation



## 3rd AHWP TC Meeting

Taipei 2004




Date: 29-30 April 2004 Venue: The Grand Hotel, Taipei

# *Asian Harmonization Working Party on Medical Device Regulation*

Website: [www.asiahwp.org](http://www.asiahwp.org)

# Host APEC Network on Pharmaceutical Regulatory Science Every Other Year Since 2000




**The 2005 Symposium of  
APEC Network on  
Pharmaceutical Regulatory Science**



亞太經合會  
— 2005藥政法規交流研討會

- Sharing Review Experience
- Good Review of Combination Products  
(pharmaceutical + medical device)
- Extrinsic Factors of Bridging Study
- Pharmacovigilance Planning
- Anti-counterfeit Drug and Rational Drug Use

November 14-15, 2005  
(Taipei 101-Taipei International Convention Center)

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Organization:  Bureau of Pharmaceutical Affairs,  
Department of Health

In Cooperation with:  Center for Drug Evaluation  
 Foundation of Medical Professionals Alliance in Taiwan

**Welcome to Taipei**  
**Nov. 27-28, 2007**