Global Development of Drugs and Co-operation among Asian Economies

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Introduction

The Main Objective of the Pharmaceutical Regulatory Authorities and Good Review Practice is to Protect Public Health.

Why Safety is a Prominent Issues in New Drug Development

- Media's major interest in accident & risk
  → General public's demand for absolutely safe drugs.
- Political Environment
  →Opposition party's competition on pleasing media and the general public.
- Liability
  →Large amount of compensation.

The Consequences of an Absolute Safety Drug

- Increase the request for enormous amount of safety data.
- Increase the cost/time for R&D.
- Increase the time lag for new drug approval.
- Decrease the accessibility of new drugs to patients.

Missions of the Pharmaceutical Regulatory Authorities

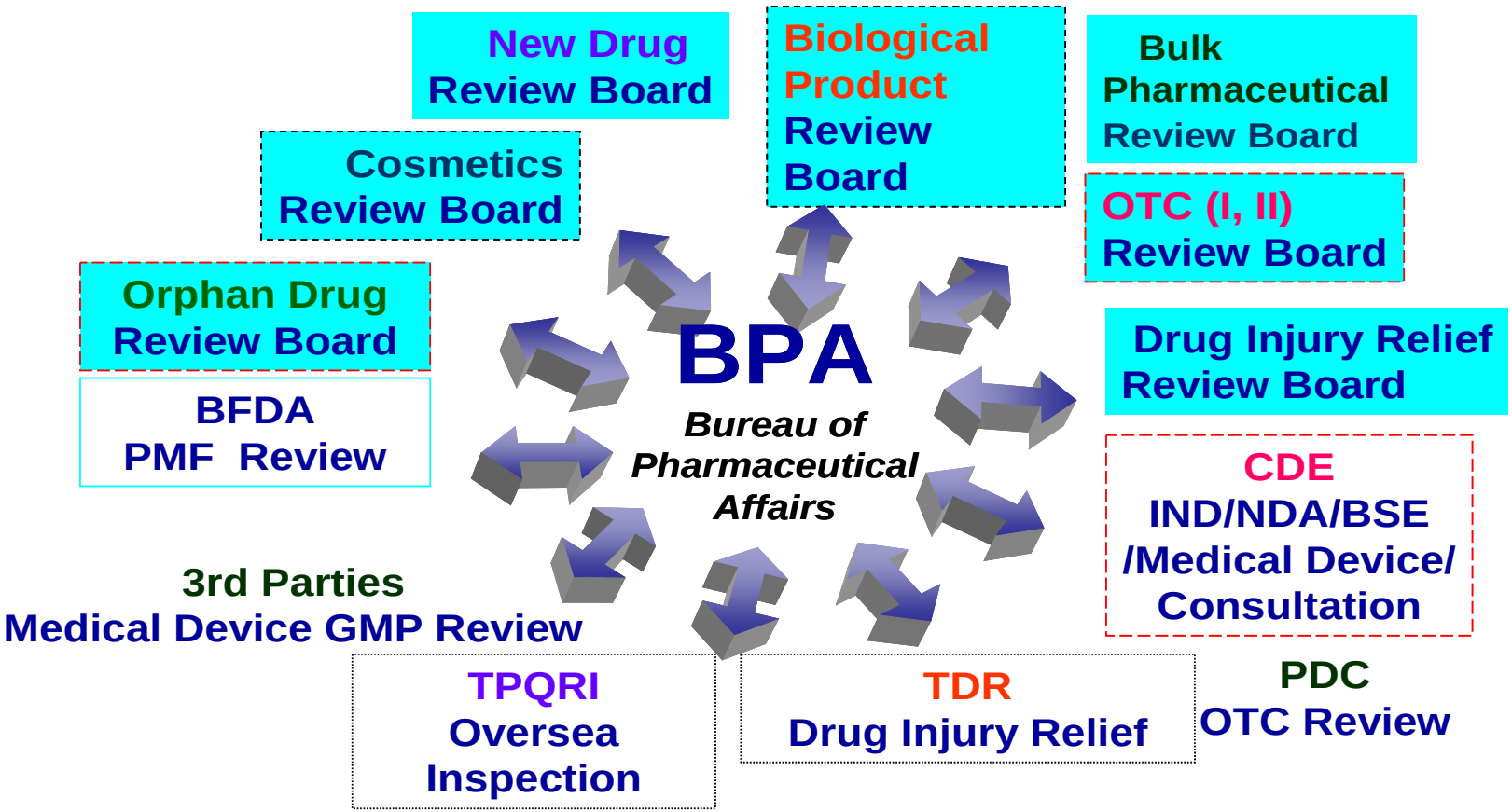
- Balance between
  - Public health protection
  - Health industry promotion
- To approve new drugs as soon as possible, without jeopardizing drug safety.

Roles of the Pharmaceutical Regulatory Authorities

Balance between Public Health Protection & Promotion

- Gate-keeper
  - Prudent evaluation based on Good Review Practice
  - Drug quality, safety and efficacy
- Health-promoter
  - Consultation and “Critical Path Program ”
  - Efficient and transparent review process
  - International harmonization

Pharmaceutical Regulatory Scheme



Drug Innovation Lag

- Retrospective study (1996~2002, n=347)
- Marketing lag after first country approval
  - USA 5.6 months
  - Europe 8.2 months
  - Canada 18.0 months
  - Chinese Taipei 30.5 months
- Drug withdrawals from market
  - US FDA 7 Drugs (1993~1999)
  - Chinese Taipei BPA 1 Drug (1993~1999)

New Drug Marketing Lag

- Drug Lag Index

  from 0 (no drug lag) to 1 (serious drug lag)

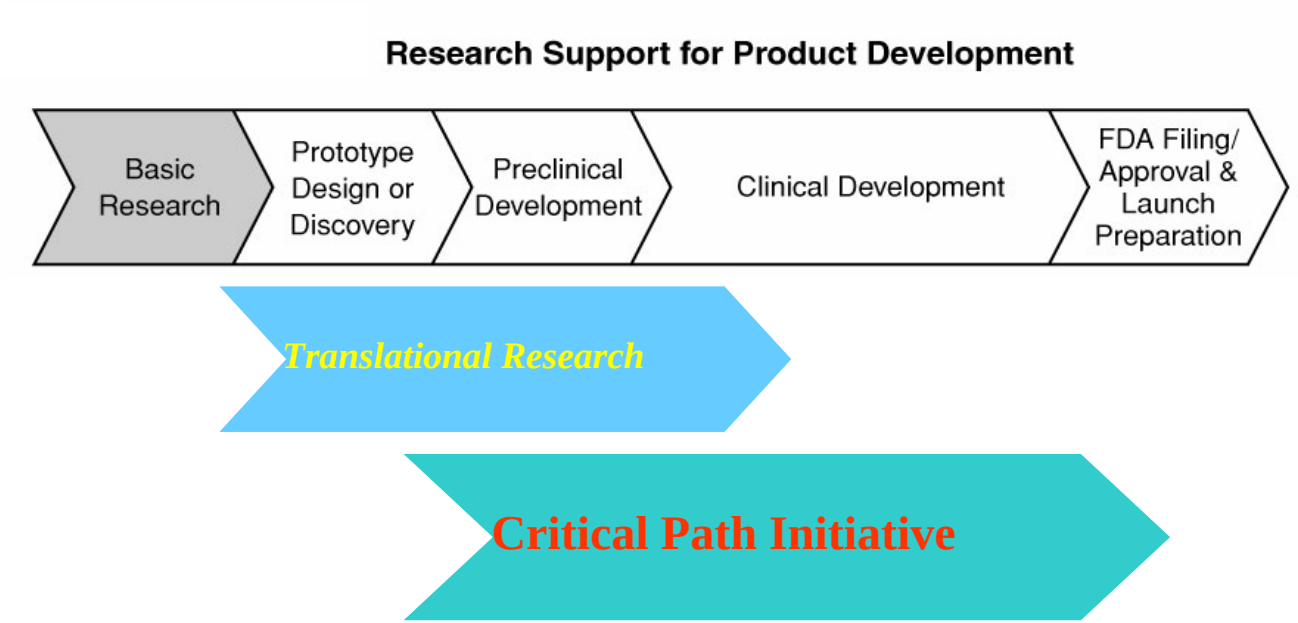
  - 0.14 in USA
  - 0.21 in Europe
  - 0.45 in Canada
  - 0.76 in Chinese Taipei

Impetuses for Drug Regulatory System Reform

- Development of pharmaceutical and biotech industry.
- Public health demands for efficient pharmaceutical review and approval.
- Compliance with international norms.

Critical Path

- FDA Critical Path Initiatives (since 2004)

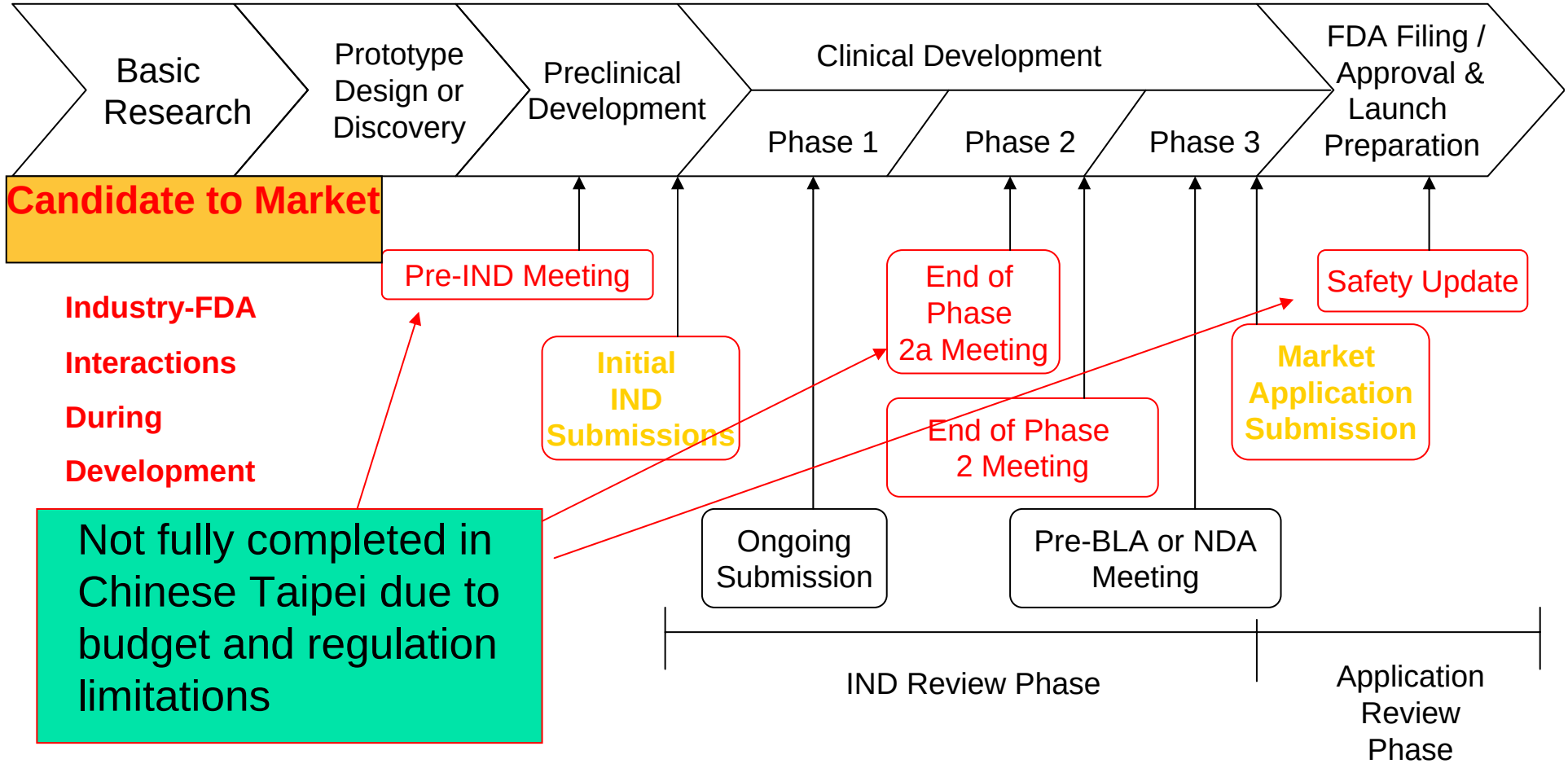


www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf

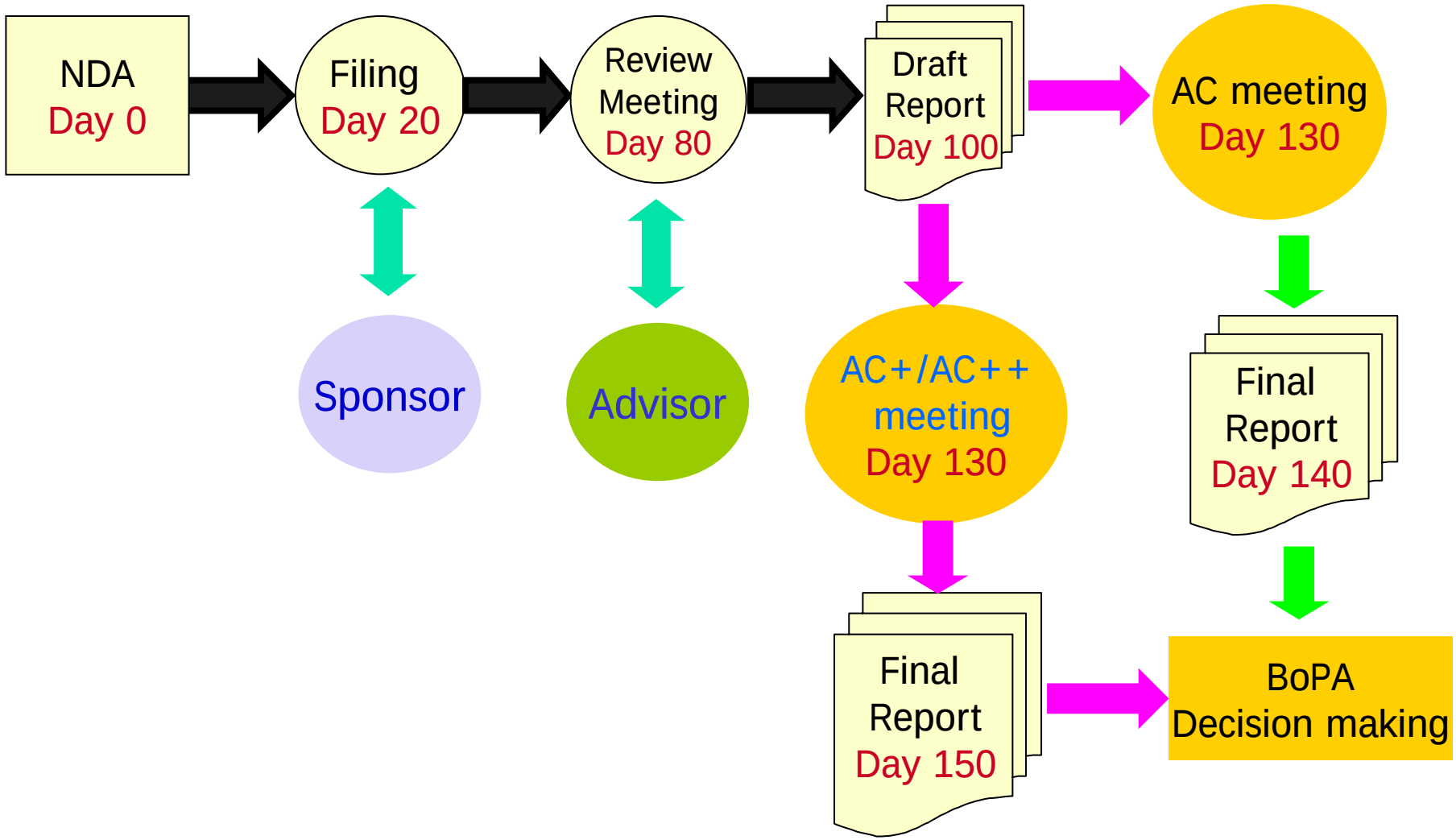
CDE's Critical Path Project

Increase interactions of new drug development and regulatory agencies

Cf. Critical Path Initiative of FDA



Timeline of the New NDA Process



The New NDA Process

- Solved the inconsistency between CDE and AC.
- NDA review is transparency and publicity.
  - Sponsor can online check the review status/progress.
  - Sponsor meeting can be arranged, if needed.
  - Inform sponsor with written letter when reject or more information is required.
  - Finish minutes of AC meeting in 2 working days.
  - New NDA Process started on January 1, 2006.

Paradigm Shift in New Drug Evaluation

Administrative Requirement	⇒ ⇒ ⇒	Risk-based Classification
External Advisory Committee	⇒ ⇒ ⇒	In-house review team following GRP
Protect Public Health	⇒ ⇒ ⇒	Promote Public Health
Local Requirement	⇒ ⇒ ⇒	International Harmonization E.g. ICH, APEC

Objectives of Harmonization

- Avoid redundant R&D studies
- More efficient utilization of resources
  - R&D
  - Formats of technical documentation
  - Sharing review reports
  - Sharing ADR information
  - Sharing review experience
- Prompt access of new drugs with guaranteed safety and efficacy.

Regional Harmonization

- APEC (Asia-Pacific Economic Cooperation)
- Japan-Chinese Taipei Joint Seminar, 2005 and 2006
- Asean (Association of South-East Asian Nations)
- GCC (Gulf Cooperation Council)
- PANDRH (PAHO) (Pan America Network of Drug Regulatory Harmonization)
- SADC (Southern African Development Community)

The ICH Approach

since 1990

- To maintain a constructive forum between regulatory authorities and the pharmaceutical industry on technical requirements for product registration in the EU, USA and Japan.
- To monitor and update harmonized technical requirements leading to a greater mutual acceptance of R&D data.
- To facilitate the dissemination and communication of information on harmonized guidelines and their use.
- To ensure a more timely introduction of new medicinal products, and their availability to patients.

The ICH Achievements

- ICH technical guidelines, Q&A and concept papers.
- Medical Dictionary for Regulatory Activities (MedDRA) Terminology.
- Global Cooperation Group (GCG): promote mutual understanding, ICH guidelines harmonisation and capacity building.
- The Common Technical Document (CTD): divided into Organization/General; Quality; Safety; Efficacy; Electronic Sections.
- ICH Conferences

The APEC Approach

What is APEC ?

- Asia-Pacific Economic Cooperation (APEC), is the premier forum for facilitating economic growth, cooperation, trade and investment in the Asia-Pacific region.
- APEC has 21 member economies.
- APEC accounts for approximately:
  - 40% of the world's population,
  - 56% of world GDP,
  - 48% of world trade.

The APEC Network on Pharmaceutical Regulatory Science Project

(the APEC Project)

Objectives

Establish an APEC network for solving common problems and for better mutual understanding on drug regulatory issues.

The APEC Project

History

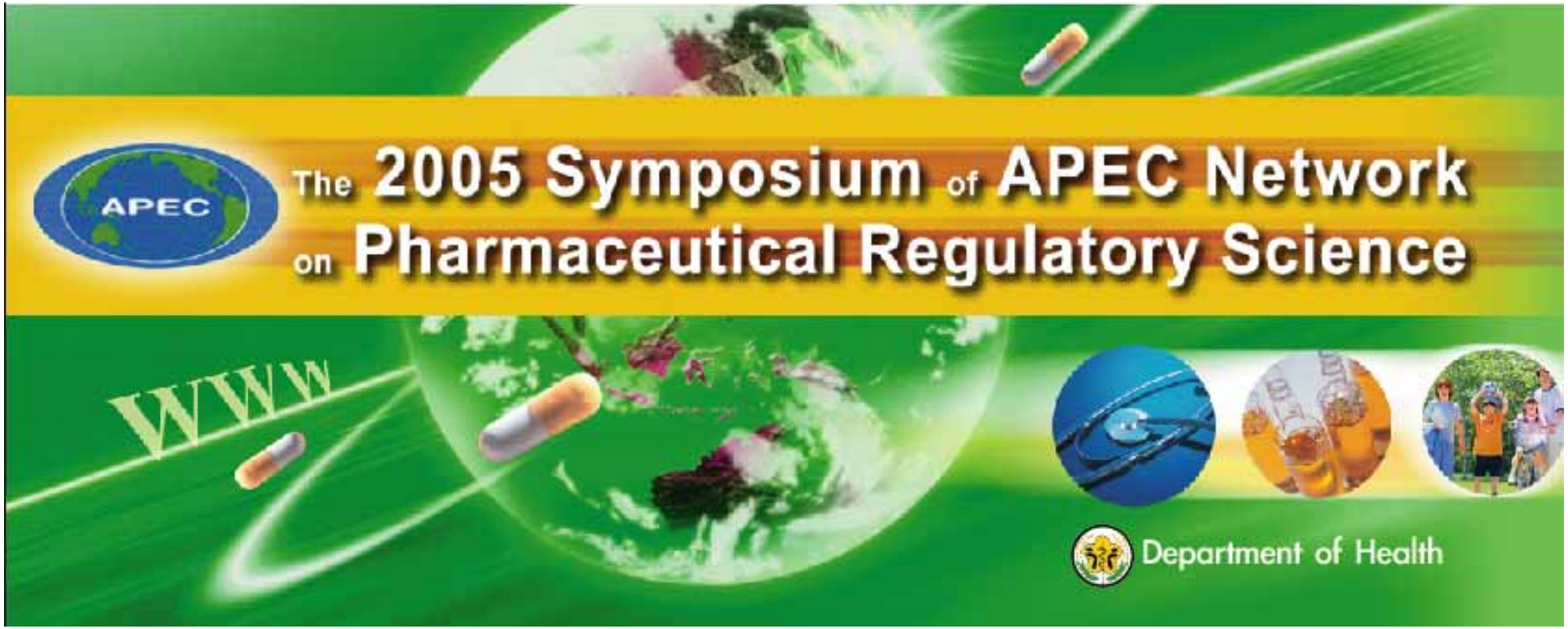
Chinese Taipei initiated the APEC Project in the 16th APEC ISTWG in March, 1999. The APEC Project was approved in the 17th APEC ISTWG in August, 1999, under the support of Australia, Mexico, Philippines and Singapore.

ISTWG: Industrial Science and Technology Working Group

The APEC Project
1999-2005

- Hosted an expert working group workshop in 2000.
- Hosted a symposium on bridging study joint research project in 2001.
- Japan hosted a symposium on bridging study joint research project in 2002.
- Hosted a bridging study conference in 2003.

- Korea hosted the “4th Conference of APEC Network on Pharmaceutical Regulatory Science” in 2004.
- Organized and sponsored the 2005 APEC symposium.



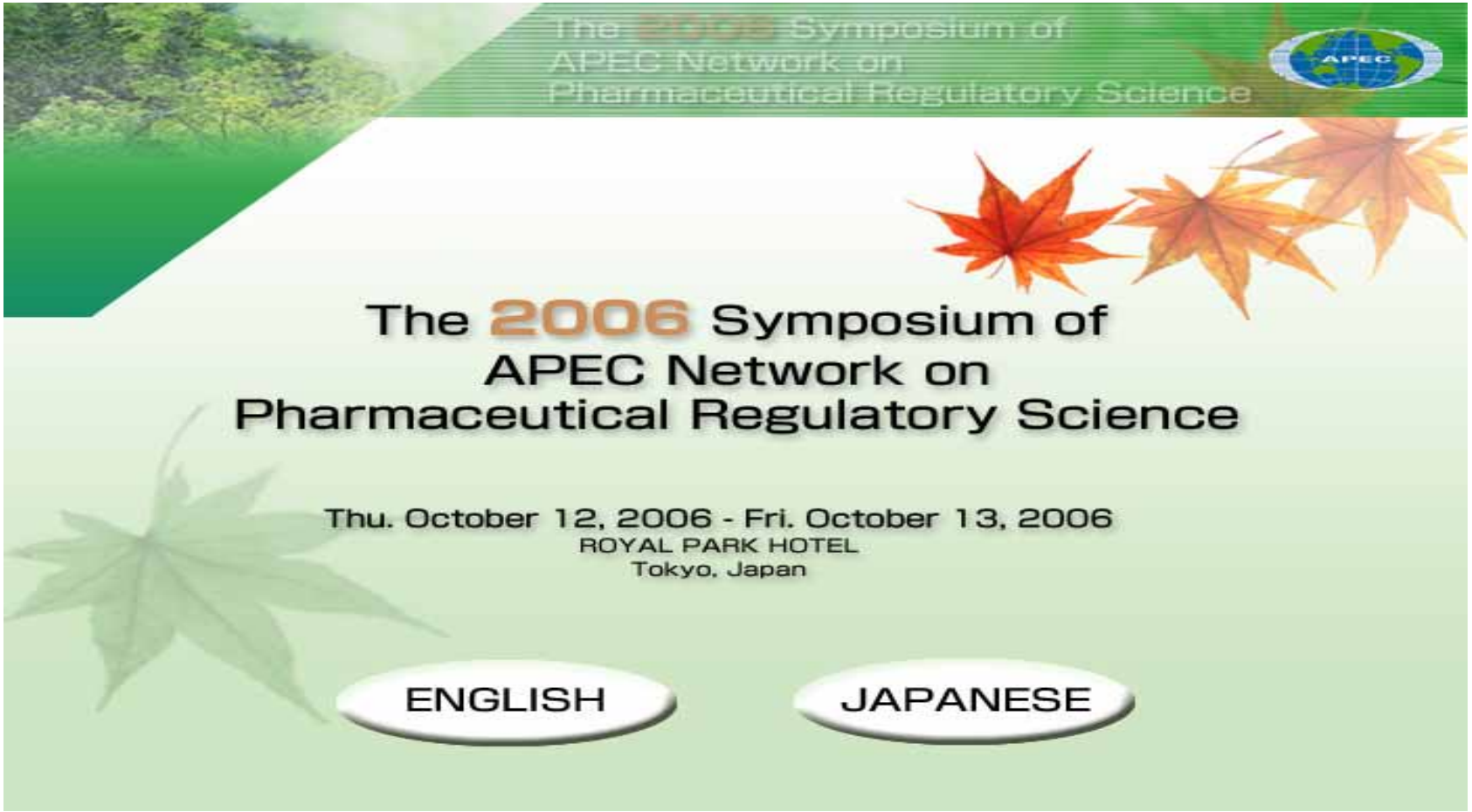
Date: November 14-15, 2005
Venue: Taipei International Convention Center,
Taipei, Chinese Taipei

Themes of the APEC 2005 Symposium

- Sharing Review Experience
- Extrinsic Factors of Bridging Study
- Anti-Counterfeiting Drug and Rational Drug Use
- Pharmacovigilance Plan
- Good Review of Combinational Products

Outcomes of the APEC 2005 Symposium

- Thirty-three speakers from ten different countries presented their remarkable opinions.
- There were almost 450 participants from 16 different countries attending this symposium.
- A regulatory meeting, including government officials from Australia, Japan, Korea, Malaysia, Singapore, Chienese Taipei, and USA, is open to all attendee to discuss current regulatory issues.



Chinese Taipei will host the APEC 2007 Symposium in Taipei!

Japan-Taiwan Joint Seminar

- Started in 2005
  - Held in Tokyo
  - Hosted by Japan
- 2nd Joint Seminar in 2006
  - Held in Taipei
  - Hosted by Chinese Taipei

Recent Development of Japan-Chinese Taipei Joint Seminar

- Exchange Reviewers between CDE, Chinese Taipei and PMDA, Japan.
- Relationship between Chinese Taipei's CDE and Japan's PMDA changes from recognizing to mutual trust each other.

Vision of Harmonization in the Asian Pacific Region

- A collective evaluate on bridging studies.
- Exchange of regulatory reviews.
- Collaborative on inspections.
- Share post-marketing surveillance.
- Joint reviews of drug applications (IND/NDA/IDE/BLA).
- Mutual recognition of licensing.

Future Perspectives on Pharmaceutical Regulatory Issues

- Sharing review experience
  - exchange review reports of IND/NDA/IDE/PMA/BLA
  - ethnic issue study by retrospective data surveillance
  - establish bridging study review consensus.
  - joint review for IND
- Enhance pharmaceutical regulatory networking
  - joint training program
  - communication and information sharing, e.g. ADR report
  - mutual recognition
- Establish reviewer exchange program

Pharmaceutical Evaluation Scheme (PER)

- A mechanism for mutual recognition of partial assessment reports
- Continuous effort through APCE Networking
- Set up GRMPs standards for members
- Exchange assessment reports, CMC/CTD
- Reviewer Exchange Program
- Training program on regulatory issues

Future Perspectives on Good Review Practices

- Reviewers: qualified teams with good training programs.
- Review: pre-specified guidances, regulatory sciences, evidence based, risk/benefit evaluation, review template, consistence and quality control.
- Process: transparent, predictable, timely, communicable with meeting minutes and SOPs.

Core Values of the Pharmaceutical Regulatory Authorities

- Safety
- Efficiency
- Quality
- Risk Management
- Health Promotion
- Globalization

MORE International Cooperation

Projects are Welcome!

Welcome to Taipei for the “2007 Symposium on APEC Network of Pharmaceutical Regulatory Science”!


Thank You
for Your Attention