Plenary II: Intra-Regional Efforts to Streamline the Conduct of Clinical Trials

The ASEAN – PPWG

by

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The Multi-Regional Clinical Trials Seoul Workshop
Inaugural Workshop of the APEC Harmonization Center

Grand Hilton Hotel, Seoul, Korea
15-18 June 2009
Topics

- the ASEAN-PPWG (background, obj., outcome, status)
- efforts to streamline the conducts of CTs
  - adoption of the same relevant ICH Tech.gls.
  - joined the same Training (APEC-LSIF)
  - the achievement & the future
ASEAN

= Association of Southeast Asian Nations

Member

- Brunei Darussalam
- Cambodia
- Indonesia
- Lao PDR
- Malaysia
- Myanmar
- Philippines
- Singapore
- Thailand
- Vietnam

Total population ~ 550 million
Economic Cooperation in ASEAN

ASEAN Summit

AEM

SEOM

ACCSQ

WG 1 on MRAs & Standards

WG 2 on Accreditation and Conformity Assessment

WG 3 Legal Metrology

PWGs

- ACC (ASEAN Committee on Cosmetic)
- PPWG (Pharmaceuticals PWG)
- EE PWG (Electrical and Electronic PWG)
- PF PWG (Prepared Foodstuff PWG)
- TMHS PWG (Traditional Medicine & Health Supplement PWG)
- MD PWG (Medical Devices PWG)
- A PWG (Automotives PWG)
- RB PWG (Rubber-based PWG)
- WB PWG (Wood-based PWG)
Ultimate Goal of the ASEAN

ASEAN Summit

ASEAN Leader

ASEAN Economic Community (AEC)
“by the year 2015..... ASEAN will be
Single Market and Single Production Base

(Free flow of Goods, of Services, of Investment, of Capitals, of Skilled Labour)

Mandate / Facilitation towards AEC

- AEC Blueprint
- AEC Scorecard
- ASEAN Charter
- ASEAN Trade Facilitation Work Programme
- ASEAN Trade in Goods Agreement (ATIGA)
Objective:

to develop harmonization scheme of Pharmaceuticals regulations of the ASEAN member countries, to complement and facilitate the objective of AFTA, particularly, the elimination of Technical Barriers to Trade posed by the regulations, *without compromising on drug quality, efficacy, and safety*”
The ASEAN – PPWG (2)

- **Establishment**: 1999

- **Aim & Target**:
  
  → for *Generic, Modified, and NCEs & Bio. products*
  
  → after achieved ‘ASEAN Harmonized Product’
  
  ↓

  ‘Trial Implementation’

  ↓

  **Full Implementation** *by 31 Dec. 2008!*
The PPWG – Lead country & Assignment (1)

**Chair country :** Malaysia

**Co-Chair country :** Thailand

- **ACTR :** Quality → Indonesia  
  Safety → Philippines  
  Efficacy → Thailand

- **ACTR-Guidelines :** Analytical Validation → Thailand  
  BA/BE Studies → Malaysia  
  Process Validation → Singapore  
  Stability Study → Indonesia
The PPWG – Lead country & Assignment (2)

- **ACTD**: Overall ACTD & ACTD Organization → Thailand
  Administrative & Glossary → Malaysia
  Quality → Indonesia
  Non-Clinical → Philippines
  Clinical → Thailand

- **IWG**: Singapore (Chair)
  Indonesia (Co-Chair)

- **MRA-GMP**: Singapore / Malaysia (Co-Chairs)

- **MRA-BA/BE**: Malaysia/Indonesia (Co-Chairs)

- **Vaccine Chapter**: Thailand / Indonesia

- **Training**: Philippines

- **Variation Guideline**: Malaysia
The PPWG Agreement

- Harmonized Key Areas
- Format for ACTR & ACTD
- Content of ACTR/ACTD/Glossary of Term
- ASEAN Harmonized Products
  (ACTR + ACTD + Glossary of Term + Technical Guidelines)
- Implementation – Trial period (July 04 onwards)
- Full Implementation by 31 Dec. 08
PPWG – Agreement on Technical Guidelines

“Guideline – Quality”
- based on International Tech.gls.
- drafted 4 ASEAN Quality gls.
  (1) Analytical Validation guideline
  (2) BA/BE Studies guideline
  (3) Process Validation guideline
  (4) Stability Study guideline

“Guideline – pre-Clinical/Safety”
- adopted 15 ICH-Safety guidelines

“Guideline – Clinical/Efficacy”
- adopted 11 ICH-Efficacy guidelines
ACTD

The part of marketing authorization application dossier that is common to all ASEAN member countries
ICH-CTD is accepted for NCE & Biotech. product
- with ACTD-part I
- compliance to ASEAN – Quality guidelines
Adoption of the same relevant ICH-E Guidelines

<table>
<thead>
<tr>
<th>E1</th>
<th>The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions</th>
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<tbody>
<tr>
<td>E2A</td>
<td>Clinical Safety Data Management: Definitions and Standards for Expedited Reporting</td>
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<tr>
<td>E2C</td>
<td>Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drug</td>
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<td>E3</td>
<td>Structure and Content of Clinical Study Reports</td>
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<td>E4</td>
<td>Dose-Response Information to Support Drug Registration</td>
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<td>E6</td>
<td>Good Clinical Practice: Consolidated Guideline</td>
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<td>E7</td>
<td>Studies in Support of Special Populations: Geriatrics</td>
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<td>E8</td>
<td>General Considerations for Clinical Trials</td>
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<td>E9</td>
<td>Statistical Principles for Clinical Trials</td>
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<td>E10</td>
<td>Choice of Control Group and Related Issues in Clinical Trials</td>
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<td>E11</td>
<td>Clinical Investigation of Medicinal Products in the Pediatric Population</td>
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</tbody>
</table>
Adoption of the same relevant ICH-S Guidelines

S1A → Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals
S1B → Testing for Carcinogenicity of Pharmaceuticals
S1C → Dose Selection for Carcinogenicity Studies of Pharmaceuticals
S1C(R) → Addendum to SIC: Addition of a Limit Dose and Related Notes
S2A → Guidance on Specific Aspects of Regulatory Tests for Pharmaceuticals
S2B → Genotoxicity: A Standard Battery for Genotoxicity Testing for Pharmaceuticals
S3A → Note for Guidance on Toxicokinetics: the Assessment of Systemic Exposure in Toxicity Studies
S3B → Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies
S4 → Single Dose Toxicity Tests
S4A → Duration of Chronic Toxicity Testing in Animals (Rodent and Non-Rodent Toxicity Testing)
S5A → Detection of Toxicity to Reproduction for Medicinal Products
S5B(M) → Maintenance of the ICH Guideline on Toxicity to Male Fertility: An Addendum to the Guideline on Detection of Toxicity to Reproduction for Medicinal Products
S6 → Safety Studies for Biotechnological Products
S7A → Safety Pharmacology Studies for Human Pharmaceuticals
M3 → Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals
# Joining the Same Training

**“APEC-LSIF Training Project” in Thailand**

<table>
<thead>
<tr>
<th>Title</th>
<th>Capacity Building for Drug Regulatory Agencies on Clinical Trial and Good Clinical Practice</th>
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<tr>
<td><strong>Major Plan</strong></td>
<td><strong>Review of Drug Development in Clinical Trial</strong></td>
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<td><strong>Preliminary WS</strong></td>
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<td>(17-21 Mar.08)</td>
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<tr>
<td>Trainer</td>
<td>- Dr. Celia LOURENCO (HC) - Dr. Junko SATO (PMDA) - Ms. Susan D’AMICO (PhRMA*) - Dr. Namrata BAHADUR (PhRMA*) - Dr. Odett MORIN (ICH)</td>
</tr>
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<td>(Note: - HC = Health Canada - PhRMA* = Novartis)</td>
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<td>Trainee</td>
<td>= 20 regulators (APEC: Chile, Id, My, Sg, Th, Vn RHi=GCC, ASEAN)</td>
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Yuppadee_AHC Inaugural WS-Korea-15-18 Jun.09
The Trainers & Trainees
Preliminary WS- Review of DD in CT
The Trainers, Trainees, and ThaiFDA
Basic WS- GCP/Clinical Research Inspection
Joined the Same Training
“the Achievement & the Future”

• **Same Learning & Understanding** → “similar/same” implementation
  - Lectures → gave “Great Information”
  - Case Studies, Exercise & Mock Exercises → provided “Know-how”
  - Ref.Link/Info. → support “further Understanding”
  - Regulator-Trainer → provided “details + interpretation + applicable approaches”
  - Industry R&D-Trainer → provided in depth knowledge on Drug Dev.

• **Supporting** Networking & Cooperation, further

• **Encouraging** a closer regional cooperation on CTs
  - Training & Working together is an essential Key to SUCCESS!
  - Together, ICH & non-ICH could collaborate on CTs
    → sharing “MRCTs Approval & Inspection”
Thank you !!!