Regional Update – ASEAN PPWG

by

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The ICH-Global Cooperation Group Meeting
Yokohama Royal Park Hotel, Yokohama, JAPAN
09 June 2009
Outcome

The 16th PPWG Meeting (28-29 May 2009, Manila, the Philippines) “related to the ICH”
Outcome (1)

• **participants** ~ 350 from 9 countries (*Regulators + Industries*)
• **official opening** by Honourable Professor Leticia-Barbara Gutierrez
  (Director of the Bureau of Food and Drugs, DOH, Ph.)
• **back to back activities**:
  - Workshop on ACTD Implementation
  - the 6th Meeting of ASEAN Taskforce on MRA-BA/BE Studies
  - Technical Discussion on:
    - Q&A on ACTD-Quality
    - Q&A on BA/BE Technical Guideline
  - the 7th Meeting of the ASEAN Taskforce MRA - GMP Inspection
  - Dialogue “IWG & P’cal Industry”
  - the 11th IWG Meeting
  - Head of Delegations (HOD) Meeting
Outcome (2)

Progress on the Implementation Issues of ASEAN Harmonized Product

“ASEAN MRA for Pharmaceuticals”

(1) ASEAN MRA-BA/BE Studies
   → agreed on Inspection Criteria for further development of the SOP
   → agreed on standard for developing Inspection Checklist
   → developing a Work Plan
   → will present the 1st Draft of BA/BE MRA in 17th PPWG Meeting

(2) ASEAN MRA-GMP Inspection
   → completion of the National Consultation of Members
   → Signed by the Leaders(AEM), on Apr.10, 09 (Pattaya, Thailand)
   → developing “post-signing implementation action plan”
Outcome (3)

Progress on the Implementation Issues of ASEAN Harmonized Product

“The Implementation Working Group-IWG”

(1) Mechanism for the revision of ASEAN Tech. gls.
   → adopted and endorsed

(2) ASEAN Variation Guidelines
   → aim to support the implementation of the ACTD
   → endorsed the formation of its Technical Working Group (TWG)
   → exploring Training and Workshops for further development of the Gls.
Outcome (4)

Other Progresses of the PPWG

- Cooperation with International Org. & Dialogue Partners
  - WHO-Vaccine Chapter
    - Capacity Building on Vaccine Regulatory Framework
      - Training on Clinical Trial Authorisation (CTA) (27-31 Jul. 09)
      - Training on GCP Inspection (09-13 Nov. 09)
      - Training on Clinical Data Evaluation (CDE) (07-11 Dec. 09)
      - Workshop for Regulatory Pathway for Dengue Vaccines (1-2 Oct. 09)
        by DCVRN & PDVI
  - ASEAN-EU
    - Capacity Building on Pharmaceuticals
    - under APRIS II programme
  - ASEAN-US Cooperation on Pharmaceuticals
    - Request by US-ASEAN Business Council
**Outcome (5)**

**Other Progresses of the PPWG**

- **Technical Assistance and Capacity Building for the P’cal Sector**
  - ASEAN-EU Programme for Regional Integration Support II (APRIS II)
    - Workshop (WS) on ACTD Implementation (25 May 09)
    - WS on Common Understanding for the ACTR requirements on Stability, Process Validation, and Analytical Validation (by Nov.09)
    - WSs(2) on BA/BE (GCP, GLP, Evaluation of the BA&BE Reports) (by Nov.09)
    - Training for GCP & GLP Inspection (By Nov.09)
    - Training on PIC/S GMP requirement, Inspection Skills, Peer Inspection (By Nov.09)
  
- ASEAN-US Enhanced Partnership
  - in the Pharmaceutical product sector in the ACTD
  - under development

  ➔ Request for *National Training* of ASEAN Member States (CLV)
**Outcome (6)**

**Other Progresses of the PPWG**

- **Establishment of the Joint Sectoral Committee (JSC)**
  - to monitor the implementation of the Sectoral MRA
  - Is in the process of developing the Term of Reference (ToR)

- **Extension the ToR of the PPWG**
  - extension of the tenure of PPWG
  - will seek endorsement for the extension by ACCSQ
Outcome (7)

ASEAN-PPWG and ICH-GCG (1)

- GCG Update to the 16th PPWG ➔ by PPWG’s Co-Chair
- presented Topics :

  ➔ GCG Meetings on Nov.11, 2008 (Venue/RHIs participation)
  ➔ GCG Update
    • Regulator Forum
    • RHI pre-meeting
    • Comment on Step 2 Guidelines
    • Webinars on Step 2 Guidelines
    • Stability Guideline development
    • RHI Survey update ➔ Review of RHI’s Profile
    • Others Important topics
      - Training – related procedural matters
      - ICH update report
      - next ICH-GCG Meeting & Co-chairmanship
## Training Requests of ASEAN

1) proposed and endorsed in ICH/ICH-GCG – Nov.08 Meeting

2) approval criteria of the ICH/ICH-GCG :

3) On Feb.19, 09 → updated from ICH Secretariat
   - lead ICH Party for the Training
   - EU for Q5C & QbD(Q8, Q9, Q10)
   - MedDRA Management Board for MedDRA for Clinical Trails
   - the Standard Procedures involving the Training Events

4) On Feb.20, 09 → conveyed of update to Malaysian Delegate

5) Seeking “Plan & Progress & Focal Point”, for ICH
### The ICH Webinar

1) **Webinar Agenda** (in general)

2) **Goal of Webinar** (to facilitate/collection Comments on Step 2 GLs)

3) **Technical Notes**
   - sitting at Computer with Internet Access
   - 1 connection per RHI/DRA
   - several People could join to view the presentation

4) **proposed dates for the Webinar**
   - propose and agree on the Date
   - normally on Working day, at 01:00 pm Geneva Time

5) **Participation** (by invitation, need preparation for joining)
Recommendation to the 16th PPWG (1)

→ to note the GCG Update, presented by PPWG Co-Chair

→ to note, among all:
  - RHI pre-meeting report
  - Regulatory Forum Report
  - the Webinar system
  - the Stability Guidelines Developments
  - posted RHIs’ profile on ICH Website, and update procedure
Recommendation to the 16th PPWG (2)

- to note the endorsement of the GCG on 3 requested Training project of ASEAN
- request Malaysia to take appropriate action, such as:
  - coordinate & manage for Date & Venue of each Events
  - contact Lead ICH Party/ ICH Secretariat) for the Events
  - provide Plan/Progress update
Recommendation to the 16th PPWG (2)

→ to note the Webinar activity of ICH-GCG:
  - could facilitate Step 2 Guidelines understanding & comments
  - decide on Lead Country for participating the Webinar
    - on Quality guideline by Indonesia
    - on Pre-clinical/Safety guideline by the Philippines
    - on Clinical/Efficacy guideline by Thailand
    - on BA/BE guideline by Malaysia
    - on GMP guideline by Singapore
Outcome (8)

ASEAN-PPWG and ICH-GCG (2)

PPWG:

→ noted:
- outcome of the ICH-GCG meeting, as briefed
- the endorsed 3 requested Training projects of ASEAN
- the Webinar of ICH on Step 2 Guidelines
- recommendations by the PPWG Co-chair

→ agreed that:
- **Malaysia** to take further action on **coordination and arrangement** of the 3 endorsed Training projects
- relevant **Lead Countries to participate** in the Webinar accordingly
**Outcome (9)**

**ASEAN-PPWG and ICH-GCG (2)**

**PPWG:**

- agreed on the 17th PPWG Meeting:
  - on *March 2010*
  - in Thailand

- requested on the 18th PPWG Meeting:
  - on *2nd Half of 2010*
  - by Indonesia
Plan/Progress after the 16th PPWG Meeting

### the endorsed 3 Training Projects of ASEAN

1) ASEAN Focal Point of the 3 Projects:
   - Mr. Selvaraja S. SEERANGAM (selva@bpfk.gov.my)

2) Tentative Schedule:
   - MedDRA on Clinical Trial → 4th week of Nov. 2009
   - Q5C → 3rd week of Jan. 2010
   - Q8, 9, 10 → last week of Feb. 2010

3) Participants and the Cost:
   - Host Country will fully support the Events
   - will invite 2 Delegate/country *(self support on Hotel & Flight)*
   - Industry will also be included *(need to pay the full fare)*

4) Venue → Malaysia

5) Request “Contact point (Name & Email Address)” of ICH Party
Recommendation to the GCG

→ noted the progress of the ASEAN- 16th PPWG Meeting
→ on the endorsed 3 Training projects of ASEAN
  - To note the Focal Point & Plan of the Events
  - To provide Contact point info. (Name & Email Address)

→ on the Webinar of Step 2 Guidelines
  - to consider relevant Lead Countries of ASEAN-PPWG, as participants
    - on Quality guideline → by Indonesia
    - on Pre-clinical/Safety guideline → by the Philippines
    - on Clinical/Efficacy guideline → by Thailand
    - on BA/BE guideline → by Malaysia
    - on GMP guideline → by Singapore
Thank You

Yuppadee – 09Jun.09, Yokohama, JAPAN