



Regional Update – ASEAN PPWG

by

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The ICH-Global Cooperation Group Meeting
Yokohama Royal Park Hotel, Yokohama, JAPAN
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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*



Presentation to PPWG

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



Presentation to PPWG

The ICH Webinar

- 1) **Webinar Agenda** (in general)
- 2) **Goal of Webinar** (to facilitate/collect 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)

Presentation to the PPWG

ASEAN-PPWG



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

Presentation to the PPWG

ASEAN-PPWG



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*



Presentation to the PPWG

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 participan
 - on Quality guideline → by *Indonesia*
 - on Pre-clinical/Safety guideline → by *the Philippines*
 - on Clinical/Efficacy guideline → by *Thailand*
 - on RA/BE guideline → by *Malaysia*
 - on GMP guideline → by *Singapore*



Thank You

