



# ASEAN PPWG

## Regional Update on ICH-related Matters

by

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The ICH-Global Cooperation Group Meeting  
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## Topics

- **International Activity**
- **ASEAN Activities**
- **the 17<sup>th</sup> ACCSQ/PPWG Meeting**

ASEAN-PPWG



**Since**

**the ICH-GCG Meeting, Yokohama, Japan  
(Jun.09)**

Yuppadee – 27Oct.09, St.Louis, USA



## International Activity

“WS on Ethical and Regulatory Issues in Global Pediatric Trials”

• <b>Date (Venue)</b>	20-22 Sep. 09 (MD, USA)
• <b>Organizer</b>	US FDA & NICHD
• <b>Participant</b>	- Regulators, Ethical Committee, Investigator, Acad. - global, including <u>ASEAN</u> (Sg, Th)
• <b>Financial Support</b>	Up to a fixed-amt. of budget (for invitee)



## ASEAN Activities :- Work in Thailand

### “Regulatory Pathways for clinical trials of Dengue Vaccines”

• <b>Date (Venue)</b>	<b>01-02 Oct. 09 (BKK, Thailand)</b>
• <b>Organizer</b>	- <b>PDVI &amp; WHO (via WHO-PPWG Vaccine Chapter)</b> - <b>ThaiFDA (Local Organizer)</b>
• <b>Participant</b>	- <b>Regulators + National Ethical Committee</b> - <b>ASEAN + Asian country</b>
• <b>Financial Support</b>	<b>full support (for Participants &amp; Events)</b>



## ASEAN Activities :- Training in the Philippines

• <b>Date (Venue)</b>	<b>26-30 Oct. 09 (Manila)</b>
• <b>Host</b>	<b>Ph-FDA</b>
• <b>Participant</b>	- Regulators & Industries (+ fee) - Self-support
• <b>Topic (Trainer)</b>	- <b>Organization of Dossier (by Ph)</b> - <b>Administrative Data (by Ph)</b> - <b>Quality (by Ph)</b> - <b>Stability (by Id)</b> - <b>Process Validation (by Sg)</b> - <b>Analytical Validation (by Th)</b> - <b>BA/BE (by My)</b>
• <b>Type of Training</b>	<b>Regional Training on ACTD (<i>Training the Trainers</i>)</b>



## ASEAN Activities :- APRIS II

**APRIS II → ASEAN-EU prog.for Regional Integration Support –Technical Assistance**

**Type of Training → Regional WS (with partial funding)**

**Funding → by EU (Trainers, Organization costs, and 1 participant/7 countries)**

	ACTR	BA/BE	PIC/S –GMP Requirement
• Date	03-04 Dec. 09	07-08 Dec. 09	10-11 Dec.09
• Host	LaoPDR	Malaysia	Singapore
• Participant	←	- Regulator (2 /country)	→



## ASEAN Activities :- ASEAN & ICH-GCG

Host → *National P'cal Control Bureau (NPCB)-Malaysia*

Venue → *Kuala Lumpur, Malaysia*

Trainers → *ICH-GCG*

	MedDRA	Q5C	Q8-10
• Date	- 23-25Nov.09, - end of Jan.10, <u>or</u> early Feb.10 (?)	3 <sup>rd</sup> wk.of Jan.10(?)	08-12 Mar. 2010 (?)
• ICH Coordinator	- Dr.Odette Morin	Dr.Spiros Vamvakas	Dr.Spiros Vamvakas
• Participant	<div style="background-color: yellow; padding: 5px; display: inline-block;">- Regulator &amp; Industries(+fee) / - Self-support</div> 		
• Type of Training	Regional Training	Regional Training	Regional Training
• Status	on-going	on-going	on-going



## The QbD Workshop

• ICH Coordinator	“Dr.Spiros Vamvakas” (Jacques MORENAS, Dr.Jean-Louis ROBERT)
• Host Coordinator	<b>Mr.Muhammad Lukmani Ibrahim</b> “lukmani@ppfk.gov.my” (Senior Principle Assistant Director, Center for Compliance and Licensing, NPCB)
• Host’s Request	- structured Programme? - # days for WS ? - # Speakers ? - max.# of Participants ? - # rooms for break-up sessions ? - any available Fund for WS?
• Status	Waiting for Mr.Morenas’s reply



## The Q5C Workshop

• ICH Coordinator	“Dr.Spiros Vamvakas” (Dr.Nick GATE, Dr.Jekerle VERONIKA)
• Host Coordinator	Ms.Arpah ABAS “arpah_abas@yahoo.com” (NPCB)
• Host’s Request	-seeking Programme, Speaker, and etc. <i>(structured Programme?, # days for WS ?, # Speakers ?, max.# of Participants ?, # rooms for break-up sessions ? any available Fund for WS?)</i>
• Status	<b>Need to communicate, further, with Dr.Gate !</b>



## The MedDRA Workshop

• ICH Coordinator	“Dr.Odette MORIN”
• Host Coordinator	<b>Dr.Kamaruzaman SALEH(NPCB)</b> “kazman@bpfk.gov.my”
• Host’s Request	-seeking Programme, Speaker, and etc. <i>(structured Programme?, # days for WS ?, # Speakers ?, max.# of Participants ?, # rooms for break-up sessions ? any available Fund for WS?)</i>
• Status	setting “WS’s Date”



# The 17<sup>th</sup> ACCSQ/PPWG Meeting

## Draft-the Programme (on 27 Oct.2009)

Date	Morning (09.00-12.30h)	Lunch	Afternoon (14.00-17.00h)
Mon.-29 Mar.10	Back-to-Back Seminar (- on Clinical Trials) (- on Quality) (-.....)		Back-to-Back Seminar (continue.....)
Tue.-30 Mar.10	1)Q& A on ACTR/ACTD Quality & Gls. 2)Q& A on ACTR/ACTD Efficacy & Gls. 3).....		1)MRA-GMP 2)BA/BE Taskforce 3).....
Wed.-31 Mar.10	1)IWG 2)MRA-GMP/-BABe .....		-Opening of the 17th PPWG meeting -The 17 <sup>th</sup> PPWG Meeting
Thu.-01 Apr.10	The 17th PPWG Meeting		The 17th PPWG Meeting
Fri.-02 Apr.10	Visiting to BE Center/ Manufacturing		Adoption of the 17 <sup>th</sup> ACCSQ/PPWG Report

**Date: 29 Mar.-02 Apr.10 or .....**

**Venue : BKK, Thailand**



*Thank You*

