

*Final*

**GLOBAL COOPERATION GROUP MEETING REPORT  
TUESDAY JUNE 3, 2008**

*Portland, Oregon, USA  
(Portland Marriott Downtown Waterfront Hotel)*

**Ref: GCG 86F**

**PARTICIPANTS:**

Dr. Peter Arlett ( <i>Co-Chair</i> )	EU
Mr. Kohei Wada ( <i>Co-Chair</i> )	JPMA
Dr. Murray Lumpkin	FDA
Dr. Justina Molzon	FDA
Dr. Alice Till	PhRMA
Dr. Peter Honig	PhRMA
Dr. Tomas Salmonson	EU
Dr. James Ritchie	EFPIA
Dr. Yves Juillet	EFPIA
Dr. Toshiyoshi Tominaga	MHLW
Mr. Mike Ward	Health Canada
Dr. Lembit Rago	WHO
Dr. Petra Doerr	EFTA
Dr. Odette Morin	IFPMA (also ICH Secretariat)
Dr. Pavitranon Sumol	APEC
Dr. Yuppadee Javroongrit	ASEAN
Prof. Dr. Saleh Bawazir	GCC
Ms. Esnat Mwape	SADC
Dr. Leonie Hunt	Drug Regulatory Authority (DRA) of Australia
Dr. Chi-Chou Liao	Drug Regulatory Authority (DRA) of Chinese Taipei
Dr. Christina Lim	Drug Regulatory Authority (DRA) of Singapore
Dr. Dong Sup Kim	Drug Regulatory Authority (DRA) of South Korea

**Also present:**

Ms. Joan Wilmarth Blair	FDA
Dr. Michelle Limoli	FDA
Ms. Tammie Bell	FDA
Dr. Michael Garvin	PhRMA
Dr. Spiros Vamvakas	EMEA
Dr. Matus Ferech	EU
Mr. Takayuki Okubo	MHLW
Dr. Kurajiro Kishi	JPMA
Mr. Nick Orphanos	Health Canada
Dr. Sabine Kopp	WHO
Dr. Dawn Ronan	IFPMA (also ICH Secretariat)

### **1. Welcoming remarks and adoption of the agenda**

The Co-Chairs, Dr. Arlett (EU) and Mr. Wada (JPMA) welcomed all participants to the meeting of the ICH Global Cooperation Group (GCG). A special welcome was extended to the representatives of the Drug Regulatory Authorities (DRAs) of Australia, Chinese Taipei, Singapore and South Korea who were participating in the GCG for the first time.<sup>1</sup>

The agenda was adopted without modification.

### **2. Review of current membership**

The GCG welcomed for the first time representatives from the DRAs of Australia, Chinese Taipei, Singapore and South Korea. Dr. Leonie Hunt was introduced as the representative for Australia, Dr. Chi-Chou Liao for Chinese Taipei, Dr. Christina Lim for Singapore, and Dr. Dong Sup Kim for South Korea. Apologies were noted from the DRAs of Brazil, China, India and Russia who were unable to participate in the meeting.

The GCG also welcomed for the first time Dr. Pavitranon Sumol as a representative of the APEC Secretariat. Ms. Esnat Mwape from Zambia was welcomed as the second representative from SADC. Unfortunately, the first representative Mr. Joseph Mthetwa was unable to join the meeting. Apologies were also received from Dr. José Luis Di Fabio of PANDRH.

### **3. Report from the First Regulators Forum**

Dr. Lumpkin (FDA) reported on the outcome of the first ICH Regulators Forum held on June 2, 2008 in Portland. The forum brought together regulators from EU, Japan, USA, Canada, Australia, Chinese Taipei, Singapore and South Korea and regulators representing ASEAN, GCC, and SADC.

The main objective of the forum is to consider how best to work together to improve global public health while focussing on the ICH process and how to work together to ensure that ICH guidelines are implemented as broadly and consistently as possible. The forum will be used to share operational and implementation issues and to arrive at joint solutions.

A number of challenges were identified at the Portland forum. One of these challenges related to the translation of the ICH guidelines which should reflect accurately the technical content of the original guidelines following translation. Consistent interpretation of ICH guidelines in different parts of the world, keeping up to date on ICH guidelines and the organization of training at various levels in the most effective way, were all identified as important challenges.

The ICH website was identified as the main vehicle for communication on ICH Guidelines and the importance of keeping it updated and focused was emphasized.

The next Regulators Forum will take place at the time of the next ICH meeting in Brussels, Belgium in November 2008.

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<sup>1</sup> It was noted that the representative for South Korea, Dr. Dong Sup Kim, had participated previously in the GCG as a representative of APEC.

#### **4. Final approval of the report of the GCG teleconference held April 23, 2008 (Ref: GCG82)**

*Action/Decision:*

- The GCG approved as final the report of the GCG teleconference held on April 23, 2008, pending the incorporation on comments from Prof. Bawazir (GCC) and Dr. Yuppadee (ASEAN).

#### **5. RHI pre-meeting report**

Prof. Bawazir (GCC) reported on the RHI pre-meeting. The RHIs discussed how to maximize the benefits of training workshops conducted by RHIs, for example, by allowing other regions to attend and by exchanging expertise. The creation of Centres of Excellence for training was also suggested. Thailand was identified as an example of a Centre of Excellence in Clinical Trials.

To facilitate RHIs to comment on ICH guidelines undergoing regulatory consultation (ICH *Step 3*), the RHIs decided to propose to their respective organizations the development of a list of regulatory contacts and experts in each country to receive and comment on ICH *Step 2* documents. They also agreed to propose to include an update on ICH guidelines on the agendas of regional regulatory meetings. The RHIs also suggested that in order to improve understanding of the ICH guidelines, each region could organise mini symposiums dedicated to ICH guideline implementation, with a focus on guidelines of high impact, and with possible participation from ICH representatives. The RHIs also expressed their support for the Regulators Forum initiative.

#### **6. RHI and DRA update on ICH-related matters**

Each of the RHIs gave formal presentations to the GCG on their respective initiatives and current activities. The presentations will be posted on the ICH website.

*GCC* Prof Bawazir reported on the organization by the GCC of the first GCC Food & Drug Conference which was held in Kuwait on March 31 – April 2, 2008. Conference themes included national drug policy, pharmacovigilance, counterfeit medicines and group purchasing of pharmaceuticals. A workshop on the Pricing of Pharmaceutical Products was also held on May 20 – 21, 2008 in Riyadh, Saudi Arabia. The GCG noted the organization of the eighth DIA Middle East Regulatory Conference in January 2009 in Bahrain.

*APEC* Dr. Sumol provided background information on the APEC Life Sciences Innovation Forum (LSIF). The fifth annual meeting of the LSIF, held in April 2007, led to the development of a multidisciplinary study on investment in health innovations. Among the current projects of the APEC LSIF are those relating to anti-counterfeiting, ICH Quality guidelines, drug development in clinical trials, certificate on pharmaceutical product, and harmonisation of medical device regulations. Dr. Sumol invited GCG members to attend the sixth annual LSIF meeting to be held in August 2008. It was noted that a two-day session on regulatory harmonisation, chaired by Mr. Ward (Health Canada) would be organized.

*SADC* Ms. Mwape presented on the foundation of SADC in 1980 and its Medicines Regulatory framework which includes a common set of guidelines to ensure quality medicines. The next step will be implementation of the guidelines at national level, use of a SADC shared network tool to facilitate communication among members, and training and capacity-building in the region with assessment of regional capacities to identify centres of excellence for training.

**ASEAN** Dr. Yuppadee provided an update on the activities of the ASEAN PPWG (Pharmaceutical Product Working Group), whose fourteenth meeting was held in February 2008. Progress was achieved on the ASEAN MRA (Mutual Recognition Arrangement) on BA/BE which is to be finalized at next PPWG meeting, and on ASEAN MRA on GMP inspection.

The Implementation Working Group (IWG) revised their ToR (Terms of Reference), agreeing that the meeting of the IWG should be open to regulatory and industry representatives. The PPWG urged all their members to actively participate in the implementation of the Post Marketing Alert System (PMAS). Members also expressed the need for training and the Philippines was asked to take the lead and work on a training module.

The GCG noted the recent appointment of Dr. Surin Pitsuwan of Thailand as the new ASEAN Secretary-General for the term of 2008-2012.

**PANDRH** Dr. Molzon (FDA) presented on behalf of Dr. Di Fabio, from the PANDRH Secretariat. Based on a presentation made by Dr. Di Fabio at the DIA Latin American Regulatory Conference (LARC) held on May 19 – 21, 2008, she provided an update on several PANDRH Working Groups.

The GCG noted that the Pharmacovigilance Working Group had conducted a situational analysis in the region, developed a glossary of terms on pharmacovigilance and a document on Good Pharmacovigilance Practices. The group would also organize a workshop for National Regulatory Authorities. An update was also provided on the Vaccines Working Group that has a draft document (currently under consultation) on common requirements for vaccine registration using the ICH CTD format. Activities were also described for the Good Laboratory Practices and the Drug Counterfeiting Working Groups. *Information on all documents being developed and working group membership can be found at: [www.paho.org/english](http://www.paho.org/english).*

## **7. Comments on Step 2 Guidelines**

The GCG noted that no comments had been received from the RHIs on the *Step 2* guidelines (Q4B Annex 2 *Test for Extractable Volume of Parenteral Preparations General Chapter*; Q4B Annex 3 *Test for Particulate Contamination: Sub-Visible Particles General Chapter*; Annex to Q8: *Pharmaceutical Development*; and S2(R1) *Guideline on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use*)

The GCG agreed that the posting of information complementary to *Step 2* guidelines on the ICH website and/or the use of webinars could facilitate a better understanding of the ICH draft guidelines and assist RHIs to comment on *Step 2* guidelines. The Secretariat confirmed that the collection of slide presentations from ICH Expert and Implementation Working Groups on *Step 2*, as well as *Step 4* guidelines was ongoing.

It was also noted that the RHIs would be considering the establishment of list of experts to strengthen the communication/consultation process in their respective regions.

## **8. Stability Guideline developments**

Dr. Kopp (WHO) reported that a meeting was being planned in September 2008 in EMRO regional offices to follow-up on the recommendation of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. The GCG noted that comments received were being classified and that a second draft revision of the WHO Stability Guideline should be discussed at the meeting.

## **9. RHI Survey update: Review of RHI Profiles**

Dr. Ronan (ICH Secretariat) informed the GCG that the RHI profiles for the GCC and PANDRH were complete, the ASEAN profile was almost complete and that the SADC still required some work. Dr. Yuppadee (ASEAN) confirmed that she would be providing some comments on the draft ASEAN profile and that she would be requesting the PPWG at their next meeting to confirm agreement with the final version for publication on the ICH public website.

The GCG noted that the aim was to make the profiles available on the ICH public website during the summer of 2008 with links embedded in the profile to the RHI guidelines. The information contained within the profiles would be reviewed on a yearly basis and the date of the last review will be added to the front page.

## **10. GCG procedural matters**

### ***Revised Procedure on Training Activities***

Dr. Ronan (ICH Secretariat) reported on the Revised Procedure on Training Activities (Ref: GCG 55R dated May 15, 2008) which describes how training activities will be selected and prioritized, and how the ICH GCG-endorsed training events will be organized. Concepts include the development by RHIs/DRAs of a two-year training plan; the submission by RHIs/DRAs of individual training requests using a standard template; the prioritization of training by the GCG; the roles and responsibilities of the RHIs/DRAs, the ICH Secretariat/ICH Coordinators and the ICH lead party(ies) in the organization of training events; and the evaluation of the training.

The GCG was supportive of the procedure, but agreed to the clarification of some points. The GCG agreed that although the procedure was intended to apply to requests from RHIs and DRAs invited to participate in the GCG by the ICH SC, the procedure did not preclude the consideration by the GCG of requests for training from other DRAs. With regards to the issue of branding, the GCG agreed that ICH experts participating in ICH GCG-endorsed training events should be encouraged to use the ICH presentation template, and that materials developed for the trainings should display the ICH logo alongside that of the RHI/DRA or other co-sponsoring organisation.

With regards to the evaluation of training, Dr. Rågo (WHO) suggested the development of a generic assessment tool to gather important feedback that could help for the delivery of further training. Dr. Rågo offered to provide examples of assessment tools that could serve as the basis.

### ***Actions/Decisions:***

- The GCG approved the Procedure on Training Activities as amended for consideration for endorsement by the ICH SC<sup>♦</sup>;
- If endorsed by the ICH SC, the document will be integrated into the GCG Principles and Procedures document;
- The GCG supported the development of a generic assessment tool to gather feedback from ICH GCG-endorsed training events.

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<sup>♦</sup> Post-meeting note: At their meeting on June 4, 2008, the ICH Steering Committee endorsed the Procedure on Training Activities.

## ***Revised GCG Principles and Procedures***

Dr. Ronan reported on the “Revised GCG Principles and Procedures” document which was revised based on the ICH SC discussions in October 2007 related to the expansion of the GCG (Ref: GCG 53R2, dated May 15, 2008). The document was adopted subject to minor amendments.

### *Actions/Decisions:*

- The GCG approved the “Revised GCG Principles and Procedures” document subject to minor amendments for consideration for endorsement by the ICH SC\*;
- If endorsed by the ICH SC, the document will be integrated as an annex into the 2008 Revised ICH Procedures document.

## **11. Training and Capacity-building implementation**

### ***APEC LSIF Sponsored Workshops***

Dr. Yuppadee (ASEAN) reported on the two ICH GCG-endorsed APEC LSIF sponsored preliminary workshops for regulators on “Review of Drug Development in Clinical Trials” and “GCP Inspections”, held on March 17-21 and May 27-30, 2008 respectively, in Bangkok, Thailand.

Dr. Yuppadee highlighted the lessons learned from the organization of the events. She commented on the importance of having an adequate number of trainers, as well as the significant administrative and funding support required. She also commented that training materials should be posted on public websites to optimize the outcome.

The GCG noted that the Clinical Trial/GCP project also included the organization of advanced workshops on these topics which would be held in October 2008 and March 2009 respectively, hopefully with the same trainers. With regards to the Clinical Trial advanced workshop, Health Canada and PhRMA confirmed their interest to participate the workshop. PMDA confirmed it would consult internally and confirm at a later stage whether it could participate.

For the GCP Inspections advanced workshop, Health Canada confirmed their interest to participate, while FDA and PhRMA proposed to follow up internally and confirm their interest.

### ***PANDRH Training Request***

Mr. Ward (Health Canada) informed the GCG that MERCOSUR had postponed its internal discussion on its Quality training request to the GCG until the MERCOSUR meeting to be held in September 2008.

### ***APEC Training Request***

Dr. Sumol (APEC) and Mr. Ward informed the GCG that a workshop on Q8, Q9 and Q10 would be organised in China in the first week of December 2008. A formal request would be forwarded to the GCG in the near future for consideration. Dr. Vamvakas (EMEA) confirmed EU interest in providing two trainers.

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\* Post-meeting note: At their meeting on June 4, 2008, the ICH Steering Committee endorsed the Revised GCG Principles and Procedures.

### ***Other Training Events of Interest***

Dr. Molzon (FDA) confirmed that the next CDER Forum for International Drug Regulatory Authorities will be held October 6-10, 2008. It will be followed by the first CBER Forum taking place on October 14-16, 2008. .

### ***Publication of Training Materials/Presentations on the ICH Website***

The GCG noted that all training materials and presentations from ICH GCG-endorsed events would be published on the ICH public website.

The GCG agreed that rather than ask speakers/trainers to assign copyright for the training materials/presentations used in the training event, speakers/trainers could instead be invited to sign a simple form granting ICH and the host RHI permission to publish their training materials/presentations on their respective websites.

### **12. Implementation of ICH guidelines in non-ICH countries**

Dr. Arlett (GCG Co-Chair, EU) reported that the industry associations had surveyed their members to gather some information on difficulties/experiences related to the implementation of ICH guidelines in non-ICH countries. The information was circulated for consideration by the ICH SC who agreed that further clarification of the information was needed.

Dr. Arlett informed the GCG that the ICH SC would continue discussions on how/whether to put an item on this matter on the agenda of the GCG.

### **13. Presentations on ICH Topics**

As a new agenda item, the GCG received presentations on two ICH topics of interest to the RHIs and DRAs.

Dr. Brian Withers, ICH Rapporteur from EFPIA, presented on the development of Q11, a new ICH guideline on Development and Manufacture of Drug Substances. He reported on the strategic discussion that led to the development of a Concept Paper and Business Plan (*available on the ICH website [www.ich.org](http://www.ich.org)*) describing the issues to be resolved and the expected benefits. The GCG noted that the timeframe would be to develop a *Step 2* document by the end of 2009 and finalize the guideline by the end of 2010.

Mr. Morell David, ICH MedDRA Management Member for the UK MHRA (Medicines and Healthcare products Regulatory Agency) presented to the GCG on the role of MedDRA in reporting adverse drug reactions and events. Mr. David highlighted the limited information available on risks at the time of authorization of a medicinal product and highlighted the need for post-marketing surveillance to collect information in real life situations, in a larger population, and in less-controlled environments.

Mr. David reported on the difficulties encountered for electronic communication due to the diversity of terminologies being used, and the ICH agreement to develop an international standard medical terminology. This terminology, MedDRA (Medical Dictionary for Regulatory Activities), launched in late 1999 is intended for use during clinical trials, registration, post-authorization and pharmacovigilance.

Mr. David informed the GCG of the regulatory status of MedDRA in US, EU, Japan and Health Canada. He also informed the GCG of the recent launch of MedDRA implemented in the WHO Global database together with WHO-ART, allowing the submission to WHO of reports coded in

either MedDRA or WHO-ART. Mr. David added that training was currently being planned for the WHO National Pharmacovigilance Centres.

The GCG noted that MedDRA is free for all regulators worldwide with further information being available from the MSSO (Maintenance and Support Services Organisation for MedDRA) and the ICH Secretariat.

#### **14. Communication about GCG**

##### ***GCG Public Website***

Dr. Ronan (ICH Secretariat) updated the GCG on improvements being made to the GCG website to improve user-friendliness. The GCG noted the creation of a new section on the ICH public website on GCG Training Activities, which includes an introductory page and links to the training materials from ICH GCG-endorsed training events.

The GCG was also updated on the creation of a new web page listing all ICH *Step 2* documents going through regulatory consultation in the ICH regions. The page would provide information on how to comment on the documents and include a mailbox to facilitate the collection of comments from non-ICH countries.

##### ***Development of a Standard Presentation on ICH and GCG***

Dr. Ronan presented a standard set of slides developed by the ICH Secretariat on the ICH and GCG. The GCG noted that the intention was that the slides could be presented at the start of ICH-GCG-endorsed events in order to increase awareness of ICH and the GCG.

##### ***Action/Decision:***

- The GCG approved the standard set of slides for use in ICH training events.

##### ***GCG Presentations at Public Meetings***

The GCG noted the organisation of a session on GCG activities that would take place at the DIA annual meeting in Boston, USA, on June 23, 2008.