

GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY OCTOBER 30, 2007

Final

Yokohama, Japan

(Yokohama Royal Park Hotel)

PARTICIPANTS:

Mr. Kohei Wada (<i>Co-Chair</i>)	JPMA
Mr. Mike Ward (<i>Co-Chair</i>)	Health Canada
Dr. Toshiyoshi Tominaga	MHLW
Dr. Justina Molzon	FDA
Dr. Alice Till	PhRMA
Dr. Peter Arlett	EU
Dr. Tomas Salmonson	EU
Dr. James Ritchie	EFPIA
Dr. Yves Juillet	EFPIA
Dr. Lembit Rägo	WHO
Dr. Petra Doerr	EFTA
Dr. Odette Morin	IFPMA (also ICH Secretariat)
Dr. Jianhua Ding	APEC
Dr. Dong Sup Kim	APEC
Dr. Yuppadee Javroongrit	ASEAN
Prof. Dr. Saleh Bawazir	GCC
Dr. James Fitzgerald	PANDRH (replacing Dr. José Luis Di Fabio)*
Mr. Johannes Gaeseb	SADC

Also present:

Dr. Kurajiro Kishi	JPMA
Ms. Joan Wilmarth Blair	FDA
Dr. Michelle Limoli	FDA
Dr. Michael Garvin	PhRMA
Dr. Spiros Vamvakas	EMEA
Dr. Sabine Kopp	WHO
Dr. Dawn Ronan	IFPMA (also ICH Secretariat)

* It should be noted that Dr. Fitzgerald was delayed and could not attend the GCG meeting.

1. Welcoming remarks and adoption of the agenda

The Co-chairs welcomed all participants to the meeting of the Global Cooperation Group (GCG) and noted that Dr. Fitzgerald, who would be replacing Dr. José Luis Di Fabio as the PANDRH representative for the present meeting, had not yet arrived but was in transit.

The draft agenda was adopted as proposed.

2. Review of current membership

Dr. Ding (APEC) reviewed the representation model that APEC has adopted for the GCG, in which the official representation rotates each meeting cycle, with the official representative accompanied by the upcoming representative to assure continuity. As such, Dr. Ding was the current official representative, but Dr. Dong Sup Kim of the Korean FDA was also attending the meeting in his capacity as the next APEC representative.

Dr. Javroongrit introduced herself as the observer for ASEAN, and Prof. Bawazir himself as the representative for GCC.

In alignment with the SADC representation model, in which the SADC Secretariat holds the position of the permanent representative to the GCG and a second representative rotates between SADC countries, Mr. Gaeseb from Namibia introduced himself as the second representative. It was noted that Mr. Mthetwa, the permanent SADC representative was unable to travel to Yokohama.

Mr. Wada announced that Dr. Arlett (EU) would replace Mr. Ward (Health Canada) as the regulatory co-chair at the end of the GCG meeting in Yokohama. Warm appreciation was extended by GCG members to Mr. Ward for his many efforts on behalf of the GCG.

3. Final approval of the revised report of the GCG meeting held in Brussels on 8 May 2007 (Ref: GCG 65R)

The draft revised report of the GCG meeting held in Brussels on 8 May 2007 was put forward for adoption. The report was adopted pending the incorporation of two comments from ASEAN.

4. RHI pre-meeting report

In keeping with the pre-established order of rotation for presenting this report, the APEC representative, Dr. Ding, reported to the GCG the outcomes of the discussion at the pre-meeting of the Regional Harmonisation Initiatives (RHIs). Topics that were discussed were: Potential RHI regional interactions; brainstorming on ways for the RHIs to be more active and supportive to the GCG; brainstorming on ways to both facilitate circulation of *Step 2* ICH guidelines intra-regionally and to receive comments to those guidelines; brainstorming on how the GCG could be more useful to the RHIs; and future plans. Some of the highlights of these points included discussion of the need for a mechanism to identify speakers from ICH for training efforts, the need for training materials, and the need for tools to enhance the efficiency of training. The RHIs also discussed that they would like to see a GCG session at the 2008 WHO International Conference of Drug Regulatory Authorities (ICDRA), and would establish two-year training plans covering 2008-2009 to facilitate requests to ICH for experts and other support.

5. RHI update on ICH-related matters

Each of the RHIs made presentations to the GCG which recalled the background of their respective initiatives, informed the GCG of current activities within their initiatives and highlighted ICH relevant efforts. Of particular interest as a case study for the organisation of training events was the APEC Life Sciences Innovation Forum (LSIF) Workshop on ICH Quality Guidelines that Dr. Ding reported on in his presentation on APEC activities. Mr. Ward noted that he would be reporting in more detail on this item later in the agenda (see Agenda item 11 for merged details).

6. Comments on Step 2 Guidelines

Dr. Ronan (ICH Secretariat) reported that the ICH *Step 2* guideline Q10 was sent to RHIs for comment on 8 June 2007, with a deadline for sending in comments of the end of November 2007. The RHIs were invited to update the GCG on the status of their internal consultation process.

The RHIs did not yet have any comments to provide on Q10 and discussed in greater detail the difficulties they have in stimulating regional comments. Some observations included the fact that the priority is to implement currently adopted ICH guidelines rather than comment on draft documents; and that face-to-face discussions are needed in order to understand the documents as they are difficult to understand simply in their written form.

7. Stability Guideline Developments

Dr. Kopp (WHO) reported on WHO efforts with respect to forging a resolution to the discrepancies in stability testing conditions for climatic zones III and IV that have been at issue in relation to the ICH Q1F guideline, now withdrawn. At the 2006 WHO ICDRA meeting, recommendations on this point were made and WHO was asked to generate a draft paper reflecting the recommendations. WHO did so then widely circulated the paper and held intense regional consultations with relevant experts. WHO held an informal consultation in June 2007 to discuss the comments received up to that point, which were quite extensive. During the October 2007 meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, a recommendation for a revision to the WHO stability guideline was submitted that would add another zone to the two existing, so there would be Zones 4a, 4b and 4c. The Committee experts found this to be very challenging and found that it would have implications for labelling. Based on this, the Committee concluded not to recommend this revision. The WHO secretariat then continued its efforts seeking comments from some member states that had not yet submitted their views. The consultation process is still deemed to be on-going. WHO is planning on holding a consultation pending available funding with a goal of generating another recommendation for the Expert Committee's consideration at its 2008 meeting.

8. RHI Survey Update

Mr. Ward (Health Canada) reported on the RHI profile effort. The GCG was provided with a profile of the GCC to serve as a sample construct and to elicit feedback. He noted that the ICH Secretariat has received many inquiries regarding the GCG so it would be helpful to have profiles done and posted on the ICH public website in light of this interest. Discussion followed on whether the level of detail was on target and relevant, on how to describe the situation when a region has adopted an ICH guideline with changes made, on concerns

regarding maintenance of the documents and the associated resource implications. It was agreed that once completed by all the RHIs, the profiles would be posted on the ICH public website. A goal of the next GCG meeting was set for the completion of all the RHI profiles.

9. Implementation of ICH Guidelines in non-ICH regions

Dr. Juillet (EFPIA) presented a proposal to establish a standing agenda item for the GCG meeting on implementation issues associated with ICH guidelines in non-ICH regions. The construct that such an agenda item would take was discussed in depth, with various views expressed. It was agreed that following discussion with the ICH Steering Committee (SC), the GCG Co-Chairs would decide whether the topic would be added to the GCG agenda, and if so, what construct this agenda item would take.

10. Update on discussions on the Future of the GCG

Mr. Ward (Health Canada) reported on the status of on-going discussions within the ICH SC regarding the future of the GCG regarding potential changes. He advised the RHIs that the discussions were not yet complete but that he could share some of the SC's current thinking on the issue. Specifically, he noted that the SC had affirmed the importance of maintaining the face-to-face GCG meeting in conjunction with the biannual ICH meetings and had affirmed the contribution of the official representatives of the RHIs as "enablers of harmonization" and the particular advantages of the participation of a RHI secretariat in this regard.

The SC sees a need for change to the GCG principles and procedures in order to fully realize the GCG objectives and thereby contribute to a number of important goals related to improving public health. The SC identified those goals to be: to reduce country and regional differences in technical requirements that impact on the availability and cost of new medicines; to promote international movement of pharmaceuticals that are safe, effective and of high quality; and to promote the conduct of clinical trials and data collection that meet international standards.

Mr. Ward informed the RHIs that the SC had endorsed proposals to create an "Expanded GCG" as ICH has recognized the need for certain changes to current GCG principles and procedures to mirror the global face of drug development. The SC has therefore decided to invite a number of individual Drug Regulatory Authorities to participate in the GCG, even if in some cases they are not part of an existing RHI. Such participation would be distinct and complementary to the participation of an official RHI representative/observer. It was noted that the expansion of GCG would be based on considerations such as source of APIs, medicinal products and clinical data for ICH regions and use or intended use of ICH guidelines.

11. Training and Capacity-building implementation

APEC LSIF sponsored workshops and training courses

- *APEC LSIF Workshop on ICH Quality Guidelines Q8, Q9 and Q10*

(The following is a merged summary of Dr. Ding's report from Agenda item 5 and Mr. Ward's report for this agenda item.) The APEC LSIF workshop that was held September 13-14, 2007 in Seoul, Korea on ICH Quality Guidelines Q8, Q9 and Q10. The workshop was attended by a capacity crowd - approximately 200 participants. The workshop confirmed the value of such events in promoting a better understanding of the ICH Quality guidelines and

the opportunities and challenges associated with their implementation. The caliber of presentations by expert speakers was high, demonstrating an excellent knowledge of the topic areas. The availability of ICH experts made it possible to have insight provided as to the intent of the guidelines, going beyond a “Table of Contents” recitation. There was representation from across the ICH regions, the session was very interactive and transparent, and the audience was fully engaged. Although substantial effort was required to construct the workshop, the program with its presentations could be reused *en toto* for other events, thus leveraging the effort.

The GCG extensively discussed the value and lessons learned of this workshop and considered potential variations to this model for future training options. Among the lessons learned was that the training was resource intensive both financially and organisationally. The workshop represented the first test of the GCG procedures for handling training requests and as such had growing pains associated with it, signalling a need for a refinement of the procedures.

- *APEC LSIF Workshops on Review of Drug Development in Clinical Trials and GCP Inspections*

Dr. Javroongrit (ASEAN) reported on the progress made with the organization of the APEC LSIF workshops on “Review of Drug Development in Clinical Trials” and “GCP Inspections”. The workshops would be hosted by the Thai FDA on behalf of APEC. In all, four workshops would be organised, with workshops for both topics to be conducted in two stages with a basic workshop to be followed by an advanced workshop.

A draft agenda for the workshops on “Review of Drug Development in Clinical Trials” was circulated to the GCG. Potential dates were discussed for holding the training. It was noted that the 5th IFPMA Asian Regulatory Conference was being held the second week of March 2008 (11-13 March) in Kuala Lumpur so perhaps the third week in March in Bangkok would be a workable option for the basic workshop. The advanced workshop would be scheduled for late 2008. With Health Canada as the lead ICH Party, PhRMA and PMDA also agreed to engage in the effort.

FDA would be the ICH lead for the organisation of the workshop on “GCP Inspections”. June 2008 and December 2008 were identified as potential dates for the basic and advanced workshops respectively.

During the GCG discussion, Dr. Javroongrit was asked if the workshops could be opened to other RHIs, which she agreed to pursue. In addition, Dr. Javroongrit did note that in response to the ICH Secretariat’s request to add the APEC LSIF workshops to the GCG training clearinghouse she would confer a final time with the APEC-LSIF Planning Group to have it included.

PANDRH training request

A PANDRH request for training on ICH quality topics that Dr. José Luis Di Fabio had put forward at the GCG teleconference on 1 October 2007 was discussed. It was noted that the need for the training was discussed at the PANDRH Steering Committee as it was recognized that the region was struggling with applying the risk based approach to GMP inspections. Funding was made available for training which would take place in São Paulo, Brazil. The GCG considered that perhaps a good first step would be to repeat the Seoul workshop on the quality topics.

In follow-on discussion, Dr. Ding (APEC) echoed the desirability of potentially repeating the Seoul workshop in China, as well as the need for training in China such as envisioned by the forthcoming APEC LSIF workshops to be held in Thailand. He noted that more and more multi-center clinical trials were moving to China and that certain regulators had already used data in submissions from clinical trials in China. In developing a two-year training plan, he offered that the APEC region should be considered as a priority region for this training topic.

12. Procedural matters

Dr. Ronan (ICH Secretariat) updated the GCG on outstanding procedural matters, including the draft procedure on training activities. The GCG discussed the resource implications of training requests and the means by which it should best respond to the requests.

It was pointed out in the discussion that it was clear from the earlier discussions on the Seoul workshop and the Thai APEC-LSIF workshops that there is a need for sharing the organizational burden of these efforts as these exercises had relied heavily upon the efforts of the GCG co-chair, Mr. Ward (Health Canada). Among the points made in the discussion were: commonalities between training events should be reviewed in order to gain efficiencies, e.g., through the reuse of meeting materials previously prepared; logistics should be the responsibility of the hosting authority; an evaluation step should be considered being added to the process. The question arose as to whether the topic of clinical trial evaluations/assessments was within the subject matter scope for training requests; the GCG affirmed that it was indeed in scope. Among issues that were highlighted for consideration by the GCG were: Should the GCG serve as the gateway to ICH “branded” training? What should the role of the GCG be regarding any training program details? Concern was also expressed that the ICH Secretariat not become burdened with these responsibilities.

The ICH Secretariat agreed to revise the draft procedure on training activities to reflect the discussions of the GCG. The revised procedure document would then be circulated to the GCG for comment.

13. GCG Website

Access to GCG working area

The GCG agreed that access be opened to the GCG working area to RHI member states upon request. The ICH Secretariat was tasked with assuring that the level of details of GCG members and other participants on the website and working area is appropriate.

Increase user friendliness

The GCG discussed improvements that could be made to the GCG public website to increase user friendliness. Among the issues considered were the establishment of a GCG mailbox to receive public comments on *Step 2* documents; the updating of the now outdated GCG informational brochures currently on the website; and the addition of region-specific sections under which the RHI profiles could be captured. The Secretariat was tasked with considering improvements to be proposed to the GCG.

14. ICH update report

The ICH Secretariat circulated a document with ICH topic updates for the RHIs. A request was made to circulate the update ahead of time rather than present it at the time of the GCG meeting. This was agreed.

Mr. Wada informed the GCG about the ICH Tokyo Symposium that would be taking place in Tokyo on 2 November 2007. The symposium represents the first regional conference in contrast to the previous biennial global ICH conferences. He noted that Dr. Ding (APEC), Dr. Kim (APEC) and Dr. Javroongrit (ASEAN) would be presenting on problems their countries faced with implementation of ICH guidelines.

15. Any Other Business

The Secretariat reported that the Drug Controller General (DGC) of India had been invited to this GCG meeting but was not able to attend, on this occasion.