

ICH GLOBAL COOPERATION GROUP

Terms of Reference

November 2003

Background

The ICH Global Cooperation Group (GCG) was established in March 1999 as a subcommittee of the ICH Steering Committee, with its membership comprising one representative from each of the six parties on the ICH Steering Committee, plus the ICH Secretariat at IFPMA. Two Observers (WHO, Canada) are also part of the GCG. Its purpose was to make information available on ICH, ICH activities, and ICH guidelines to any country or company that requested the information. The GCG undertook these activities through the development of a series of informational brochures on ICH, and through GCG members speaking about ICH activities at public meetings.

In September 2001 the GCG members agreed to further develop the GCG activities in collaboration with other harmonisation initiatives. As a first step in this direction, the GCG established the following criteria that organisations the GCG partners or collaborates with should fulfil:

Criteria for Harmonisation Initiatives to be Invited to Work with the GCG

1. International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH).
2. The initiative should be founded on the principle of harmonising drug regulation across a defined group of countries.
3. The initiative should be science-based, with clear scientific harmonisation objectives.
4. The initiative should be currently active with meetings/activities regularly scheduled.

GCG members further agreed that as a first activity the GCG would work in collaboration with identified harmonisation initiatives to develop a symposium to take place at the ICH 6 conference on 'Partnerships in Harmonisation'. As part of these preparations, the GCG held joint meetings with the identified partner harmonisation initiatives in February and July 2003. The invited initiatives were the APEC Joint Research Project on Bridging Studies, the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), the Gulf Cooperation Countries (GCC), the Pan American Network on Drug Regulatory Harmonization (PANDRH) and the South African Development Community (SADC).

Based on the success of these expanded activities, the GCG has developed the following Terms of Reference to provide structure and definition to activities it undertakes in the future building on this initial outreach program.

Terms of Reference for the ICH GCG

1. The ICH GCG will act as the primary representative of ICH Steering Committee outside the ICH regions, and equally as such as a conduit for non-ICH parties to the ICH Steering Committee.
2. The ICH GCG will invite other non-ICH harmonisation initiatives (rather than individual countries) to be 'Permanent Representatives' to the ICH GCG.
3. The ICH GCG will invite nomination of 'Permanent Representatives' to the ICH GCG from those harmonisation initiatives that undertake activities meeting criteria established by the ICH GCG and ICH Steering Committee as follows:
 - a. The initiative should be founded on the principle of harmonising drug regulation across a defined group of countries.
 - b. The initiative should be science-based, with clear scientific harmonisation objectives.
 - c. The initiative should be currently active with meetings/activities regularly scheduled.
 - d. The initiative will have available, or establish, a mechanism to disseminate information on its activities with the ICH GCG to its members.
4. ICH GCG meetings in future will be opened to the 'Permanent Representatives' of non-ICH partner initiatives unless, on occasion procedural discussions are required. Furthermore, to ensure complete transparency of its activities the ICH GCG will:
 - a. Publish summaries of its meetings and other associated documents on public ICH website.
 - b. Establish a 'mailbox' on the ICH website to receive questions for the GCG.
5. The ICH GCG will use its meetings to identify, with the partner initiatives, topics and process issues associated with harmonisation for discussion, collaboration, and potential development into a joint program of activities. The ICH GCG will meet regularly (2-3 times per year), and at the time of ICH Steering Committee and Expert Working Group Meeting.
6. On a case by case basis the ICH GCG will invite other initiatives not meeting the criteria in point 3 above to present to the GCG on a specific topic of interest and relevance to the ICH GCG.
7. The ICH Steering Committee will be consulted for approval on all proposed ICH GCG activities before they are undertaken.