

Current and Future Role of ICH GCG

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Objectives

- Examine the evolution of the Global Cooperation Group (GCG), including the changing role of the GCG
- Reflect on value and future directions of the GCG

ICH's Response:

Global Cooperation Group:

- Established March 1999 as sub-committee of ICH Steering Committee
- Same membership as ICH
- Name reflective of desire to establish links with non-ICH regions
- **Role:** *Promote a better understanding of ICH and ICH guidelines*
- How: **information-sharing**

NB – not a technical body

The Early Years...

- Characterized by good intentions, however...soon became clear that a more proactive approach was necessary in order to effectively respond to growing interest in ICH

Important guiding principles nonetheless established:

- ICH will not impose its views on any country or region – rather, role to facilitate understanding and use of ICH
- The GCG will work with the WHO and other international organizations to achieve its goals
- Recognition that non-ICH countries may not be in a position to (fully) utilize ICH (all) guidelines

ICH 6, Osaka, Nov. 2003: An Important Milestone

Marked beginning of ‘second phase’ in the GCG’s evolution with endorsement of new mandate and terms of reference that called for

- the **participation** of regional harmonisation initiatives (RHIs)
- greater **transparency**

Expanded Membership

- To include representatives from other harmonization initiatives
- Criteria established for such participation

Philosophy

- ICH should actively engage with other harmonisation initiatives that show an interest in ICH guidelines and standards as an effective means of understanding needs, leveraging resources and achieving overall GCG goals

GCG Goals Linked to Improving Public Health

- Reduce differences in technical requirements that negatively impact availability and cost of new medicines
- Promote international movement of pharmaceuticals that are safe, effective and of high quality
- Promote the conduct of clinical trials that meet international standards

Regional Harmonization Initiatives (RHIs) now part of GCG



APEC (LSIF)

Asia-Pacific Economic Cooperation



ASEAN (PPWG – Observer)

Association of the Southeast Asian Nations



GCC

Gulf Cooperation Council



PANDRH

Pan American Network for Drug Regulatory Harmonization



SADC

Southern African Development Community

Mission Statement Embodies Changing Role of GCG

*“To promote a **mutual understanding** of regional harmonisation initiatives in order to facilitate the harmonisation process **related to ICH guidelines** regionally and globally, and to **facilitate the capacity** of drug regulatory authorities and industry to **utilise** them”*

Importance of Openness and Transparency

- As of June 2004, regional partners have been invited to attend technical working group meetings and Steering Committee discussions
- Allows for first hand experience of ‘how ICH works’
- Also allows regional partners to gain understanding of the ‘theme’ and intent of ICH guidelines – key to proper interpretation and future implementation considerations

Training: a Key Focus

Framework and mechanisms established:

- Strategy document lays out principles for effective, strategic use of training resources
- Clearing house of training events created to identify opportunities
- Procedures and templates developed to improve efficiency and effectiveness of process – including 2 year planning cycle
- Public access: training materials to be posted to ICH website
- Forms part of general library of ICH training material under development: *rich source of freely available materials!*

ICH/APEC Q8,Q9,Q10 Workshop: September 2008, Seoul, Korea

- First training request endorsed and coordinated through GCG
- Workshop confirmed value of such events in promoting a better understanding of the ICH guidelines and opportunities/challenges associated with their use
- Over 200 participants from 17 countries
- Model for future training workshops:
 - **Shared responsibility**: APEC, ICH, KHIDI/KFDA
 - **Interactive session**
 - **Representation from across three ICH regions**

Capacity-building - Clinical Trials: Assessment and GCP Inspection

- First of two APEC workshops on clinical trial assessment (March 2008) and GCP inspection (May 2008) held in Bangkok, sponsored by Thai FDA and APEC LSIF
- Unique in that joint regulator agency-industry effort geared specifically to regulators; also open to regulators from other RHIs – a desired approach
- Sessions included mix of lectures and case studies and mock exercises
- Moves GCG-endorsed training beyond understanding of ICH guidelines to their application from a regulatory perspective
- Extensive training materials now available on ICH website
- Advanced workshops currently under development

Other Progress to Date

GCG is also actively working on ways to:

- Improve transparency of activities (redesigned webpage, publication of RHI profiles, etc.)
- Identify options for promoting feedback from non-ICH countries/regions on draft ICH guidelines (mini-symposiums, regional pool/network of experts, etc.), and
- Promote awareness of the GCG and ICH in the regions (branded workshops, etc.)

A Time for Reflection

- While recognizing the considerable progress made by the GCG in promoting a better understanding and use of ICH guidelines beyond the ICH regions, ICH also felt that it was important to reflect on the progress made and possible ways of increasing its effectiveness

Important New Developments

- ICH Steering Committee, at its October 2007 meeting in Yokohama, has endorsed proposals to create an 'Expanded GCG' and establish a 'Regulators Forum'
 - marks start of 'third phase' in evolution of GCG

Expanded GCG

- ICH has recognized need for certain changes to current GCG principles and procedures to mirror 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 not part of an existing RHI

Expanded GCG (2)

- Such participation would be distinct and complementary to participation of official RHI representative/observer
- Expansion of GCG would be based on considerations such as
 - Source of APIs, medicinal products and clinical data for ICH regions;
 - Use or intended use of ICH guidelines

ICH Regulators Forum

- New forum for discussion and sharing of best practices between regulatory authorities on issues related to the implementation of ICH guidelines and impact on regulatory systems
- Discussions would assist in identifying training and capacity needs for action by GCG and therefore serve to complement activities and objectives of GCG
- Principles for participation in forum would mirror those for the expanded GCG

Shared Objectives - Complementary Actions: Facilitate understanding and use of ICH Guidelines

Expanded GCG

Forum for dialogue:
Regulators, RHIs, industry

Translate identified
training needs into action
based on priorities
of non-ICH and ICH regions



Regulators Forum

Forum for discussion
between regulators on issues
related to use of
ICH guidelines and
impact on regulatory systems

June 2008: Inaugural Meeting of Regulators Forum and Expanded GCG

- Attended by regulatory authorities from Australia, Chinese Taipei, Korea and Singapore in addition to regulatory representatives from RHIs
- Discussions confirmed value of Regulators Forum as means to enable broad and consistent implementation of ICH guidelines through information-sharing and building of confidence and trust
- Approaches and challenges identified, including with respect to translation and interpretation
- Participation of additional regulators will be sought for next meeting in Brussels, November 2008

A Natural Progression...

1st Phase 1999-2003

- ICH centric
- Information-sharing
- Mostly reactive



2nd Phase 2003 - 2007

- Regional partnerships
- 2-way Dialogue
- Proactive
- Enabling frameworks, processes, tools



3rd Phase 2007 -

- Expansion
- Refinement
- Strategic focus
- Results-oriented
- Branded

Same overall objective: promote better understanding and use of ICH guidelines and standards

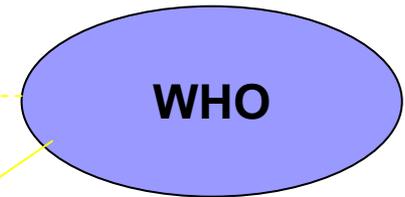
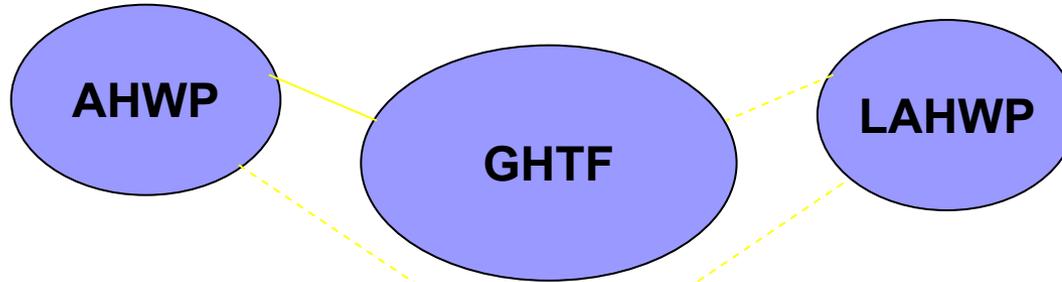
Reflections on Value of GCG

- Unique forum for discussion and directed action on issues related to use of ICH guidelines and harmonisation amongst key players involved in process
- Conduit to ICH experts and process
- Strategic, global role, approach and reach
- Collective effort

Conclusion

- Considerable progress to date in promoting a better knowledge of ICH guidelines and the challenges faced by other regions in their use
- GCG efforts have evolved from information sharing to active dialogue to results-oriented actions
- Important new developments should further accelerate progress
- Spirit of trust and cooperation established between ICH and colleagues from RHIs perhaps most important key to future success

A World of Possibilities



APEC LSIF with:

→APEC Network on
Pharmaceutical
Regulatory Science

→APEC Harmonization
Center



ICH

