Review of Drug Development
in Clinical Trials
Bangkok, 17-21 March 2008

Overview of ICH and the Global Cooperation Group

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International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

Objectives

- To provide a brief overview of ICH
- Explain the role of the Steering Committee
  - Responsibilities
  - Membership
  - Function
- Report on the mandate of the Global Cooperation Group
  - Shift from information-sharing to training
  - Membership (RHIs and Individual DRAs)

I C H

INTERNATIONAL CONFERENCE ON HARMONISATION
of
Technical Requirements
for the Registration of
Pharmaceuticals for Human Use

http://www.ich.org

Hosted by ICH Secretariat
IFPMA-Geneva, Switzerland

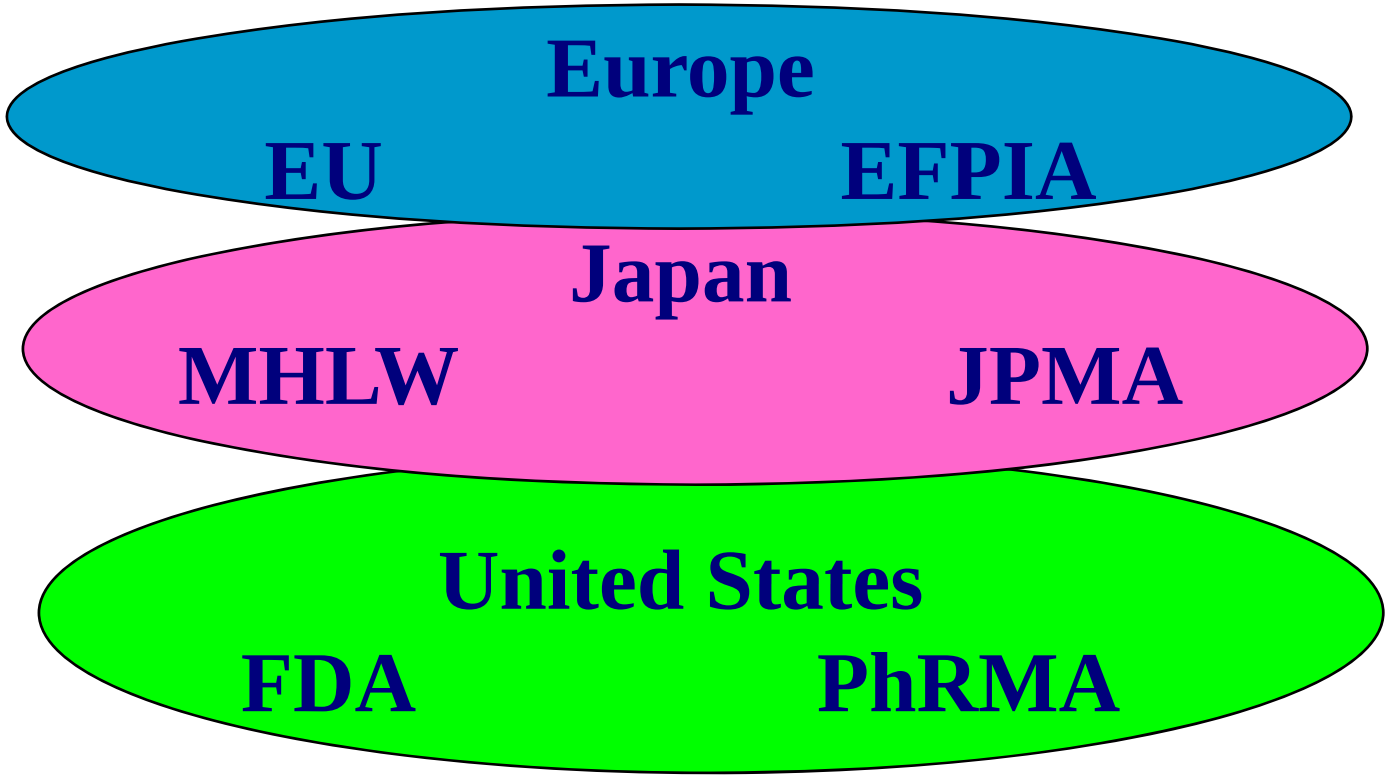
ICH Background

- Unique harmonization project involving the regulators and research-based industries of US, EU and Japan—started in 1990
  - WHO, Canada, and EFTA are observers
- Well-defined objective: to improve efficiency of new drug development and registration process
- Accomplished through the development and implementation of harmonized guidelines and standards

ICH Steering Committee Responsibilities

- The body that governs ICH
- Determines ICH policies and procedures
- Decides on the adoption of ICH projects
  - Selects topics for harmonization
  - Endorses the creation of Expert Working Groups
- Monitors and facilitates the progress of Expert Working Groups
- Signs off ICH documents

ICH Founding Members

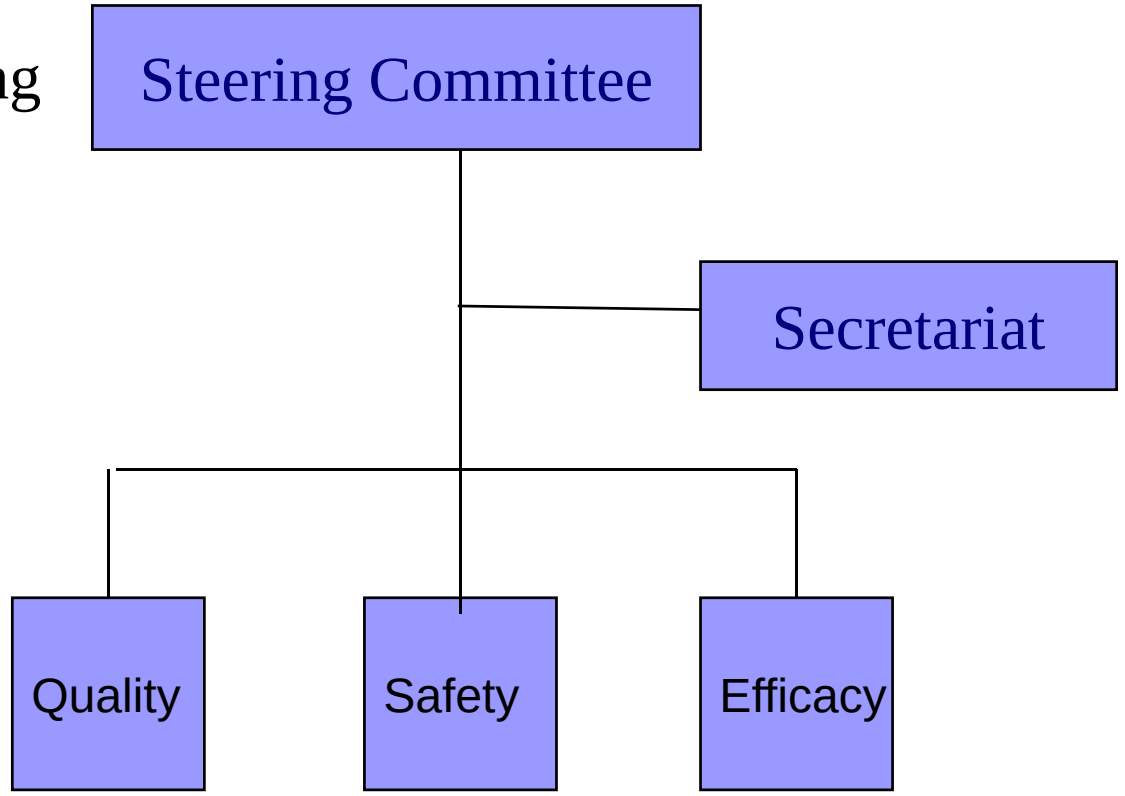


Observers: WHO, Canada, EFTA

ICH

ICH Structure

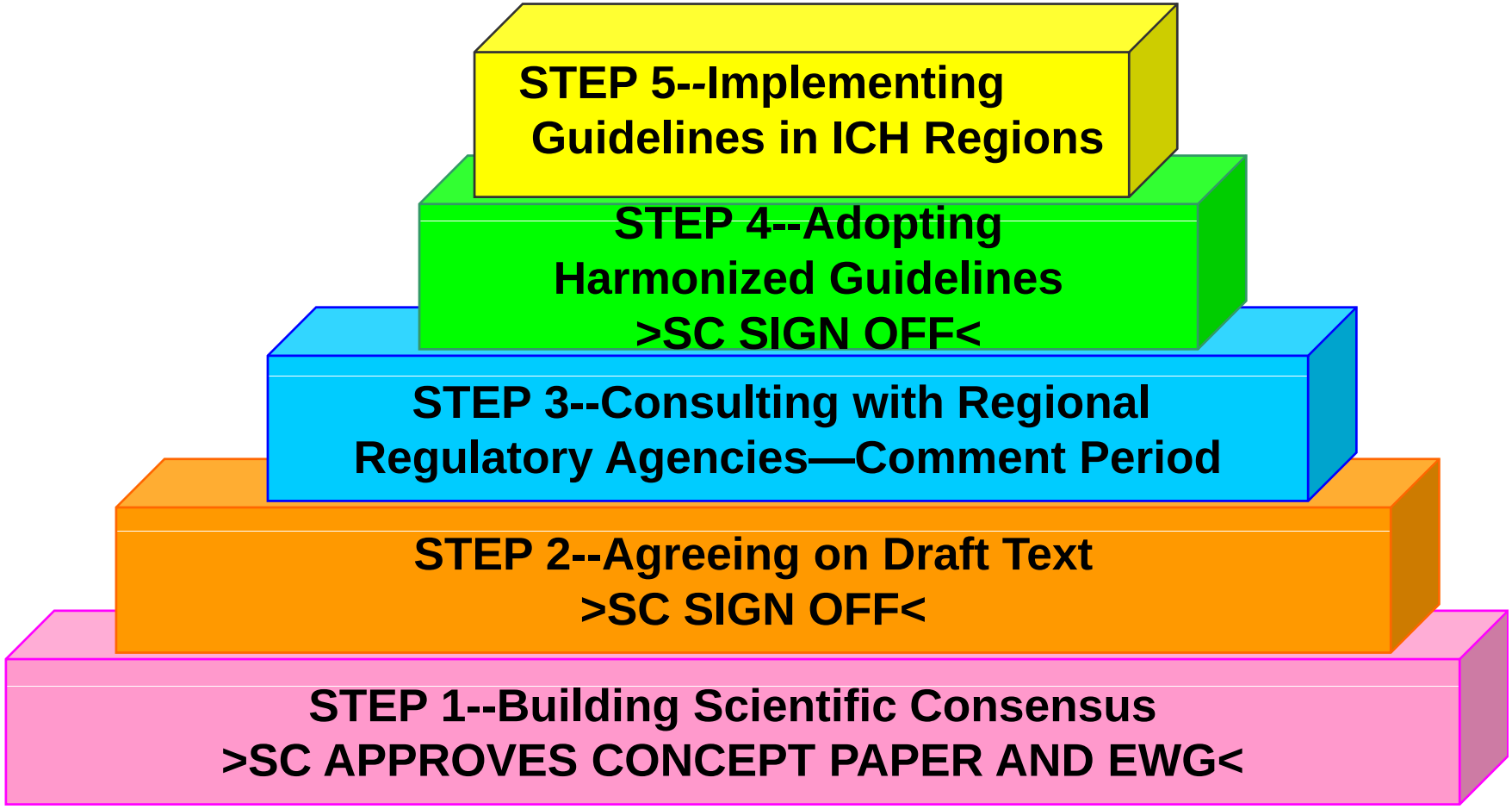
Decision-making body



Working Groups
(development + Implementation)

Steering Committee + Working Groups meet twice a year

Steps of ICH Harmonization



Accomplishments

- 50+ harmonized guidelines on technical requirements (quality, safety, efficacy)
- Medical dictionary (MedDRA)
- Electronic standards (ESTRI, E2B)
- Common format and electronic specification for marketing applications : CTD and eCTD

ICH: Keys to Success

- Effective management and administration
  - Through Secretariat and Steering Committee
- Limited number of members with common focus and objectives
- Comparable regulatory, technical and financial capacity of participants
- Commitment of all parties to implement harmonized guidelines
- Well-defined process

- The ICH GCG - Transparency & Communication

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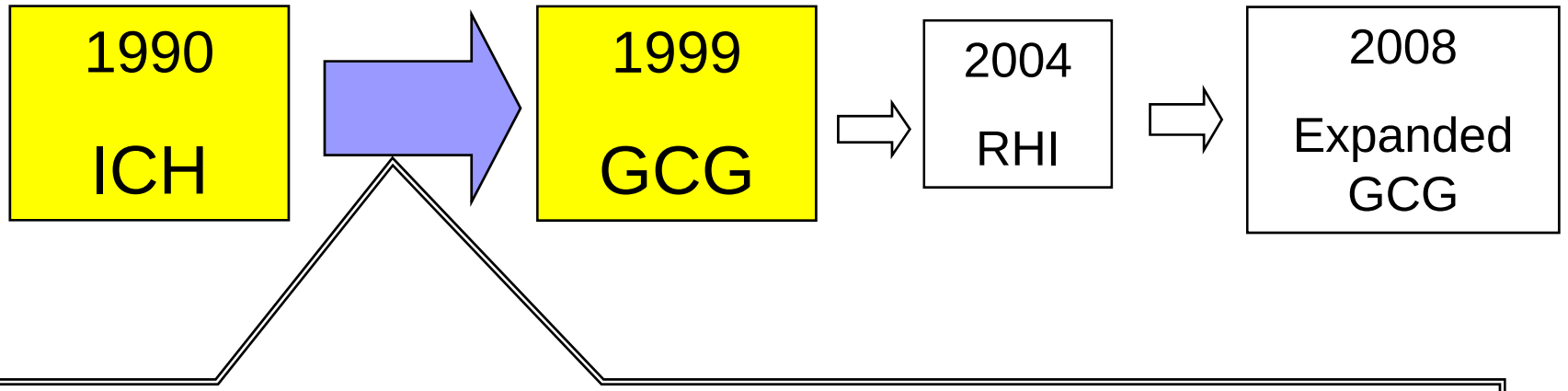
Interest beyond the 3 regions



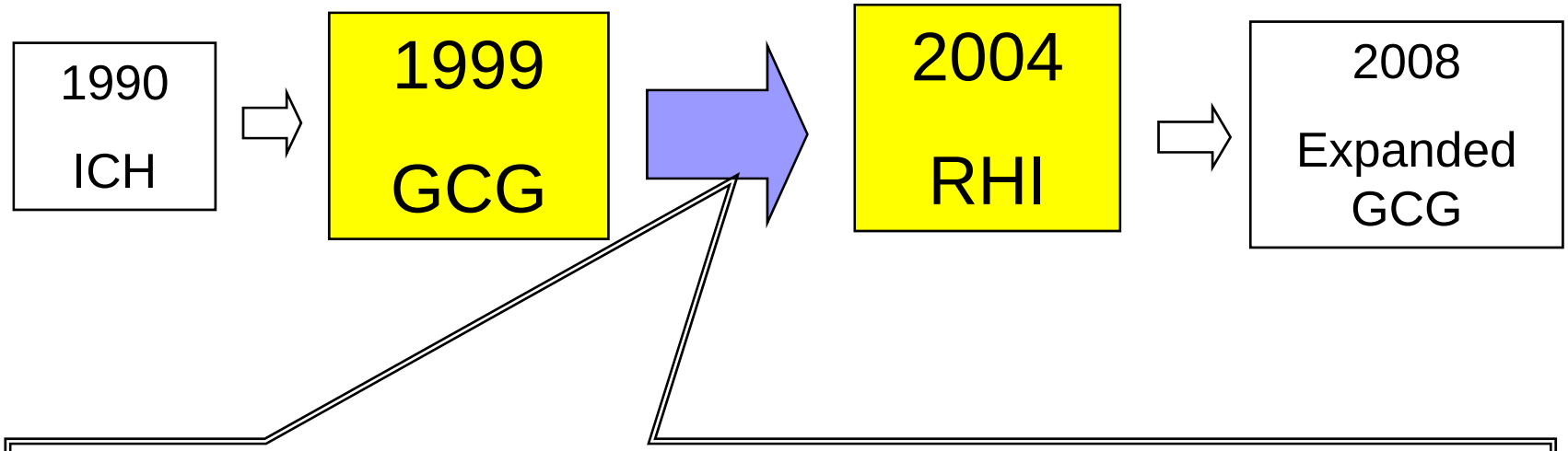
Initially focused on development of guidelines and standards for use in the ICH “regions”

Growing interest in ICH products beyond ICH countries

Global Cooperation Group (GCG)

- Established March 1999 as sub-committee of ICH Steering Committee
- Formed to respond to this growing interest in ICH guidelines
- Name reflective of desire to establish links with non-ICH regions
- Same membership as ICH

……Not enough



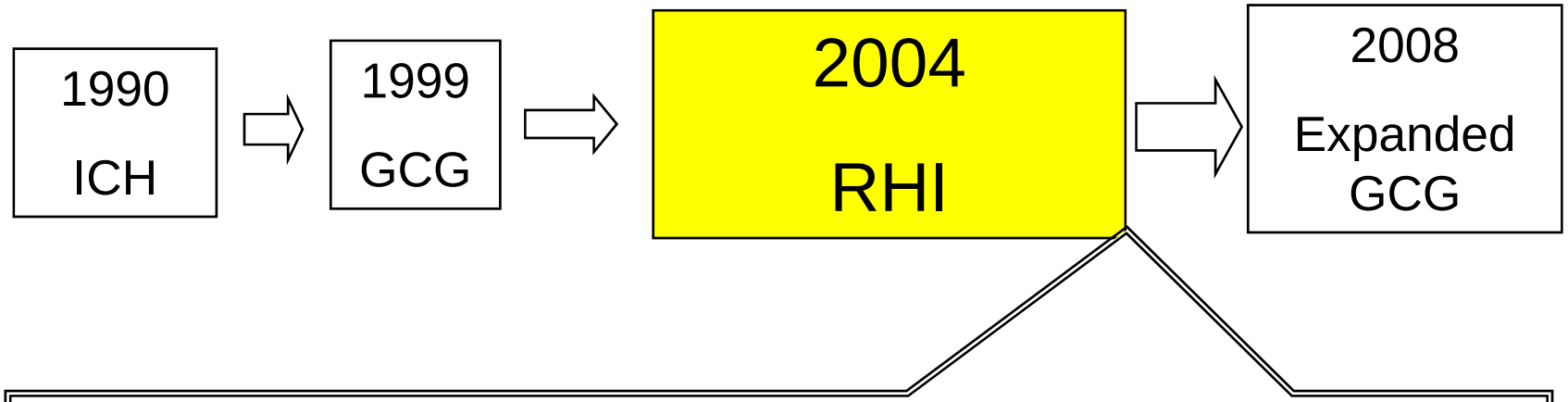
More proactive approach was necessary.

Decided to invite representatives from non-ICH regions to be part of GCG.

Regional Harmonization Initiatives

- **APEC**
  - Asia-Pacific Economic Cooperation
- **ASEAN**
  - Association of the Southeast Asian Nations
- **GCC**
  - Gulf Cooperation Council
- **PANDRH**
  - Pan American Network for Drug Regulatory Harmonization
- **SADC**
  - Southern African Development Community

Adopted new GCG mission statement



May 2005, Brussels:

"To promote a mutual understanding of regional harmonization initiatives in order to facilitate the harmonization process related to ICH guidelines regionally and globally, and to facilitate the capacity of drug regulatory authorities and industry to utilize them"

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 under development to improve efficiency and effectiveness of process – including 2 year planning cycle
- Public access: training materials to be posted to ICH website

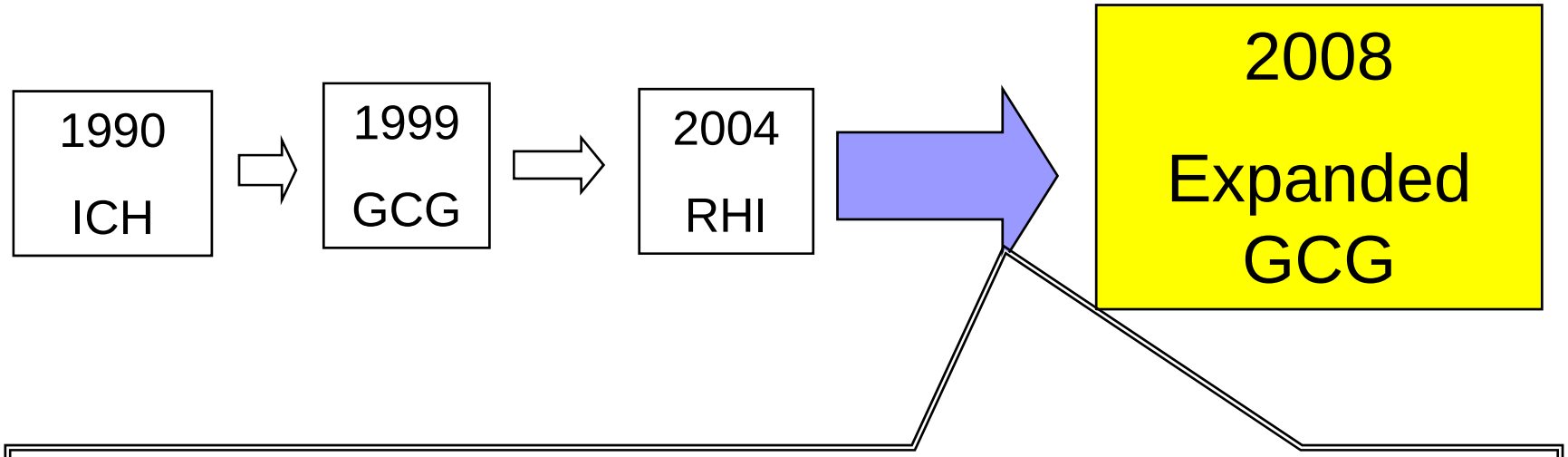
ICH/APEC Q8,Q9,Q10 Workshop: September 13-14, 2008, Seoul, Korea

- 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

Additional Training Activities

- APEC workshops on clinical trial assessment (Bangkok: March, August 2008)
- APEC workshops on GCP inspection (Bangkok: May, November 2008)
- PANDRH (Mercosur region) Quality workshop related to risk-based GMP inspection approach (Sao Paulo: falls 2008)

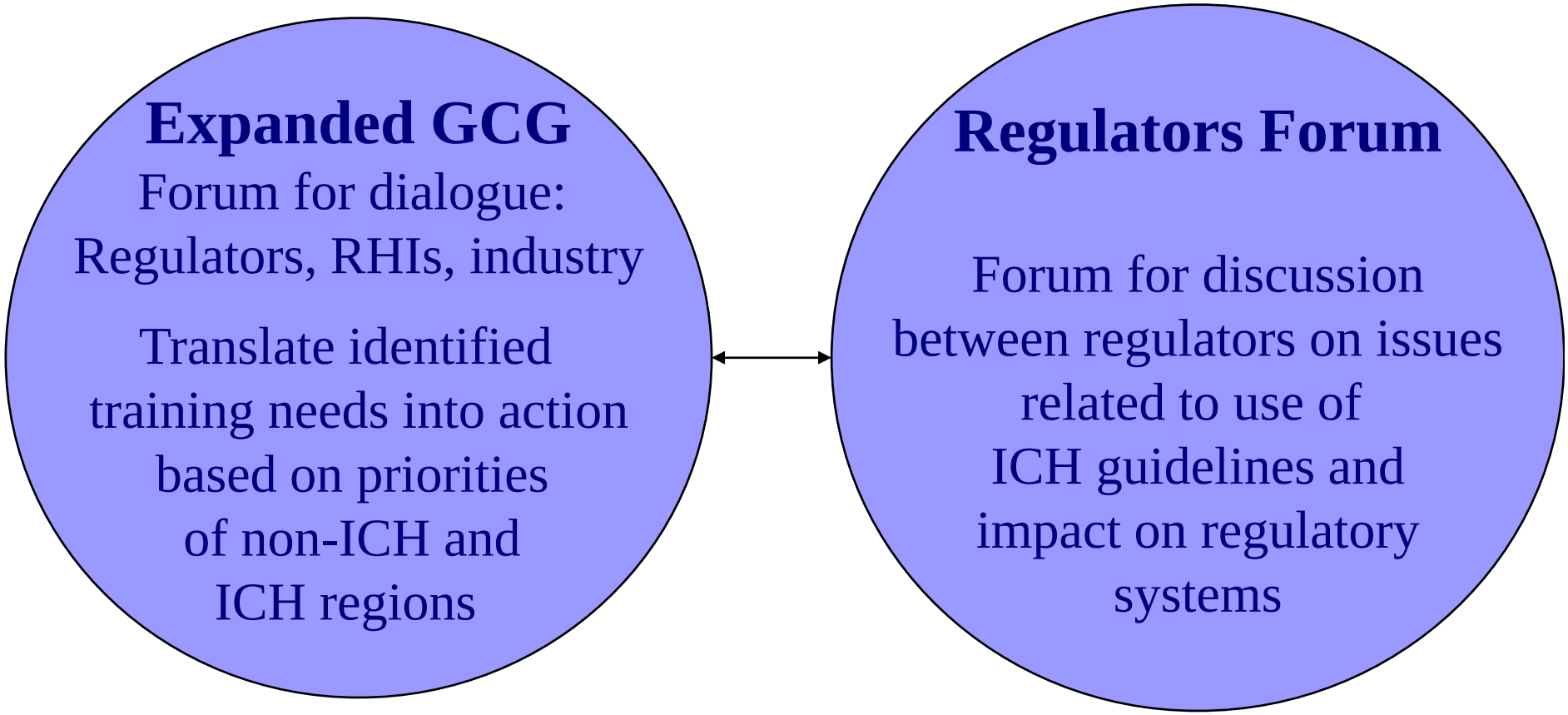
Further progress – Expanded GCG



ICH has recognized need for changes to mirror global face of drug development.

In Oct 2007, the ICH SC has decided to invite a number of individual Drug Regulatory Authorities.

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



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
- Learning from each other, in a climate of trust and cooperation, can greatly increase the strength of all harmonization efforts
- Moving towards more efficient regulatory systems and increased availability of safe, effective and quality pharmaceuticals on a global level

Thank you for your attention

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