



Recent Development of ICH GCG

**Japan Pharmaceutical Manufacturers Association
ICH Project Committee
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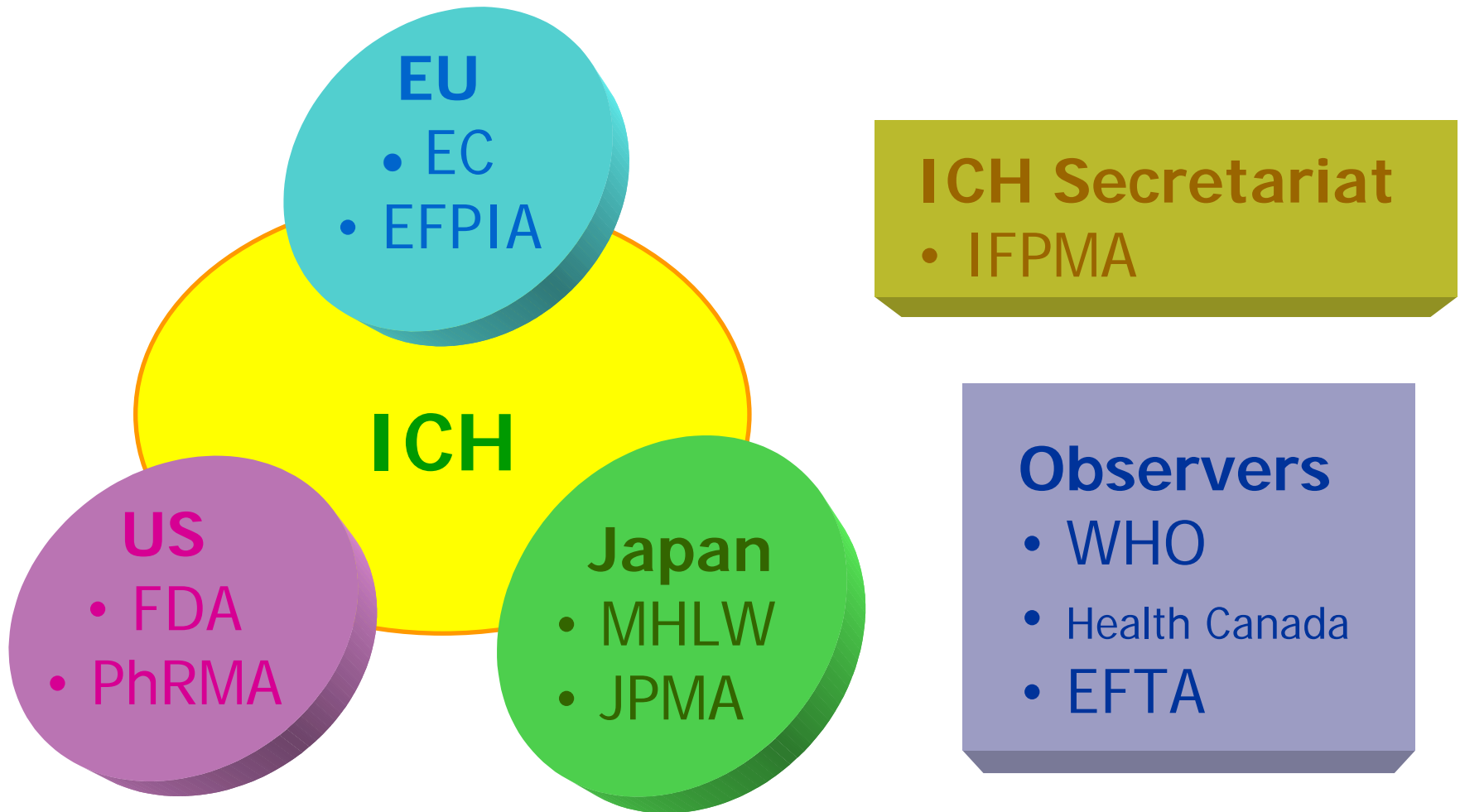
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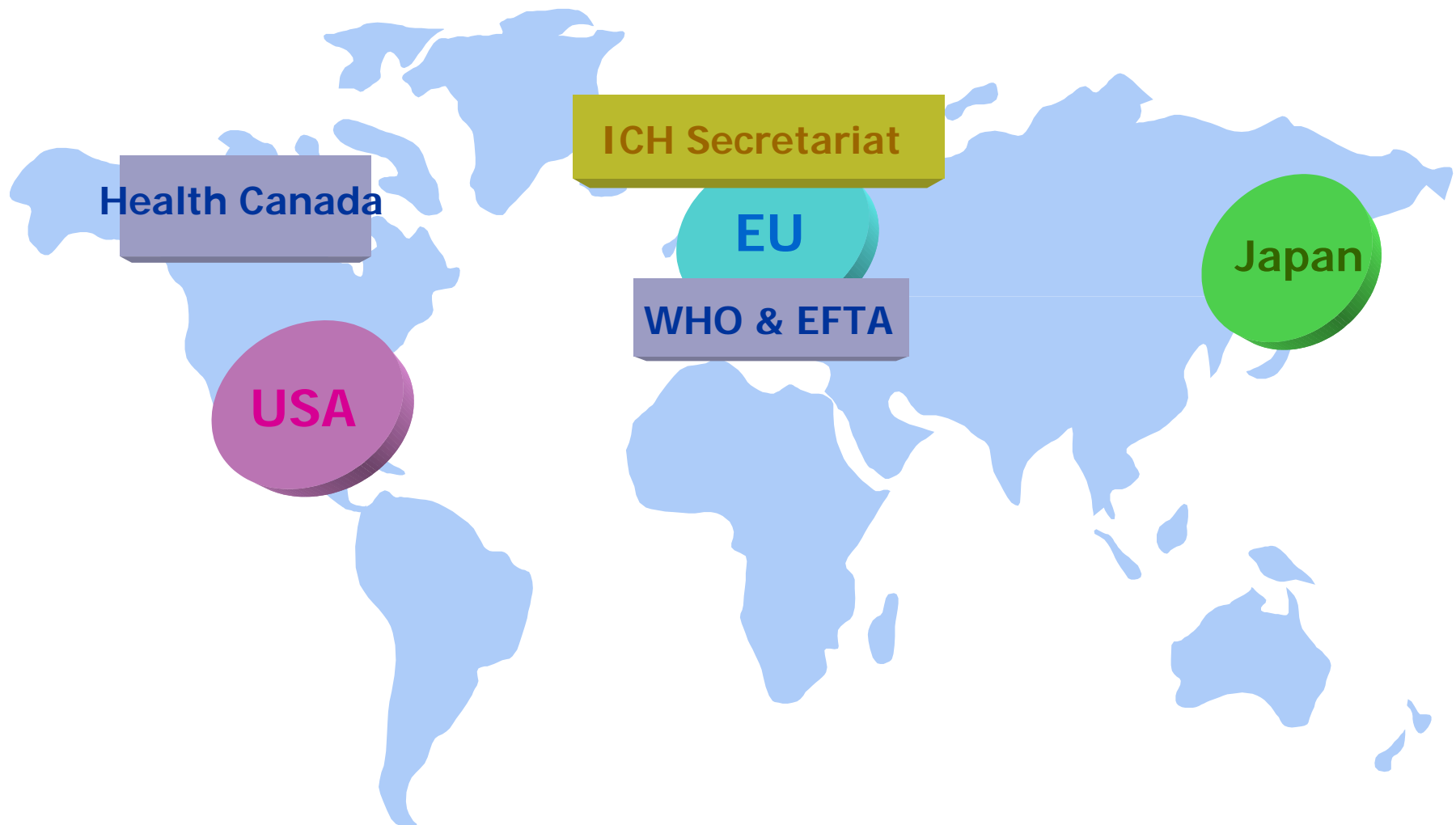
ICH Objectives

- Identification and elimination of the need to duplicate studies to meet different regulatory requirements
- More efficient use of resources in the R&D process
- Quicker access for patients to safe and effective new medicines

ICH Activity by the regulators and industry



ICH Member Countries



International Conference on Harmonisation

- ICH 1 : 1991 Brussels, Belgium
- ICH 2 : 1993 Orlando, U.S.A
- ICH 3 : 1995 Yokohama, Japan
- ICH 4 : 1997 Brussels, Belgium
- ICH 5 : 2000 San Diego, U.S.A
- ICH 6 : 2003 Osaka, Japan
- ICH 7 : *200? EU*

Where is ICH now ?

- A 'mature' harmonisation initiative
- Over fifty technical guidelines
- Increased interest in and use of ICH guidelines globally
- Formation and evolution of Global Cooperation Group (GCG)



ICH and non-ICH regions

- ICH outcomes have influenced regulatory activities in non-ICH countries
- Some ICH Guide Lines (GLs) are not adopted to non-ICH countries
- Adoption by non-ICH countries may lead to local disharmony if variations or amendments are not made

Global Cooperation Group (GCG)

Formed in 1999 as a sub-Committee reporting directly to Steering Committee (SC)

- Objective: establish relationship with non-ICH regions/countries to inform and to develop interactions
- Membership: one representative of each six parties and observers (Health Canada, WHO)



Mission of ICH-GCG

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

Principles of ICH-GCG

ICH

- Not seek to impose ICH views on any country/company
- Work as closely as possible with WHO and other international organizations to achieve these goals

GCG (ICH sub-committee)

- Provide information upon request from non-ICH countries, also information available ICH Web site

Regional Harmonisation Initiatives (RHI)

- **APEC**

Asia-Pacific Economic Cooperation

- **ASEAN (ACCSQ PPWG)**

Association of South-East Asian Nations

- **GCC**

Gulf Cooperation Council

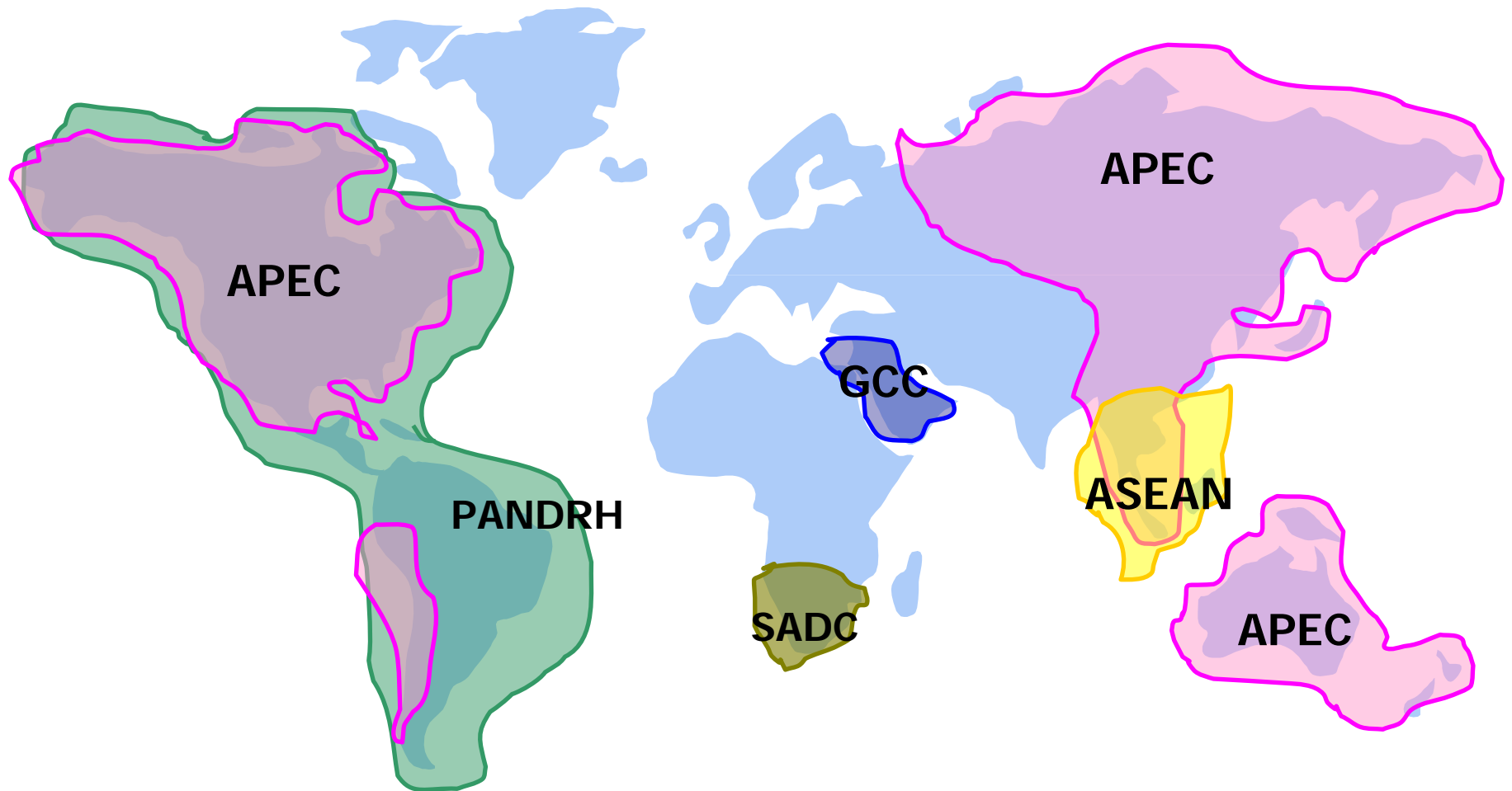
- **PANDRH (PAHO)**

Pan American Network for Drug Regulatory
Harmonisation

- **SADC**

Southern African Development Community

RHI countries



Common Understanding

GCG meeting

- Attend, make presentations, raise questions

SC meeting

- Attend technical discussions
(do not raise questions)
- Attend GCG reports to SC, comment
(usually asked by SC chair)

EWG (Expert Working Group) meeting

- Present to learn about harmonisation activities

**** participated in Q10, Yokohama 2006**

GCG Opportunities

- GCG is open to permanent representatives of non-ICH regions with harmonisation initiatives
- GCG identifies with RHIs the topics and process issues for discussion, collaboration and potential development
- All proposed GCG actions have to be endorsed by ICH SC
- Discuss specific issues with ICH regulators and industry representatives
- Building confidence and trust

GCG recent developments

- Training strategy document endorsed by SC
- Ongoing Survey on structure organisation of local RHIs and Good Harmonisation Practices

Strategy on Training and Capacity Building Related to the Use of ICH Guidelines

- Issue & Background
- Principles and Recommendations of the GCG in responding to Training Requests
- Delivery of training and capacity-building within a regional strategy

Reference :

**<http://www.ich.org/>
Global Cooperation Group => Reports**

Progress on Outputs from RHI Survey - 1

■ Objectives :

Collect and publish (baseline) information on RHIs and on identifying GHPs

■ Yokohama 06 <GCG considered> :

Proposal for a public paper on comparative study of RHIs and keys to successful harmonisation outcomes

Progress on Outputs from RHI Survey - 2

- **Agreement in principle to proceed in stepwise fashion :**

Collect necessary information from RHIs and complete sample comparative table and profile narrative using PANDRH as model

- **Goals :**

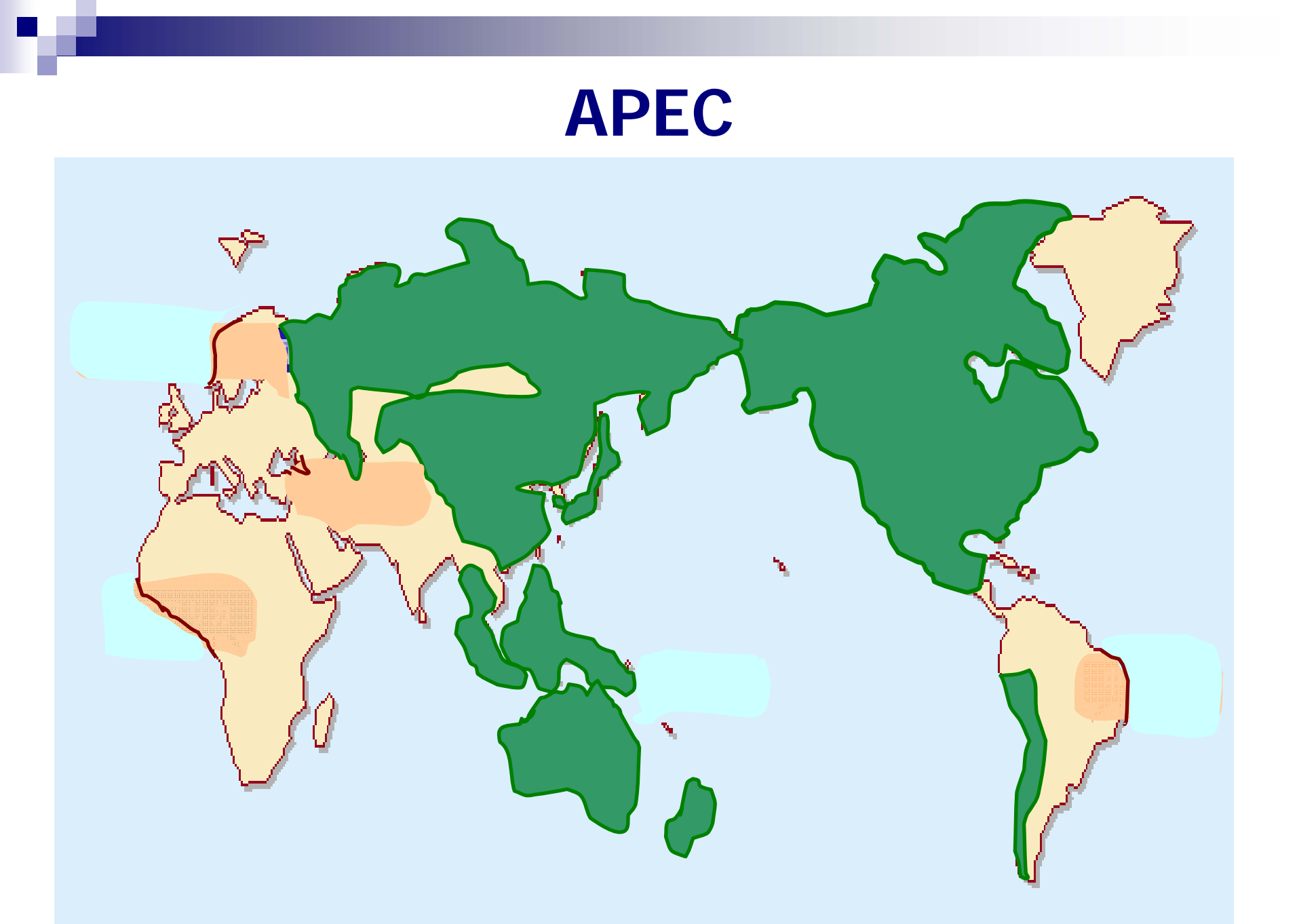
Promote understanding of RHIs, GCG and best practices in harmonisation

Summary - 1

- GCG discussed options for reflecting on progress made to date; periodic review also mandated by SC
- Proposal for Chicago 06 meeting to update GCG Procedures according to the progress made
- Transparency, communication and engagement through GCG seen as increasingly important

Summary - 2

- Necessary enhanced interaction between ICH and non-ICH regions win activity
- ICH continues to balance development of important new topics with maintenance and implementation activities



APEC

