

# Evolution and achievements of ICH-GCG (Global Cooperation Group)

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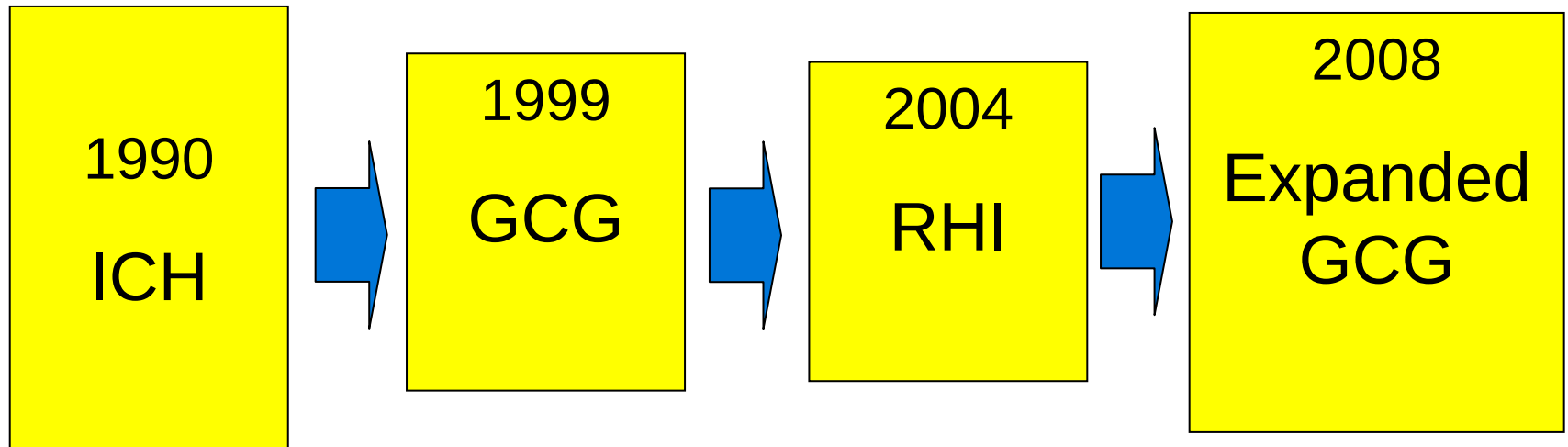
# Non-ICH regions are now integral part of drug development

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- Arena of clinical trials is now expanded into non-ICH regions including Asia, Eastern Europe, Central/South America, Gulf countries and Africa.
- Non-ICH countries are becoming major supplier of APIs

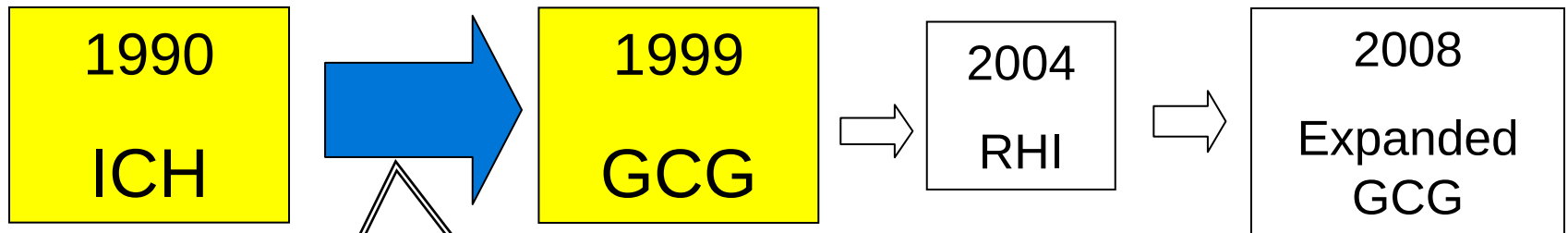
# Evolution of ICH-GCG

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# Interest beyond the 3 regions

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

Growing interest in ICH products beyond ICH countries

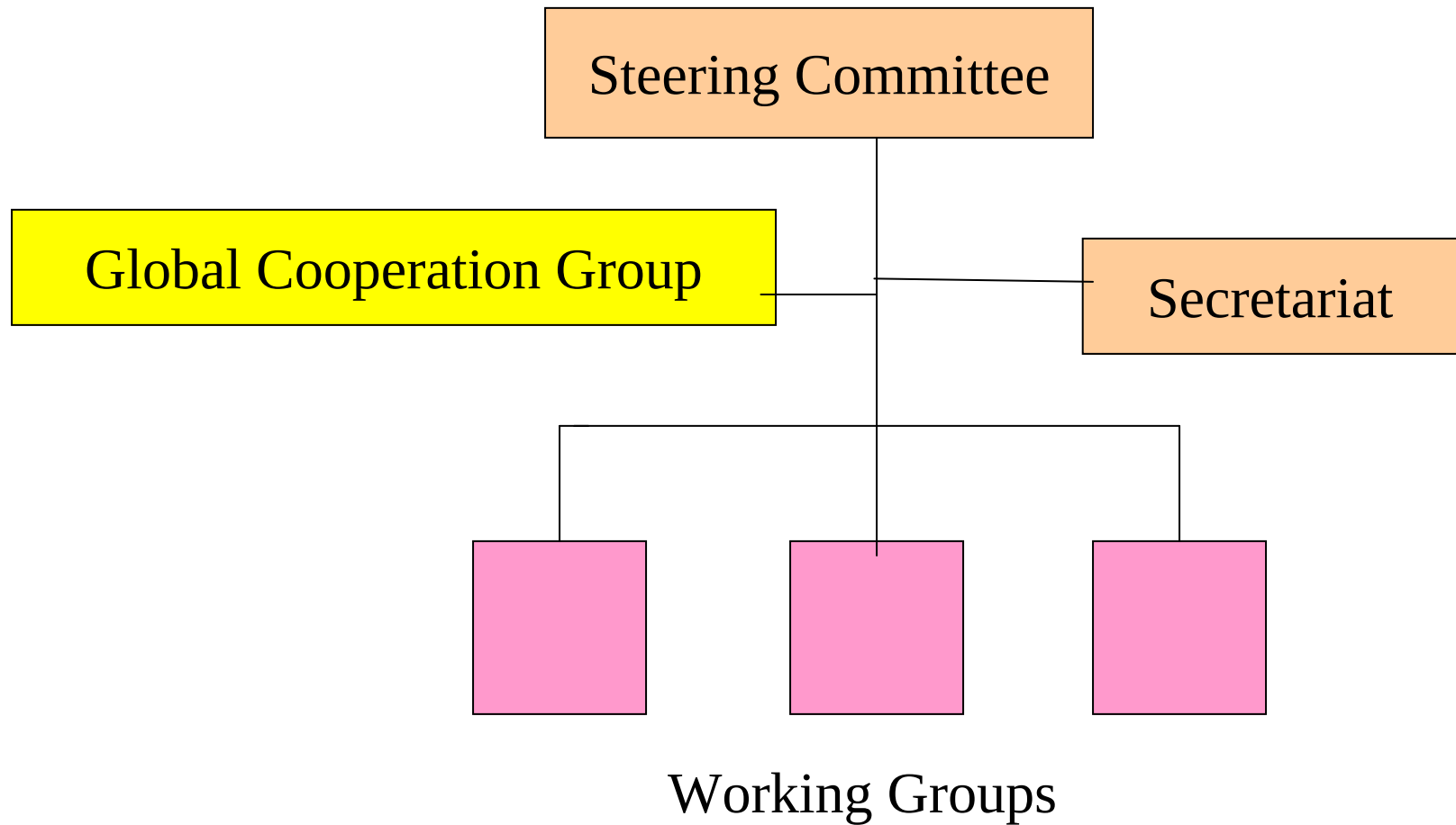
# Global Cooperation Group (GCG)

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- Established March 1999 as sub-committee of ICH SC
- Name reflects desire to establish links with non-ICH regions

# GCG, a sub-committee of ICH SC

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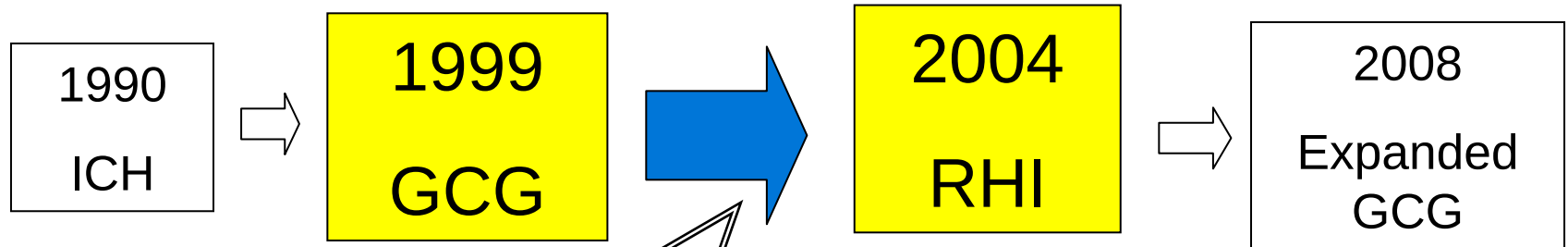
# GCG's Mandate

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- Role: Promote better understanding of ICH and guidelines
- How: **information-sharing**
  - Information brochures (posted to ICH website)
  - Presentations by GCG members at int'l meetings
  - Respond to questions
- Not a technical body!

**Good intentions, but ...**

# .....Not enough



More proactive approach was necessary.

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

# Expanded membership – RHIs

## (Regional Harmonization Initiatives)

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### Criteria (e.g.)

Engaged in efforts to harmonize drug requirements across a defined group of countries.

Possess or develop mechanism to disseminate information on ICH GCG activities.

# List of RHIs

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## **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

# Adopted new GCG mission statement



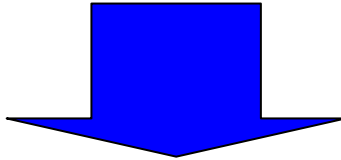
May 2005, Brussels:

*“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”*

# RHIs brought in New Opportunities

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- Establish two-way dialogue, collaboration
- Opportunity to better understand the needs of other regions
- Opportunity to better understand ICH guidelines and process



Shift from information-sharing  
to implementation/training

# Training: Now a Key Focus

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Framework and mechanisms established:

- Strategy document
- Clearing house of training events
- Procedures and templates under development
- Public access

# Training opportunities

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APEC Q8-10 Quality guideline workshop

September 2007, Seoul, Korea

APEC workshops on review of clinical trials

March 2008 / March 2009, Bangkok, Thailand

APEC workshops on Clinical research inspections

May 2008 / March 2009, Bangkok, Thailand

APEC Quality guideline workshop

December 3-5, 2008, Beijing, China

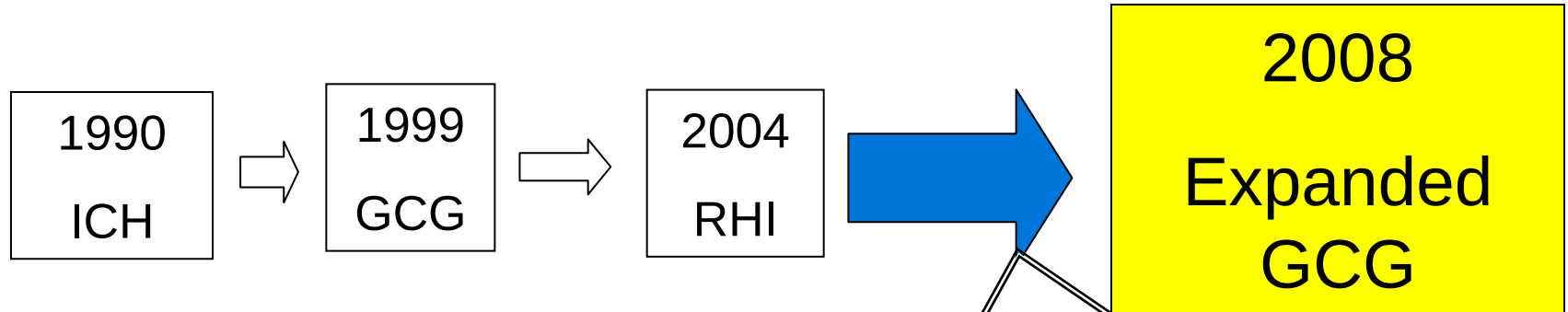
PANDRH MERCOSUR Quality workshop

2009, Sao Paulo

More to come

# Further progress – Expanded GCG

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ICH has recognized need changes to meet current global drug development trends.

ICH SC endorsed proposals to create 'Expanded GCG' in Yokohama Oct 2007, and to **invite a number of individual Drug Regulatory Authorities.**

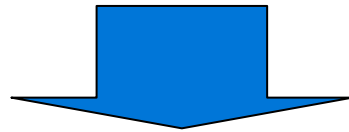
# New needs from non-ICH countries

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Countries with advanced understanding of ICH concepts

Countries which have been the arena of multinational clinical trials

Countries functioning as global API supplier



Certain individual countries can establish two way collaboration / interaction with the ICH.

# Expanded GCG

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- Participation would be **distinct and complementary** to participation of official RHI representative/observer
- Individual countries were invited to ICH meetings  
Portland (June) and Brussels (Nov) 2008

## Countries present

Australia

China

Chinese Taipei

Korea

Russia

Singapore

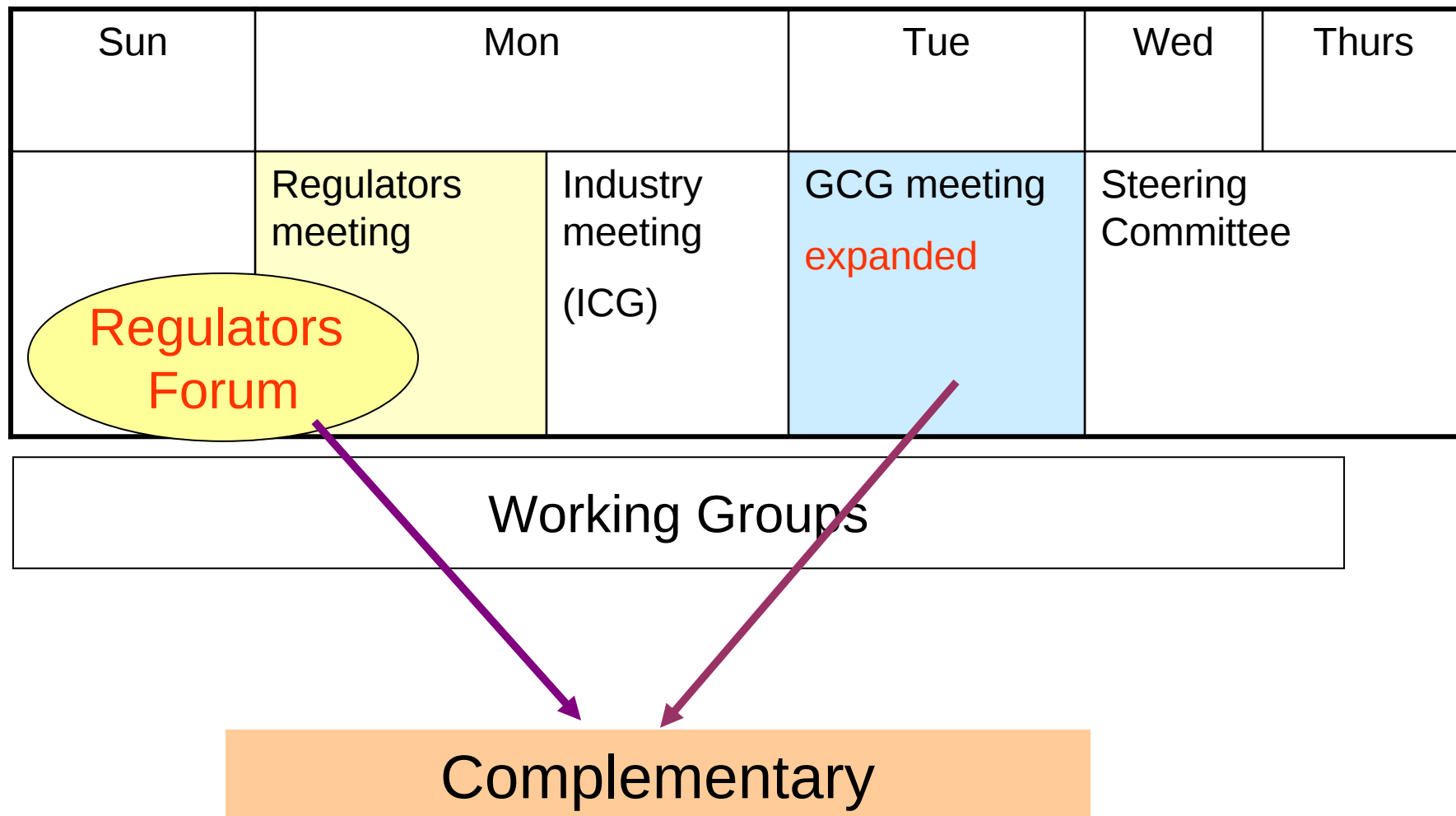
# also endorsed was ICH Regulators Forum

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- For discussion and sharing of best practices among regulatory authorities on issues related to the implementation of ICH guidelines and impact on regulatory systems
- The Regulators Forum will complement activities and objectives of GCG

# How the ICH Week looks like

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# Important Guiding Principles of GCG

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- ICH will not impose its views on any country or region – rather, 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 utilize ICH guidelines

# Conclusion

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- ICH is committed to responding to needs of regions and countries interested in implementing ICH guidelines
- GCG has been playing important role to disseminate ICH information/concept to non-ICH regions.
- It is now expanding to individual countries, and shifting its focus to implementation, especially training
- Success dependant on collective effort and spirit of cooperation

Thank you!!