ICH-GCG ASEAN
Training Workshop
Introduction to ICH

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ICH Q8, Q9, Q10 Implementation Working Group

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

ICH: 20 years process (1)

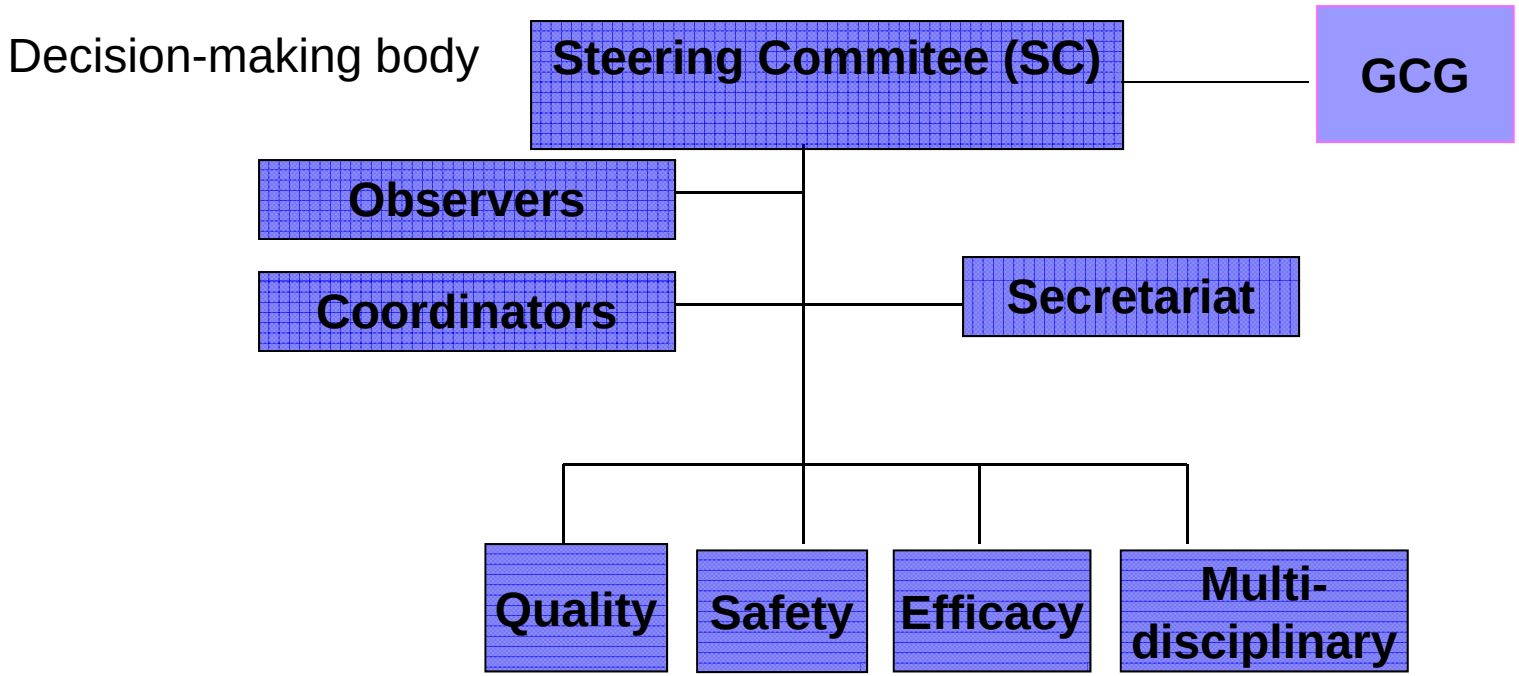
- **Start in 1990 (Brussels)**
- **Objective of ICH:**
  Technical and scientific harmonisation between Japan, Europe and USA.
- **Scope:**

  New chemical entities and biotechnology derived products
- **Sponsors:**
  - Regulators: EU, FDA, MHLW
  - Industry: EFPIA, JPMA, PhRMA
- **Observers:**
  - EFTA, Health Canada, WHO, IFPMA
- **Steering Committee**

ICH: 20 years process (2)

- 1990: Pharmacopoeial Discussion Group
  - EP, JP, USP, WHO
- 1997: Interested Parties: IGPA, WSMI
- 1999: Global Cooperation Group
  - 2004 RHIs: APEC, ASEAN, GCC, PANDRH, SADC
  - 2008 DRAs: Australia, Brazil, China, India, Russia, Singapore, South Korea
  - 2008: DoH: Chinese Taipeh
- 2003: Quality New Paradigm
- 2006: Biotech Industry
- **2010: ICH Training: Implementation Q8, Q9, Q10**

ICH Structure



Working Groups: Development and Implementation

ICH Global Cooperation Group

- The Global Cooperation Group (GCG) was formed as a subcommittee of the ICH Steering Committee (SC) in March 1999 in response to a growing interest in ICH beyond the three ICH regions. The original purpose of the GCG was to make information available on ICH, ICH activities, and ICH guidelines to any country or company that requested such information. The GCG is made up of the one representative from each of the six parties on the ICH Steering Committee, plus the ICH Secretariat at IFPMA. The ICH Observers (WHO, Canada and EFTA) are also part of the GCG
- In November 2003, new rules were endorsed with the aim of establishing partnerships with Regional Harmonization Initiatives (RHIs) and promoting a better understanding of ICH guidelines.

ICH Global Cooperation Group

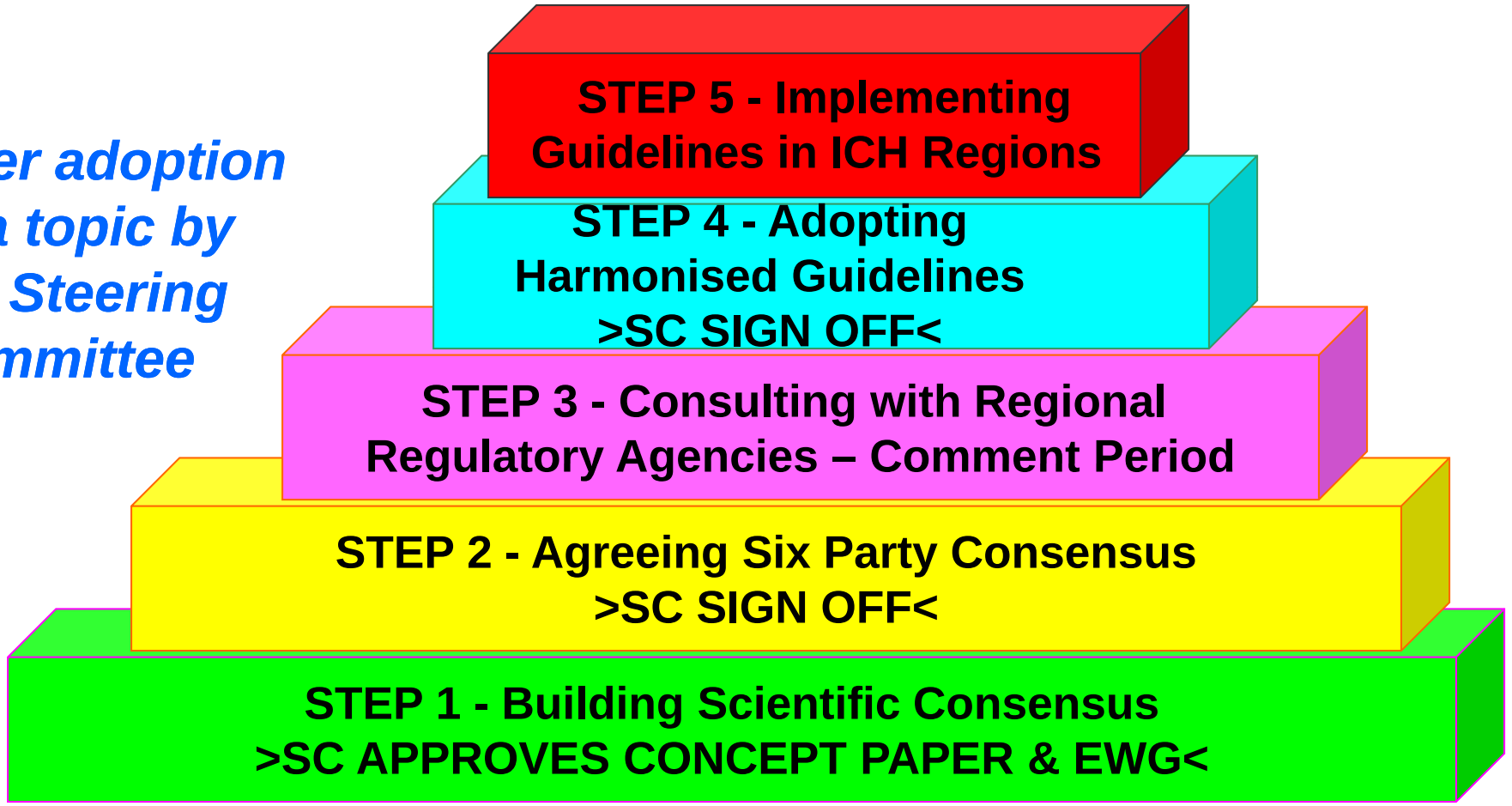
- In October 2007, the ICH SC discussed the need for a change to the GCG principles and procedures in order to fully realize the GCG objectives and thereby contribute to achieving a number of important goals related to improving public health. The SC identified these goals to be:
  - to reduce country and regional differences in technical requirements that impact on the availability and cost of new medicines;
  - to promote international movement of pharmaceuticals that are safe, effective and of high quality;
  - to promote the conduct of clinical trials and data collection that meet international standards.

Achieved so far

- **Areas**
  - Quality, Safety, Efficacy
  - Multidisciplinary areas: MedDRA, e-submission, …
- **Initial ICH Quality topics**
  - Scientific/technical guidelines mostly:
    Stability, Method Validation, Impurities, Specifications, Q5 series (Biological)
  - System oriented: GMP for APIs
  - Structure: Common Technical Document

Steps in the ICH Process

After adoption of a topic by the Steering Committee



Quality: A New Paradigm

'Develop a harmonised pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to quality risk management and science'

(Brussels July 2003)

- Q8: Pharmaceutical Development
- Q8 (R2): Pharmaceutical Development Revision
- Q9: Quality Risk Management
- Q10: Pharmaceutical Quality System
- Q11: Development and Manufacture of Drug Substances (chemical/biological entities): in progress.

Quality: A New Paradigm

The new paradigm emphasize:

1. Quality must be mainly built in and it will not only improve by additional testing and inspection
2. Better utilization of modern science throughout product lifecycle
3. QRM is a key enabler throughout product lifecycle
4. Robust PQS, with appropriate knowledge management, assures quality throughout product lifecycle
5. An integrated approach to development, manufacturing and quality for both industry and regulators

Quality: A New Paradigm

Main message

Science is no longer isolated; it is living across the lifecycle of the product/process within a Quality Management System

Implementation WG on Q8, Q9, Q10

- **Task of IWG Q8, Q9, Q10:**
  - Scope: ensuring harmonised implementation
  - "….due primarily to departure from the traditional approaches to quality guidance, proper implementation of these concepts is provided by bringing clarity, further explanation and removing ambiguities and uncertainties".
  - Technical issues & related documentation:
  - Additional implementation issues: influence on existing ICH guidelines;
  - Communication and training
- Unique training programme for industry and regulators (assessors and inspectors) in the three regions:
  - Tallinn (Estonia) June 2-4, 2010
  - Washington October 6-8, 2010
  - Tokyo October 25-27, 2010

Implementation WG on Q8, Q9, Q10

- Identified areas needing further clarification:
  - Knowledge Management
  - Design Space, Real Time Release, Control Strategy
  - Pharmaceutical Quality System:
    - Impact on inspection
    - Collaboration assessor/GMP inspector
- Publication of Q&A
- Comments and questions access from ICH website www.ich.org, Quality-Guidelines-menu, under Q8, Q9 and Q10

ICH-GCG-ASEAN ICH July 2010
Training Workshop Program

- Introduction and plenary presentations
- Breakout sessions
  - A. Design Space
  - B. Control Strategy
  - C. Pharmaceutical Quality
  - D. ICH Q8, Q9, Q10

    Impact and Challenges for Pharmacopoeia
- Conclusions