Overview of recent developments in ICH

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EMEA
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EMEA: Enhancement of International activities

- EMEA Roadmap: Enhancement of International activity to better protect public health, facilitate access to medicines and stimulate innovation

- EC-EMEA Bilateral relationships: Confidentiality arrangements with USA (2003), Japan (2007), Canada (2007)

- Mutlinational relatioships: ICH remains the key forum for harmonisation of human pharmaceuticals. ICH is an important technical basis for our international collaboration success

ICH History

- Harmonisation of regulatory requirements for medicinal products was pioneered by the European Community in the 1980s as the EU moved towards a single market for pharmaceuticals
- In the WHO Conference of Drug Regulatory Authorities (ICDRA) in Paris in 1989 plans for harmonisation among the leading regions for new pharmaceuticals EU, USA and Japan began to materialise

ICH History 1990 - 2008

- Birth: April 1990, in a meeting hosted by EFPIA in Brussels, establishment of the ICH Steering Committee (SC)
- First SC meeting in October in 1990 Tokyo
- 2008: ICH comes of age – 18 years old

ICH objectives

- Objective: to improve efficiency of new drug development and registration process

- Accomplished through the development and implementation of harmonized guidelines and standards

ICH Structure

The six parties: Committed to implementation of guidelines

Regulators : EC (EU), MHLW (JP), FDA (US)

Industry: EFPIA, JPMA, PhRMA

Secretariat: IFPMA

Observers: EFTA, Health Canada, WHO

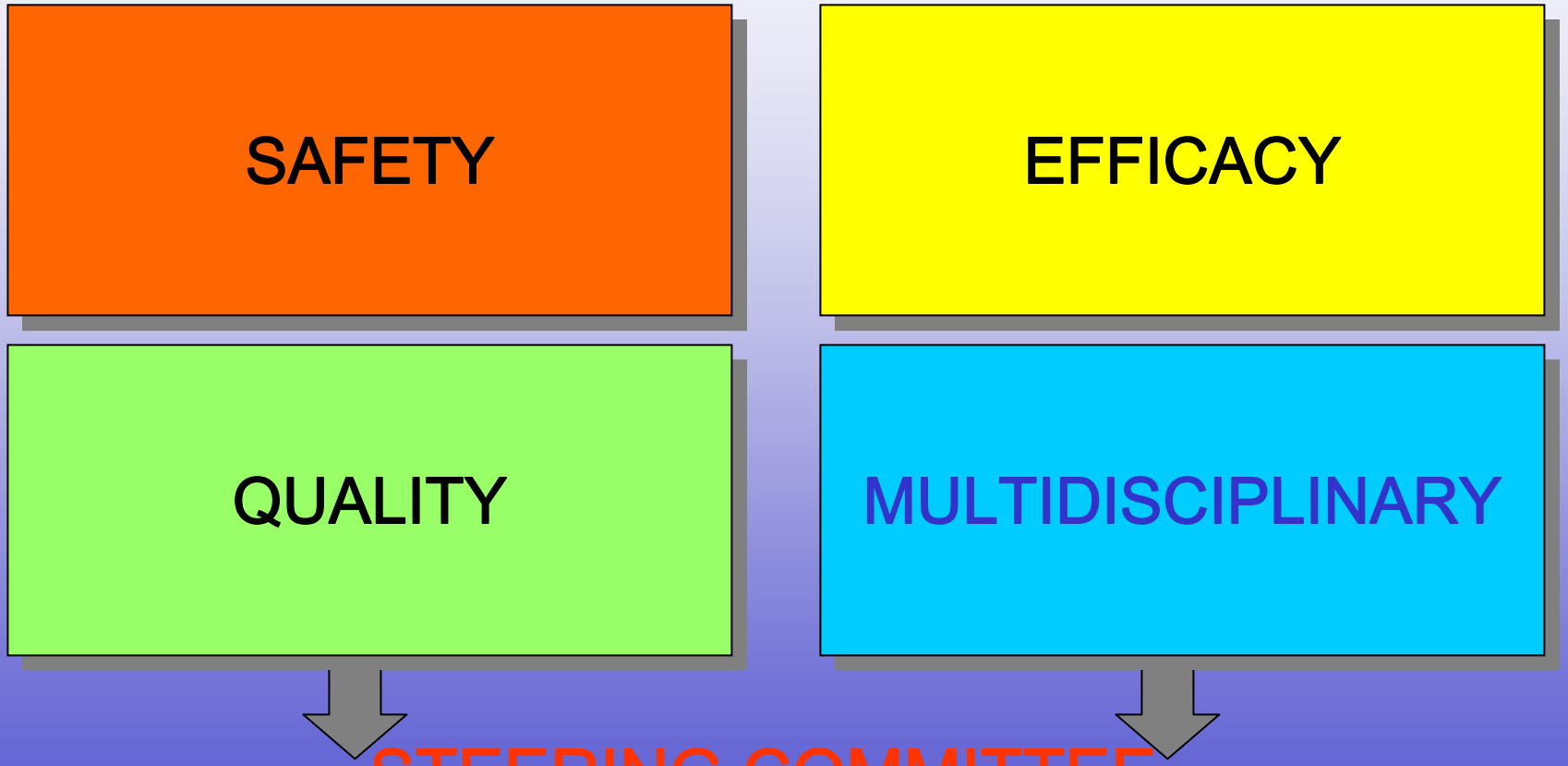
ICH Structure

- ICH Steering Committee
- ICH Coordinators
- ICH Expert Working Groups
- Secretariat

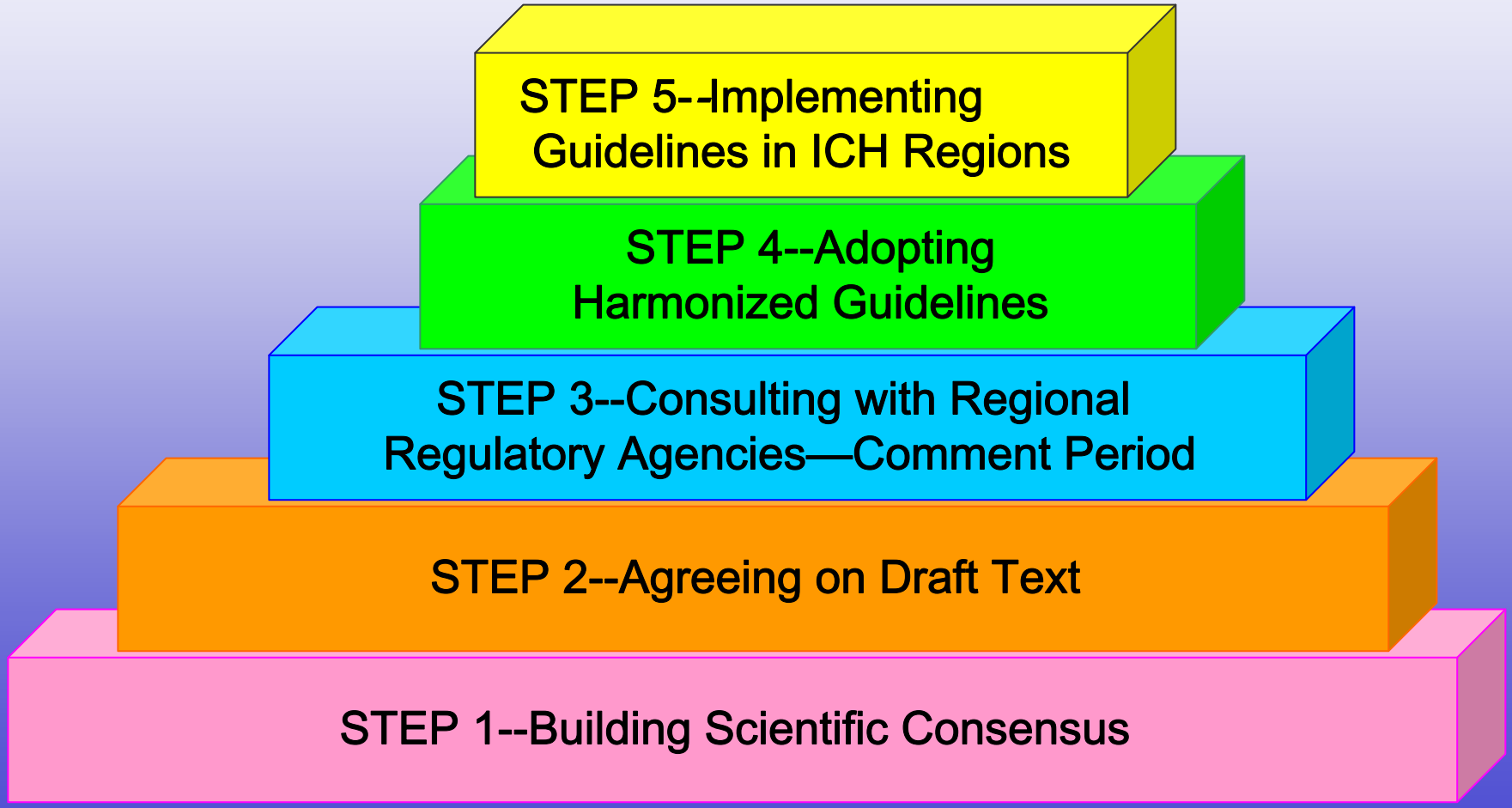
ICH Structure

- Steering Committee meetings
  - Usually two per year
  - Location rotates between the three regions
  - Expert Working Groups meet at the same time
  - Reporting to the Steering Committee
  - Milestones at the end of each meeting

Expert Working Groups



Steps of ICH Harmonization



Over 50 ICH Guidelines
finalised, new, under revision

- **Efficacy** - 14 topics/17 guidelines
- **Safety** - 8 topics/16 guidelines
- **Quality** - 9 topics/23 guidelines
- **Medical Dictionary** - MedDRA
- **Electronic Standards** - eCTD, ESTRI, E2B,
- **Common Technical Document** - CTD

Guidelines extend over entire product life cycle

Guidelines: Quality

- Stability, Analytical validation, Impurities
- Pharmacopoeia harmonisation ongoing
- Quality of Biotechnological Products
- Specifications
- Good Manufacturing Practice

<u>Recent / New: Quality by design</u>

- Pharmaceutical Development annex just finalised
- Quality Risk Management
- Quality systems ongoing
- chemical/biotech common guideline on the active substance starting

Guidelines: Safety

- Carcinogenicity Studies, Toxicokinetics and Pharmacokinetics, Toxicity Testing, Reproductive Toxicology, Pharmacology Studies Immunotoxicology Studies

New: Non-clinical requirements for anti-cancer products Step 2

<u>Under revision based on EMEA proposal: evolving science and Refining, Reducing, Replacing animal experiments</u>

- Genotoxicity Studies revision ongoing
- Biotechnological Products revision ongoing
- Requirements for preclinical experiments in relation to clinical trials revision ongoing

Guidelines: Efficacy

- Clinical Safety, Clinical Study Reports, Dose-Response Studies, Ethnic Factors, Good Clinical Practice, General guidance on Clinical Trials, Statistics, Paediatrics

<u>Under revision based on EMEA proposal</u>

- Geriatrics Development of Q&A started

<u>Recent / New</u>

- Pharmacogenomics definitions
- Pharmacogenomics data submission ongoing
- Development safety update report ongoing

Guidelines: Multidisciplinary

- MedDRA: Medical Dictionary for Regulatory activities Terminology
- Common Technical Document CTD
- Reflection papers: Gene therapy several ongoing

<u>Recent: ICH opens up to speed up development</u>

Involvement of International Standards Organisations

- Electronic Standards e-CTD
- Data elements and standards for drug dictionaries ongoing

ICH: Keys to Success

- Well-defined process
- Secretariat: effective management and administration
- Limited number of players with common focus
- Comparable regulatory, technical and financial capacity
- Commitment of all parties: implementation and resources

Beyond ICH:Global Cooperation Group → Training

- All parties
- Representatives from non-ICH regional harmonization initiatives including APEC (Asian-pacific countries), ASEAN (south-Asian countries), Golf Cooperation Countries (GCC), Panamerican Network on Drug Regulatory Harmonisation (PANDRH) and Southern African Development Community (SADC) are invited to participate as observers in SC and expert groups.
- ICH Regions and certain individual Drug Regulatory Authorities provide training
- Certain EMEA Working Party Meetings (Efficacy, Safety, Quality) open to GCG partners

Beyond ICH: New Regulators' Forum → Implementation

- Regulators only: ICH + Regional Harmonisation Initiatives + China, India, Brazil, Russia, Taiwan, Singapore, Australia

- Goal: Facilitate Implementation of ICH Guidelines focussing on areas of greatest interest, e.g. manufacturing and clinical trials

Better Communication

- ICH Conferences: Brussels 1991, Orlando 1993, Yokohama 1995, Brussels 1997, San Diego 2000, Osaka 2003

- 1st regional Public Meeting: Tokyo 2007
- 2nd ICH regional Public Meeting: Brussels November 2008

www.ich.org

- Press releases
- Since 2005: Summarized version of Steering Committee Reports

Thank you for your attention