International Council on Harmonisation (ICH)

International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

What is ICH?

ICH is a joint initiative involving both regulators and research-based industry representatives of the European Union, Japan and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines.

Purpose

- The objective of ICH is to increase international harmonisation of technical requirements to ensure that safe, effective, and high quality medicines are developed and registered in the most efficient and cost- effective manner.
- These activities have been undertaken to promote public health, prevent unnecessary duplication of clinical trials in humans, and minimize the use of animal testing without compromising safety and effectiveness.

Goal of ICH

- To promote international harmonisation by bringing together representatives from the three ICH regions (EU, Japan and USA) to discuss and establish common guidelines.
- To make information available on ICH, ICH activities and ICH guidelines to any country or company that requests the information, and to promote a mutual understanding of regional initiatives in order to facilitate harmonisation processes related to ICH guidelines regionally and globally, and to strengthen the capacity of drug regulatory authorities and industry to utilise them.
- The ICH Global Cooperation Group (GCG) was formed in 1999 and is charged with this task.

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, as a consequence.
- Quicker access for patients to safe and effective new medicines.

ICH-Participants

The six cosponsors of ICH are

- ✓ European Commission - European Union (EU)
- ✓ The European Federation of Pharmaceutical Industry Association (EFPIA).

ICH Steering Committee

- ✓ The Steering Committee is the body that governs the ICH, determines the policies and procedures for ICH, selects topics for harmonisation and monitors the progress of harmonisation initiatives.
- ✓ Each of the six ICH parties has two seats on the ICH Steering Committee. Each of the Observers nominates non-voting participants to attend the ICH Steering Committee Meetings. IFPMA also participates as a non-voting member.

ICH Working Group

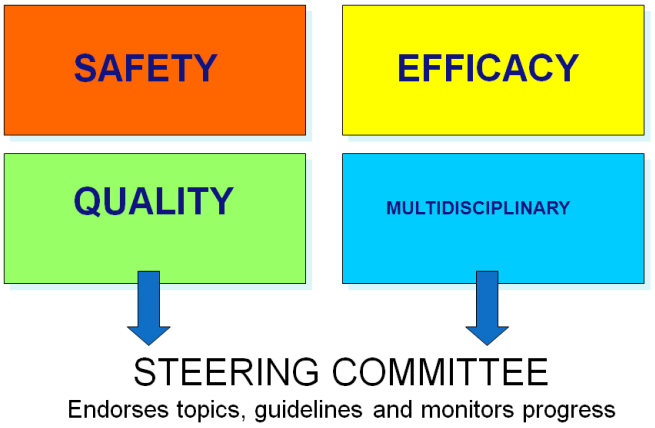
- Depending on the type of harmonisation activity needed, the Steering Committee will endorse the establishment of one of three types of working group
  - Expert Working Group (EWG)
  - Implementation Working Group (IWG) or
  - Informal Working Group.
- Ministry of Health, Labour and Welfare, Japan (MHLW)
- Japan Pharmaceutical Manufacturers Association (JPMA)
- US Food and Drug Administration (FDA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)

Observers

- The World Health Organisation (WHO).
- The European Free Trade Association (EFTA), currently represented at ICH by Swissmedic Switzerland.
- Canada, represented at ICH by Health Canada.

Expert Working Group (EWG)

- An Expert Working Group is created by the Steering Committee when a new topic is accepted for harmonisation, and is charged with developing a harmonised guideline that meets the objectives outlined in the Concept Paper and Business Plan.
- Each of the six official ICH parties nominates official representatives to each EWG and, unless otherwise specified by the Steering Committee, the official membership is limited to two officials per party per working group and one representative per ICH Observer, and also if applicable, one per interested party (those organisations that are expected to implement or to be regulated by the outcome of ICH efforts like World Self- Medication Industry (WSMI) and the International Generic Pharmaceutical Alliance (IGPA)).



ICH Quality Topics

Within the Quality section, there are ten topics:

1. Stability
2. Validation
3. Impurities
4. Pharmacopoeial harmonization
5. Biotechnological products
6. Specifications
7. GMP) guide for Active Pharmaceutical Ingredients
8. Pharmaceutical Development
9. Quality Risk Management
10. Pharmaceutical Quality System
11. Development and manufacture of drug substances
12. Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

Global Cooperation Group (GCG)

- The ICH Global Cooperation Group (GCG) was formed on March 11, 1999, as a subcommittee of the ICH Steering Committee.
- It is made up of one representative from each of the six parties on the ICH Steering
- Committee, plus the ICH Secretariat at IFPMA. Three Observers (WHO, Canada and EFTA) are also part of the GCG.
- Other regional harmonisation initiatives (RHIs), namely Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), Gulf Cooperation Countries (GCC), Pan American Network on Drug Regulatory Harmonization (PANDRH) and South African Development Community (SADC), have been invited to designate permanent representatives to the GCG.

Step1: Consensus building by EWG - Preliminary discussions of which, consider existing guidelines in the region and elsewhere, known areas of similarity and differences, and scientific advances in the subject area. The drafts are prepared and circulated through many revisions until a "final harmonised draft" is completed.

Step 2: Consensus agreed by six parties - This draft is signed by the EWG as the agreed-upon draft and forwarded to the Steering Committee for signing which signifies acceptance for consultation by each of the six parties.

Step 3: Regulatory consultation - After obtaining all regulatory consultation results, the EWG who organised the discussion for consensus building will be resumed. This EWG consists of regulatory and industry parties, and Observers. If both regulatory and industry parties of the EWG are satisfied that the consensus achieved then the document is signed by the EWG regulatory experts. The document with regulatory EWG signatures is submitted to the steering committee to request adoption.

Step 4: Adoption of ICH guidelines – When the steering Committee agrees that there is sufficient scientific consensus on the technical issues, it endorses the guidelines. This endorsement is based on the signatures from the three regulatory parties to ICH affirming that the guideline is recommended for adoption by the regulatory bodies of the three regions.

Step 5: Implementation - The process is complete when the guidelines are incorporated into national or regional internal procedures.

Products of ICH

- ICH has developed over 50 harmonised guidelines. These guidelines also include the Common Technical Document (CTD), which describes the common format for the preparation of a well-structured CTD for applications that will be submitted to regulatory authorities.
- Electronic Common Technical Document (eCTD), which allows for the electronic submission of the Common Technical Document (CTD) from applicant to regulator.
- The Medical Dictionary for Regulatory Activities (MedDRA) T has been developed.

ICH - Summary

- Effective global planning is necessary because drugs are more frequently developed and marketed worldwide, and therefore involves differing patient populations and different government regulations. ICH guidelines have helped to standardize regulations worldwide.
- ICH continues to balance development of important new topics with maintenance and implementation activities.
- New procedures and harmonized procedures are meant to improve efficiency and value of ICH process.
- Transparency, communication and engagement through GCG seen as increasingly important.