International Committee on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

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International Committee on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

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ICH

Project that brought together the regulatory authorities of three regions
- European Union
- Japan
- United States

and experts from the pharmaceutical industry to discuss scientific and technical aspects of product registration.
SIX FOUNDER MEMBERS of ICH

- European Commission (EC)
- European Federation of Pharmaceutical Industries’ Associations (EFPIA)
- Ministry of Health, Labor and Welfare (MHLW)
- Japanese Pharmaceutical Manufacturers Association (JPMA)
- Food & Drug Administration (FDA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
PURPOSE
of Harmonization

To harmonize:
- interpretation and application of technical guidelines and requirements for product registration
- to reduce or obviate duplicate testing during the research and development of new medicines.
OVERALL OBJECTIVES

- More economical use of human, animal and material resources
- Elimination of unnecessary delay in the global development.
- Make new medicines available while maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.
Part 1 of Harmonization

Focused on the technical requirements for developing and registering products containing new drug substances, in these regions.

Have developed over 40 guidelines for new drug products.
Part 2 of Harmonization

Developed a:

- mechanism to harmonize **new technical requirements** resulting from scientific progress and developments in innovative drug research;

- process for updating and supplementing current guidelines and monitoring their use
Specific Objectives

- Achieved through the development of Guidelines
- Each Guidance has its own specific objectives
Examples from E8
General Considerations for Clinical Trials
Protection of Clinical Trial Participant

- Need results of nonclinical investigations or previous human or animal studies
Scientific Approach in Design and Analysis

Sound scientific principles are needed for the design, conduct or analysis of a clinical trial.

– Trials are classified based on objectives
For each type of study, ICH outlines considerations relating to the development plan for the study

- E.g. Safety Study
  - Dose to be determined by examination of nonclinical pharmacokinetic, pharmacological and toxicological evaluations
  - Early nonclinical studies should support initial human dose, safe duration of exposure to the drug, and information about the new drug’s physiological and toxicological effects
Quality of Investigational Medical Products

- Outlines drug phases
- Addresses special considerations
  - E.g. Special populations
    - Pregnant women
    - Children
Consideration of Individual Clinical Trials

- Objectives
- Design
- Conduct
- Analysis
- Reporting
Process for Development of New ICH Guideline or Recommendation

1. Consensus building within Expert Working Group
2. Start of Regulatory Action
3. Regulatory Consultation within the Regions
4. Adoption of a Tripartite Harmonised Text (confirm that consultation did not alter text)
5. Implementation according to national/regional requirements
ICH TOPICS/GUIDELINES

"Quality" Topics, i.e., those relating to chemical and pharmaceutical Quality Assurance.

"Safety" Topics, i.e., those relating to in vitro and in vivo pre-clinical studies.

"Efficacy" Topics, i.e., those relating to clinical studies in human subject.

(E6) Good Clinical Practices

"Multidisciplinary" Topics, i.e., cross-cutting Topics which do not fit uniquely into one of the above categories.

- Medical Terminology (MedDRA)
- Electronic Standards Timing of Pre-clinical Studies in Relation to Clinical Trials
Efficacy Topics/Guidelines
English/Japanese

E6 Guideline for Good Clinical Practice