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Original Research Article

A REVIEW ON CLASSIFICATION OF INTERNATIONAL COUNCIL FOR HARMONIZATION GUIDELINES

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ABSTRACT
Through industry and regulatory participation, ICH has successfully unified technical guidelines globally. After ICH reform, ICH has transparent governance and membership that is becoming more international. There are five clear steps in the ICH guideline formulation process. The goal of the International Council of Harmonization (ICH) is to secure global harmonization in the development and registration of safe, efficient, and high-quality pharmaceuticals.

Keywords: ICH guidelines; Q- series; Harmonization; Stability studies; GMP.

INTRODUCTION
The International Council for Harmonization (ICH), formerly the International Conference on Harmonization (ICH), held its inaugural assembly meetings on October 23, 2015, establishing ICH as an international association and a legal entity under Swiss law. Since its inception in 1990, ICH has gradually evolved to respond to increasingly global developments in the pharmaceutical sector, and these ICH guidelines are being applied by a growing number of regulatory authorities. This step built upon a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development as well as their regulation and a longer-standing recognition of the need to harmonize.

What does ICH stand for?
The complete name of ICH is the "International Conference on Harmonization 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 EU, Japan and the US in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines. It was established in April, 1990.

ICH is comprised of representative from the six cosponsoring parties as well as three observers and The International federation of pharmaceutical manufactures associations (IFPMA)
Japan: The ministry of health and welfare-**MHW**
The Japan pharmaceutical manufacturer's association-**JPMA**
European: European Commission-**EC**
European federation of pharmaceutical industry association- **EFPIA**
USA: Food and drug administration **–FDA**

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The pharmaceutical research and manufacture's of America-**PHRMA**

Observers: WHO, EFTA, Canada

Purpose of ICH:
The objective of ICH is to increase international coordination of technical requirements to ensure that safe, effective, and high quality medicines are developed and registered in the most efficient and cost-effective manner.

ICH Guidelines:
ICH has developed over 45 harmonized guidelines. The ICH Topics are divided into four major categories:

- **Quality (Q),** i.e., those relating to chemical and Pharmaceutical Quality Assurance.
- **Safety (S),** i.e., those relating to toxicity tests of drugs in preclinical studies.
- **Efficacy (E),** i.e., those relating to clinical studies in human subject.
- **Multidisciplinary topics (M),** i.e., cross-cutting Topics which do not fit uniquely into one of the above categories.

ICH: Quality
The European Medicines Agency publishes scientific guidelines on human medicines that are harmonized by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
For a complete list of scientific guidelines currently open for consultation, see Public consultations.

- Stability
- Analytical validation
- Impurities
- Regulatory acceptance
- Quality of biotechnological products
- Specifications
- Good manufacturing practice
- Pharmaceutical development
- Lifecycle management

Stability

- ICH Q1A (R2): Stability testing of new drug substances and drug products: a scientific guideline
- ICH Q1B: Photo stability Testing of New Active Substances and Medicinal Products: A Scientific Guideline
- ICH Q1C Stability Testing: Requirements for New Dosage Forms: A Scientific Guideline
- ICH Q1D Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products: A Scientific Guideline
- ICH Q1E Evaluation of Stability Data: A Scientific Guideline
- ICH Q1F Stability Data Package for Registration in Climate Zones III and IV: Scientific Guidelines

Analytical validation and development

- ICH Q2(R2) Validation of analytical procedures - Scientific guideline
- ICH Q14 Analytical procedure development - Scientific guideline

Impurities

- ICH Q3A (R2) Impurities in new drug substances - Scientific guideline
- ICH Q3B (R2) Impurities in new drug products - Scientific guideline
- ICH Q3C (R8) Residual solvents - Scientific guideline
- ICH Q3D Elemental impurities - Scientific guideline

Regulatory acceptance

- ICH Q4B Evaluation and recommendation of pharmacopoeia texts for use in the ICH regions - Scientific guideline
- ICH Q4B Annex 1 Residue on ignition/sulphated ash - Scientific guideline
- ICH Q4B Annex 2 Test for extractable volume in parenteral preparations - Scientific guideline
- ICH Q4B Annex 3 Test for particulate contamination: sub-visible particles - Scientific guideline
- ICH Q4B Annex 4A Microbiological examination of non-sterile products: microbial enumeration tests - Scientific guideline
- ICH Q4B Annex 4B Test for microbiological examination of non-sterile products: tests for specified microorganisms - Scientific guideline
- ICH Q4B Annex 4C Test for microbiological examination of non-sterile products: acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use - Scientific guideline
- ICH Q4B Annex 5 Disintegration test - Scientific guideline
- ICH Q4B Annex 6 Uniformity of dosage unites general chapter - Scientific guideline
- ICH Q4B Annex 7 Dissolution test - Scientific guideline
- ICH Q4B Annex 8 Sterility test - Scientific guideline
- ICH 4 QB Annex 9 Tablet friability - Scientific guideline
- ICH Q4B Annex 10 Polyacrylamide gel electrophoresis - Scientific guideline
- ICH Q4B Annex 11 Capillary electrophoresis - Scientific guideline
- ICH Q4B Annex 12 Analytical sieving - Scientific guideline
- ICH Q4B Annex 13 Bulk density and tapped density of powders - Scientific guideline
- ICH Q4B Annex 14 Bacterial end toxins tests - Scientific guideline

Quality of biotechnological products

- ICH Guideline Q5A(R2) on viral safety evaluation of biotechnology products derived from cell lines of human or animal origin - Scientific guideline
- ICH Q5B Analysis of the expression construct in cell lines used for production of rDNA-derived protein products - Scientific guideline
- ICH Q5C Stability testing of biotechnological/biological products - Scientific guideline
- ICH Q5D Derivation and characterization of cell substrates used for production of biotechnological/biological products - Scientific guideline
- ICH Q5E Biotechnological/biological products subject to changes in their manufacturing process: comparability of biotechnological/biological products - Scientific guideline

Specifications

- ICH Q6A specifications: test procedures and acceptance criteria for new drug substances and new drug products: chemical substances - Scientific guideline
- ICH Q6B Specifications: test procedures and acceptance criteria for biotechnological/biological products - Scientific guideline

Good manufacturing practice

- ICH Q7 Good manufacturing practice for active pharmaceutical ingredients - Scientific guideline

Pharmaceutical development

- ICH Q8 (R2) Pharmaceutical development - Scientific guideline
- ICH Q9 Quality risk management - Scientific guideline
- ICH Q10 Pharmaceutical quality system - Scientific guideline
- ICH Q8, Q9 and Q10 - questions and answers - Scientific guideline
- ICH Q11 Development and manufacture of drug substances (chemical entities and biotechnological/biological entities) - Scientific guideline
- ICH guideline Q13 on continuous manufacturing of drug substances and drug products - Scientific guideline

Lifecycle management

- ICH Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management - Scientific guideline

ICH: safety

For a complete list of scientific guidelines currently open for consultation, see Public consultations.

- Nonclinical safety in pediatric medicines
- Carcinogenicity studies
- Genotoxicity studies
- Toxic kinetics and pharmacokinetics
- Repeat-dose toxicity
- Reproductive toxicology
- Biotechnological products
- Safety pharmacology studies
- Immunotoxicology studies
- Therapeutic area-specific
- Photo safety evaluation

Nonclinical safety in pediatric medicines

- ICH guideline S11 on nonclinical safety testing in support of development of pediatric pharmaceuticals - Step 5 - Scientific guideline

Carcinogenicity studies

- ICH S1 Regulatory notice on changes to core guideline on rodent carcinogenicity testing of pharmaceuticals - Scientific guideline
- ICH S1A Need for carcinogenicity studies of pharmaceuticals - Scientific guideline
- ICH guideline S1B(R1) on testing for carcinogenicity of pharmaceuticals - Scientific guideline
- ICH S1C (R2) Dose selection for carcinogenicity studies of pharmaceuticals - Scientific guideline

Genotoxicity studies

- ICH S2 (R1) Genotoxicity testing and data interpretation for pharmaceuticals intended for human use - Scientific guideline

Toxic kinetics and pharmacokinetics

- ICH S3A Toxic kinetics: the assessment of systemic exposure in toxicity studies - Scientific guideline
- ICH S3A Toxic kinetics: the assessment of systemic exposure in toxicity studies - questions and answers - Scientific guideline
- ICH S3B Pharmacokinetics: repeated dose tissue distribution studies - Scientific guideline

Repeat-dose toxicity
- ICH S4 Duration of chronic toxicity testing in animals (rodent and non-rodent toxicity testing) - Scientific guideline

Reproductive toxicology
- ICH S5 (R3) Guideline on detection of reproductive and developmental toxicity for human pharmaceuticals - Scientific guideline

Biotechnological products
- ICH S6 (R1) Preclinical safety evaluation of biotechnology-derived pharmaceuticals - Scientific guideline

Safety pharmacology studies
- ICH S7A Safety pharmacology studies for human pharmaceuticals - Scientific guideline
- ICH S7B Non-clinical evaluation of the potential for delayed ventricular depolarization (QT interval prolongation) by human pharmaceuticals - Scientific guideline

Immunotoxicology studies
- ICH S8 Immunotoxicity studies for human pharmaceuticals - Scientific guideline

Therapeutic area-specific
- ICH S9 Non-clinical evaluation for anticancer pharmaceuticals - Scientific guideline

Photo safety evaluation
- ICH S10 Photo safety evaluation of pharmaceuticals - Scientific guideline

ICH: efficacy
- Clinical safety
- Clinical study reports
- Dose-response studies
- Ethnic factors
- Good clinical practice
- Clinical trials
- Clinical evaluation by therapeutic category
- Clinical evaluation

Clinical safety
- ICH E1 Population exposure: the extent of population exposure to assess clinical safety - Scientific guideline
- ICH E2A Clinical safety data management: definitions and standards for expedited reporting - Scientific guideline
- ICH E2B (R3) Electronic transmission of individual case safety reports (ICSRs) - data elements and message specification - implementation guide - Scientific guideline
- ICH E2C (R2) Periodic benefit-risk evaluation report - Scientific guideline
- ICH E2D Post-approval safety data management - Scientific guideline
- ICH E2E Pharmacovigilance planning (Pvp) - Scientific guideline
- ICH E2F Development safety update report - Scientific guideline
- ICH guideline E19 on a selective approach to safety data collection in specific late-stage pre-approval or post-approval clinical trials - Scientific guideline

Clinical study report
- ICH E3 Structure and content of clinical study reports - Scientific guideline

Dose response studies
- ICH E4 Dose response information to support drug registration - Scientific guideline

Ethnic factors
- ICH E5 (R1) Ethnic factors in the acceptability of foreign clinical data - Scientific guideline
- ICH E5(R1) Ethnic factors in the acceptability of foreign clinical data - questions and answers - Scientific guideline

Good clinical practice
- ICH E6 (R2) Good clinical practice - Scientific guideline

Clinical trials
- ICH E7 Studies in support of special populations: geriatrics - Scientific guideline
- ICH E7 Studies in support of special populations: geriatrics - questions and answers - Scientific guideline
- ICH E8 General considerations for clinical studies - Scientific guideline
- ICH E9 statistical principles for clinical trials - Scientific guideline
- ICH E10 Choice of control group in clinical trials - Scientific guideline
- ICH E11(R1) step 5 guideline on clinical investigation of medicinal products in the pediatric population - Scientific guideline
- ICH guideline E11A on pediatric extrapolation - Scientific guideline
- ICH guideline E17 on general principles for planning and design of multi-regional clinical trials - Scientific guideline
- ICH E18 Guideline on genomic sampling and management of genomic data - Scientific guideline

Clinical evaluation by therapeutic category
- ICH E12 Principles for clinical evaluation of new antihypertensive drugs - Scientific guideline

Clinical evaluation
- ICH E14 Clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-ant arrhythmic drugs - Scientific guideline
- ICH E14 (R3) Clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-ant arrhythmic drugs - questions and answers - Scientific guideline
- ICH E15 Definitions for genomic biomarkers, pharmacogenomics, pharmacokinetics, genomic data and sample coding categories - Scientific guideline
- ICH E16 Genomic biomarkers related to drug response: context, structure and format of qualification submissions - Scientific guideline

ICH: multidisciplinary
- ICH M2 Electronic common technical document (eCTD) - file format criteria - Scientific guideline
- ICH M2 Electronic common technical document (eCTD) - Scientific guideline
- ICH M2 Business requirements - Scientific guideline
- ICH M3 (R2) Non-clinical safety studies for the conduct of human clinical trials for pharmaceuticals - Scientific guideline
- ICH M4 Common technical document (CTD) for the registration of pharmaceuticals for human use - organization of CTD - Scientific guideline

- ICH M4 Common technical document for the registration of pharmaceuticals for human use: questions and answers - Scientific guideline
- ICH M4Q Common technical document for the registration of pharmaceuticals for human use - quality - Scientific guideline
- ICH M4Q Location issues for common technical document for the registration of pharmaceuticals for human use - quality: questions and answers - Scientific guideline
- ICH M4E Common technical document for the registration of pharmaceuticals for human use - efficacy - Scientific guideline
- ICH M4E Common technical document for the registration of pharmaceuticals for human use - efficacy: questions and answers - Scientific guideline
- ICH M4S Common technical document for the registration of pharmaceuticals for human use - safety - Scientific guideline
- ICH M4S Common technical document for the registration of pharmaceuticals for human use - safety: questions and answers - Scientific guideline
- ICH M5 Data elements and standards for drug dictionaries - Scientific guideline
- ICH M5 EWG Routes of administration controlled vocabulary - Scientific guideline
- ICH M5 EWG Units and measurements controlled vocabulary - Scientific guideline
- ICH M7 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk - Scientific guideline
- ICH M8 Electronic common technical document (eCTD) v4.0 draft ICH implementation guide v2.0 - Scientific guideline
- ICH M9 on biopharmaceutics classification system based biowaivers - Scientific guideline
- ICH M10 on bioanalytical method validation - Scientific guideline
- ICH M11 guideline, clinical study protocol template and technical specifications - Scientific guideline
- ICH M12 on drug interaction studies - Scientific guideline
- ICH Guideline M13A on bioequivalence for immediate-release solid oral dosage forms - Scientific guideline

Conclusion: Scientifically grounded ICH guidelines that eliminate superfluous research will lower development costs, enhance safety, and enable the release of drugs worldwide based on a single compliance. These guidelines are especially important for developing nations that lack the knowledge and resources to assess biosimilar submissions.

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