ICH Guidelines: PROCESS

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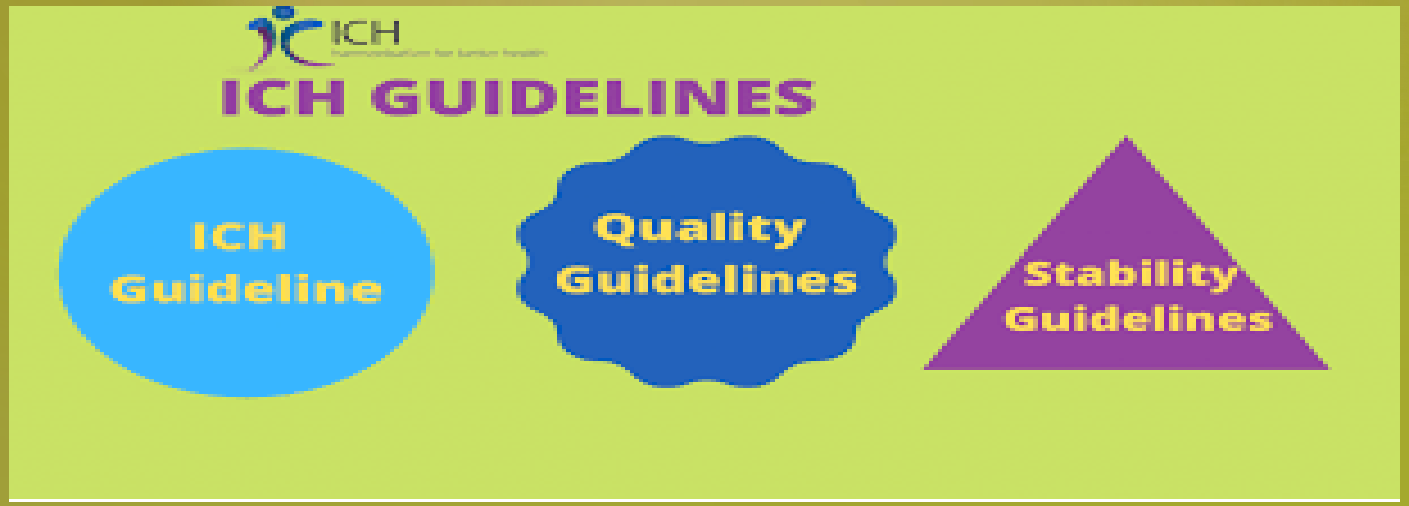
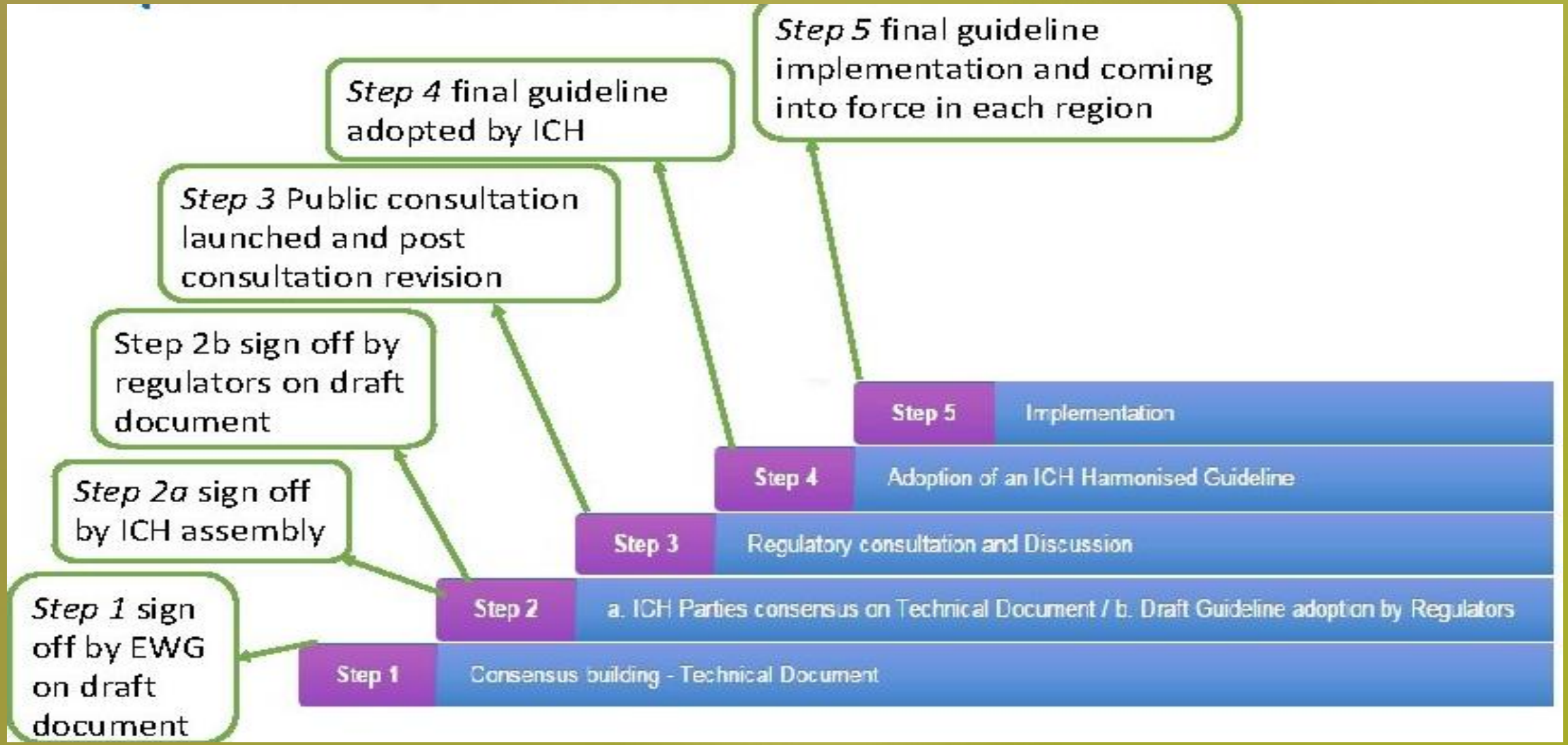


Steps involved in ICH Procedures



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- **Step 1:- Drafts are prepared and circulated through many revisions until a "final harmonized draft" is completed under the leadership of the Rapporteur.**
- **Step 2:-This draft is signed by the expert working group (EWG) as the agreed-upon draft and forwarded to the Steering Committee for signing, which signifies acceptance for consultation by each of the six co-sponsors.**
- **Step 3:-This comment period normally takes six months. If both regulatory and industry parties of the EWG are satisfied that the consensus achieved at Step 2, the document with regulatory EWG signatures is submitted to the Steering Committee to request adoption as Step 4 of the ICH process.**
- **Step 4: It is reached when the Steering Committee agrees that there is sufficient scientific consensus on the technical issues.**
- **Step 5: The process is complete when the guidelines are incorporated into national or regional internal procedures**

ICH Guidelines(Q.S.E.M)

- **ICH Guidelines have been adopted as law in several countries, but are only used as guidance for the US Food and Drug Administration.**
- **The guidelines of ICH may be broadly categorized into four types:-**

Quality Guidelines

Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.

Safety Guidelines

ICH has produced a comprehensive set of safety Guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy for assessing the QT interval prolongation liability: the single most important cause of drug withdrawals in recent years.

Efficacy Guidelines

The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/genomics techniques to produce better targeted medicines.

Multidisciplinary Guidelines

Those are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories. It includes the ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

Quality Guidelines

Q1A - Q1F Stability

Q2 Analytical Validation

Q3A - Q3E Impurities

Q4A - Q4B Pharmacopoeias

Q5A - Q5E Quality of Biotechnological Products

Q6A- Q6B Specifications

Q7 Good Manufacturing Practice

Q8 Pharmaceutical Development

Q9 Quality Risk Management

Q10 Pharmaceutical Quality System

Q11 Development and Manufacture of Drug Substances

Q12 Lifecycle Management

Q13 Continuous Manufacturing of Drug Substances and Drug Products

Q14 Analytical Procedure Development

Safety Guidelines

- S1A - S1C Carcinogenicity Studies
- S2 Genotoxicity Studies
- S3A - S3B Toxicokinetics and Pharmacokinetics
- S4 Toxicity Testing
- S5 Reproductive Toxicology
- S6 Biotechnological Products
- S7A - S7B Pharmacology Studies
- S8 Immunotoxicology Studies
- S9 Nonclinical Evaluation for Anticancer Pharmaceuticals
- S10 Photosafety Evaluation
- S11 Nonclinical Paediatric Safety
- S12 Non-clinical Biodistribution Considerations for Gene Therapy Products

Efficacy Guidelines

- E1 Clinical Safety for Drugs used in Long-Term Treatment
- E2A - E2F Pharmacovigilance
- E3 Clinical Study Reports
- E4 Dose-Response Studies
- E5 Ethnic Factors
- E6 Good Clinical Practice
- E7 Clinical Trials in Geriatric Population
- E8 General Considerations for Clinical Trials
- E9 Statistical Principles for Clinical Trials
- E10 Choice of Control Group in Clinical Trials
- E11 - E11A Clinical Trials in Pediatric Population
- E12 Clinical Evaluation by Therapeutic Category
- E14 Clinical Evaluation of QT
- E15 Definitions in Pharmacogenetics / Pharmacogenomics
- E16 Qualification of Genomic Biomarkers
- E17 Multi-Regional Clinical Trials
- E18 Genomic Sampling
- E19 Safety Data Collection
- E20 Adaptive Clinical Trials

Multidisciplinary Guidelines

M1 MedDRA Terminology
M2 Electronic Standards
M3 Nonclinical Safety Studies
M4 Common Technical Document
M5 Data Elements and Standards for Drug Dictionaries
M6 Gene Therapy
M7 Mutagenic impurities
M8 Electronic Common Technical Document (eCTD)
M9 Biopharmaceutics Classification System-based Biowaivers
M10 Bioanalytical Method Validation
M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)
M12 Drug Interaction Studies
M13 Bioequivalence for Immediate-Release Solid Oral Dosage Forms

References

- https://www.ich.org/page/multidisciplinary-guidelines
- https://www.ich.org/page/process-harmonisation
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