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Overview on ICH guidelines for pharmacovigilance

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ABSTRACT

ICH- international council for harmonization of technical requirements for pharmaceuticals for human use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH mission is to achieve greater harmonization worldwide to ensure that safe, effective and high quality medicines are developed and registered in the most resource –efficient manner. Harmonization achievements in quality area include pivotal milestone such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more manufacturing practice (GMP) risk management. The major aim of ICH To achieve greater harmonization in the interpretation and application of technical guidelines for the registration of new active substances or products obtained by biotechnology by its members; to improve the efficiency of global drug development; to reduce redundant studies; and to improve pharmacovigilance activities and quality assurance.

Keyword: ICH, Hormonisation, ICH Guidelines, Stability Studies, Regulatory Guidelines.

INTRODUCTION

ICH is the "International Conference on Harmonization" of technical requirements for the registration of pharmaceuticals for human use.To assure safety, quality and efficacy of medicines, the members of ICH who include members from drug regulatory authorities and research based industries of European Union, US and Japan.[1]The guideline addresses the submitted in registration applications for new information to be molecular entities and associated drug products. This guideline does not currently seek to cover the information to be submitted for abbreviated or abridged applications, variations, clinical trial applications, etc. [2] First decade saw significant progress in the development of Tripartite ICH Guidelines on Safety, Quality and Efficacy topics. Work was also undertaken on a number of important multidisciplinary topics, which included MedDRA (Medical Dictionary for Regulatory Activities) and the CTD (Common Technical Document). [3]

Objectives of ICH

- Harmonization of legislative & technical requirements
- Mutual acceptance of data between Europe, Japan & US
- To reduce cost of research work duplications
- To reduce time-frame for global marketing of newer drugs after approval
- To maintain & formulate guidelines on quality, safety & efficacy-basedregulations, for consumer & patient benefits. [4]

Location of ICH

- The ICH Secretariat is based in Geneva

- Biennial meetings & conferences of ICH Steering Committee shuffle betweenthe European Union, Japan & the US. [5]

ICH members

- ICH consists of representatives from 6 parties that represent the regulatorybodies& research-based industry in the EU, Japan & the USA
- In Japan, the members include:a.Ministry of Health, Labour &Welfare(MHLW), b.Japan Pharmaceutical Manufacturers Association(JPMA)
- In Europe, the members include:a.European Union(EU), b.European Federation of Pharmaceutical Industries and Associations(EFPIA)[6].

Process of Harmonisation

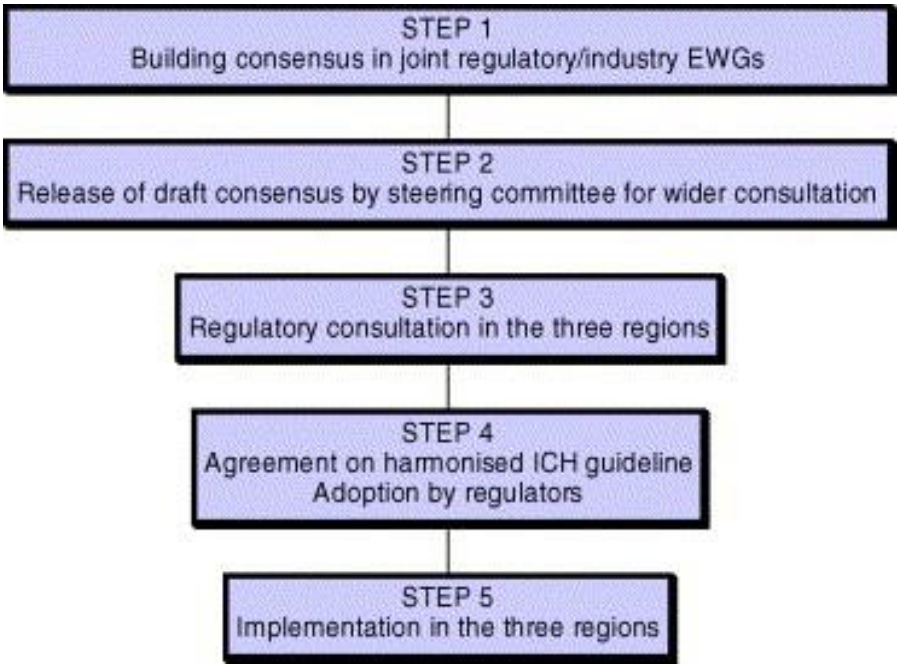

Fig 1: Process of Hormonization[7]

ICH guidelines

Quality Guidelines

This guideline is intended to provide recommendations on how to use stability data generated in accordance with the principles detailed in the ICH guideline "Q1A(R) Stability Testing of New Drug Substances and Products" to propose a retest period or shelf life in a registration application[8].This guideline describes when and how extrapolation can be considered when proposing a retest period for a drug substance or a shelf life for a drug product that extends beyond the period covered by "available data from the stability study under the long-term storage condition". [9]

Quality Guidelines

Q1A - Q1F	Stability
Q2	Analytical Validation
Q3A - Q3D	Impurities
Q4 - 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

Fig 2: Quality Guideline [9]

Efficacy Guidelines

The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, and safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/ pharmacogenomics techniques to produce better targeted medicines. [10]Refer to topics that deal with clinical studies in human subjects.

Examples include

a.Dose Response Studies
b.Good Clinical Practices, etc

Guidelines mainly deal with

1.Clinical safety
2.Structure& content of clinical safety reports
3.Dose-Response Information to Support Drug Registration
4.Ethnic Factors in the Acceptability of Foreign Clinical Data
5.Good Clinical Practice: Consolidated Guidelines
6.Guidelines for Clinical Trials
7.Guidelines for Clinical Evaluation by Therapeutic Category
8. Genomic Biomarkers Related to Drug Response: Context, Structure andFormat of Qualification Submissions, etc.[11]

Safety Guidelines

ICH has produced a comprehensive set of safety Guidelines to uncover potential risks like carcinogenicity,genotoxicity and reprotoxicity[12]. 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.• Include S1-S9 guidelines• Mainly deal with in-vivo& in-vitro pre-clinical studies. [13]

Multidisciplinary Guidelines

Those are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories [14]. 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). [15]

CONCLUSION

Present study sums up the important land marks in the development of the guidelines for stability studies. It is hoped that a ready to start reference is generated by the study. FDA, ICH, CPMP, & WHO guidelines of specific conditions for stability studies and specifically, ICH Q1A (R2) are needed to be taken into account for stability study. Its value has not been quantified; however, the companies able to embrace these principles today will be the world leaders tomorrow. Companies who fail to see the value of harmonization the value that is already being felt by the scientists carrying out the development, and the value that is yet to be realized in the full drug development cycle- will be left at the starting line of the industry's globalization race.Harmonization 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.The ICH is a major global undertaking to affect the harmonization of regulatory requirements in the 3 major regions involved. The creation of the ICH – the International Conference of Harmonization, was fuelled by trade reasons, to even out the competition between markets and end the aforementioned stagnation. ICH was created to deliver health care technology providers a common, almost global regulatory framework for them to develop their products. The ICH's work is far from over, as more and more regulatory scrutiny is demanded from manufacturers and investigators and more pressure is applied to Pharmaceutical companies to increase data transparency, who look up for ICH's guidance.

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