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ICH- INTERNATIONAL CONFERENCE ON HARMONIZATION

INTRODUTION:-

- The complete name of (ICH) is the (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use).
- Originally founded in April 1990
- It is a global organization that brings together regulatory authorities and the pharmaceutical industry to develop guidelines and standards for drug development and registration.
- It aims to promote international harmonization to ensure the safety, efficacy, and quality of medicinal products.

OBJECTIVES

- Promotion public health by early availabiliaty of drug in market.
- Maintaining safeguards on quality safety and efficacy.
- Improve efficiency of new drug development reduce the registration cost.
- Prevention the duplication clinical trials in human .
- Minimize the animal use.
- Mutual acceptance of clinical data by regulatory authority.
- Reducing testing duplication .

WHY...?

The Disasters

- **1937:** 100 patients died, due to diethylene in sulpha preparation(sulfanilamide)
- **1950:** Aplastic anaemia on Chloramphenicol
- **1961:** Softenon (thalidomide) catastrophe in Europe
- **March 2006:** The drug TGN1412 caused catastrophic systemic failures in the subjects during. Its first human clinical trials (phase I). Following this, an Expert Group on Phase in One Clinical Trials published a report.

GOAL

- To promote international harmonization 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 activites and ICH guideline to any country or company that requests the information.
- To promote the mutual understanding of regional initiatives in to faciliatate harmonization processes related to ICH guidelines regionally and globally .

ICH MEMBERS

- EU- European Union
- EFPIA- (European Federation of Pharmaceutical Industries Associations)
- MHLW-(Ministry of Health Labour and Welfare Japan)
- JPMA-(Japan Pharmaceutical Manufacture Association)
- US FDA
- PhRMA(Pharmaceutical research and manufacturings Assoication
- Observers:- WHO, TPP (Canada)

ICH GUIDELINE

- **EFFICACY:-**
- **SAFETY:-**
- **QUALITY:-**
- **MULTIDISCIPLINARY:-**

QUALITY

- Harmonization achievements in the quality area include such as the conduct of stability studies defining relevant thresholds for impurities testing a more flexiable approach to pharmaceutical quality based on good manufacturing Practice (GMP) risk management.
- **Quality guidelines ;**
- Q1A-QIF**:**Stability
- Q2: Analytical validation
- Q3A-Q3D:Impurities
- Q4A-4B:Pharmacopoeia
- Q5A-Q5E:Quality of biotechnological product
- Q5A-Q6B :Specification
- Q7:Good manufacturing practice
- Q8:Pharmaceutical development

Continued…….

- Q9:Quality risk managements
- Q10:Pharmaceutical quality system
- Q11:Development and Manufacturing of Drug substance
- Q12:Life cycle Managements
- Q13:Continuous Manufacturing of Drug substance and Drug Product
- Q14:Analytical Procedure Development

SAFETY

- ICH has produced a comprehensive set of safety Guidelines to potential risks like carcinogenicity, genotoxicity and reprotoxicity etc..,
- **Safety Guidelines;**
- S1A-S1C:Carcinogenicity studies
- S2:Genotoxicity studies
- S3A-S3B: Toxicokinetic and Pharmacokinetics
- S4:Toxicity testing
- S5:Reproductive Toxicology
- S6: Biotechnological Product

Continued…..

- S7A-S7B: Pharmacology studies
- S8:Immunotoxicology studies
- S9 : Non clinical evaluation for Anticancer Pharmaceuticals
- S10 : Photosafety evaluation

EFFICACY

- The work carried out by ICH under the efficacy heading is concerned with the design ,conduct, safety , and reporting of clinical trials .
- It covers novel types of medicine derived from biotechnological processes and the use of pharmacogenetic/ genomics techniques to produce better targeted medicine.
- **Efficacy guidelines:**
- E1**:** Clinical safety for drugs used in long Term Treatment
- E2A-E2F: Pharmacovigilance
- E3:Clinical study reports
- E4:Dose Responce studies
- E5: Ethic Factors

Continued ……

- E6: Good clinical Practice
- E7: Clical Trials in Geriatics Population
- E8: General Considerations for Clinical Trials
- E9:Statistical Principles for clinical Trials
- E10:Choice of Controls groups in Cinical Trials
- E11-E11A:Clinical Trials in Pediatric Population
- E12:Clinical Evaluation by Therapeutics Category
- E14:Clinical Evaluation of QT
- E15:Definations in Pharmacogentics/Pharmacogenomics
- E17:Multi-Regionals Clinical Trials
- E18: Genomics sampling

MULTIDISCIPLINARY

- These are the cross-cutting topics which do not fit uniquely into one of the Quality, safety and Efficacy categorises.
- It included the the ICH medical terminology (Med DRA),the common techincal document (CTD)and the development of Electronic standards for the Transfer of Regulatory Information (ESTRI).
- **Multidisciplinary Guideline:**
- M1:MedDRA Terminology
- M2: Electronic standards
- M3:Non Clinical Safety Studies
- M4:Common Technical Document

Continued…..

- M5: Data Elements and Standards for Drug Dictionaries
- M6:Gene Therapy
- M7:Mutagenic Impurities
- M8:Electroinc Common Technical Document
- M9:Biopharmaceutics Classification System
- M10:Bioanalytical Method Validation