- ICH-GCP is an International Conference on Harmonization Good Clinical Practice.
- The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Heath Organization.
- The birth of ICH (International Conference on Harmonization) took place at a meeting in April 1990, hosted by the European Federation of --- Pharmaceuticals Industries and Association (EFPIA) in Brussels.
- The ICH screening Committee which was established at the meeting has since met at least twice in a year, with the location rotating between the three regions.

- Sponsors and regions of ICH-GCP:

.EMEA: The European Medicines Agency

.EFPIA: European Federation of Pharmaceutical Industries Association.

PhRMA: Pharmaceutical Research and Manufactures of America

- JMHW: Japanese Ministry of Health Welfare
- JPMA: Japanese Pharmaceutical Manufacture Association

□ Members of ICH:

- All the Sponsors are members of ICH. Additional members include observers from WHO, European Free Trade Association (EFTA), Canada and Switzerland.
- European commission: represents (نمایندگی کردن) 25 members of the EU. The commission has set up (تاسیس کردن) the European medicines agency (EMEA) and the committee for medicinal products for human use (CHMP) of the EMEA provides the technical and scientific support for all the ICH activities. EMEA is situated in London
- EFPIA: situated in Brussels and comprises 25 national pharmaceutical industry associations, including 6 associations with liaison status,

and 43 leading pharmaceutical companies involved in research, development and manufacturing of medicinal products in Europe, for human use.

- JMHW: All technical support and scientific support for ICH related activities are provided by the pharmaceuticals and medical device agency, national institute of health sciences and other expert academic bodies.

- JPMA: consist of 90 major research based pharmaceutical manufacturers in Japan.

- USFDA: largest regulatory agency in the world, is responsible for the approval of all drug products used in US. Two centres namely, Centre for Research and the Centre for Biologics evaluation and research give technical advice for ICH work.

PhRMA: 67 member companies and 24 research affiliates involved in the discovery, development

and manufacture of prescription medicines.

Good clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this Standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

□Objectives:

- To provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

• To identify and then to reduce differences in technical requirements for drug development among regulatory agencies.

AIMS:-

• Unify registration requirements for new products
• Reduce medicinal product development cost, more economic use of animal, human and material resources.
• Accelerate medicinal product licensing times, avoid repeat testing in different regions
• Increase patent protection times through reducing delay in licensing times.

Principles of Guidelines:

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2. Before a trial is initiated; foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3. The rights, safety and well being of the trial subjects are the most important considerations and should prevail over interests of science and society.

4. The available non-clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol

6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/Independent ethics committee

(IEC) approval/favorable opinion.

7. The medical care given to, and medical decisions made on behalf of subjects should always be the responsibility of a qualified physician or when appropriate of a qualified dentist.

8. Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s).

9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.

10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

12. Investigational products should be manufactured, handled, and stored in accordance with the applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

13. Systems with the procedures that assure the quality of every aspect of the trial should be implemented.

□ The ICH topics are basically divided into four broad and major Categories:

• Quality: relating to chemical and pharmaceutical quality assurance. These comprise of Q1-stability testing, Q3-impurity testing, Q5-quality of biotechnol-

ogical products and Q7: good manufacturing practices.

- Safety: topics related to invivo and in vitro preclinical Studies for eg, S1- carcinogenicity studies, S2- genotoxicity Studies, S5- reproductive toxicology, S7- pharmacology studies.

- Efficacy- topics related to clinical studies in human subjects for eg, E4- dose response studies, and E7 clinical trials.

- Multidisciplinary: those that do not fit into one of the above. M1- medical terminology, M2- electronic standards for transmission of regulatory information (ESTRI), M3- timing of preclinical studies in relation to clinical trials, and M4- the common technical document.

[redacted]

The Declaration of Helsinki is a statement of ethical Principles developed by the World Medical Association to "provide guidance to physicians and other participants in medical research involving human subjects" (Para 1, Declaration of Helsinki).

- This includes research on people, identifiable human material or identifiable data.
- The Declaration was first adopted in 1964 and has since undergone several revisions (1975, 1983, 1989, 1996, 2000 and in 2008) to accommodate advances in medical science and ethical problems.

The Declaration includes principles on:

- Safeguarding research subjects
- Informed consent
- Minimising risk
- Adhering to an approved research plan/protocol

The Declaration is considered a fundamental document in the ethics of healthcare research.

As a result, the principles have been embodied in subsequent UK and International guidance and regulations.