

# The Essentials of Good Clinical Practice (GCP)

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# *Objectives*

**Upon completion of this module, you will be able to:**

- **Explain the origin and purpose of Good Clinical Practice (GCP).**
- **Describe the International Conference on Harmonization's Good Clinical Practice Guidelines (ICH GCP Guidelines)**
- **Discuss the GCP Guidelines and their importance in conducting safe, ethical, and sound clinical research**

## *Objectives (Continued)*

- **Discuss the rationale for the development and implementation of Standard Operating Procedures (SOPs).**

# *Good Clinical Practice*

- **Is a standard for designing, conducting, performing, monitoring, auditing, recording, analyzing, and reporting clinical trials**
- **Provides assurance that data and reported results are credible and accurate and that the rights and confidentiality of subjects are protected**

# *Elements of Good Clinical Practice*



- **Federal Regulations**  
“The letter of the law”
- **Regulatory Agency Guidelines**
- **ICH GCP Guidelines**  
“The spirit of the law”

- **Other government regulations**
- **State and local laws**
- **Sponsor, site, ERC/EC/IRB, SOPs**
- **Practice Acts and Licensure**
- **Standards of Care**

# *Relationship Between GCP Elements*

**ICH Guidelines**

*Country Laws*

*Sponsor SOPs*

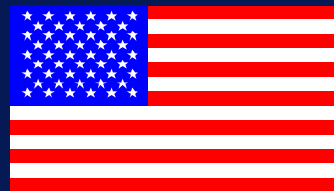
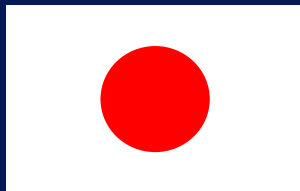
*State Regulations*

*Site SOPs*

*IRB SOPs*

# ICH (International Conference on Harmonization) GCP Guidelines

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



# *ICH GCP Guidelines*

**The ICH Guidelines are an effort to define GCP and to create and provide a unified standard for designing, conducting, recording and reporting trials that involve the participation of human subjects**



# *Objectives of the ICH GCP Guidelines*

- **Achieve greater agreement in interpreting and applying technical guidelines and requirements for product registration**
- **Eliminate unnecessary delay in:**
  - Global development
  - Availability of new medicines
- **Maintain safeguards to protect public health**

# *Organization of ICH GCP Guidelines*

**GCP Guidelines are organized into eight sections:**

- 1) Glossary of Terms
- 2) The Principles of ICH GCP
- 3) Institutional Review Board (IRB), or  
Independent Ethics Committee (IEC)
- 4) The Investigator
- 5) The Sponsor
- 6) Clinical Trial Protocol and Protocol Amendments
- 7) The Investigator's Brochure
- 8) Essential Documents for the Conduct of a Clinical Trial

# *Organization of ICH GCP Guidelines*

**Each section contains specific definitions and outlines the essential responsibilities of Investigators and Sponsors in conducting clinical trials and the elements that must be contained in trial protocols and the Investigator's Brochure.**

# *The Principles of ICH GCP*

- 2.1 - Clinical trials should be conducted in an ethical manner**
- 2.2 - A trial should be initiated and continued only if the anticipated benefits outweigh the risks**
- 2.3 - Protecting the rights, safety, and well-being of human subjects is more important than the interests of science and society**
- 2.4 - The available nonclinical and clinical information on an investigational product should adequately support the proposed trial**

## *The Principles of ICH GCP (Cont.)*

- 2.5 - Clinical trials should be scientifically sound, and described in a clear, detailed protocol**
- 2.6 - A trial should be conducted in compliance with the protocol that has received prior IRB/IEC approval**
- 2.7 - Qualified physicians are responsible for the medical care given to, and medical decisions made on behalf of, the subjects**
- 2.8 - Individuals involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)**

## *The Principles of ICH GCP (Cont.)*

- 2.9 - Freely given informed consent should be obtained from every subject prior to clinical trial participation**
- 2.10 - All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification**
- 2.11- Protect the identity of the subjects, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements**

## *The Principles of ICH GCP (Cont.)*

- 2.12 - Investigational products should be manufactured, handled and stored according to Good Manufacturing Practice (GMP). They should be used in accordance with the approved protocol**
- 2.13 - Systems with procedures that assure the quality of every aspect of the trial should be implemented**

## ***3.1 - 3.4 ICH GCP and the IRB***

- **The Institutional Review Board (IRB) exists to safeguard the rights, safety, and well being of all trial subjects**
- **ICH GCP Guideline for IRBs outlines the following:**
  - 3.1 Responsibilities**
  - 3.2 Composition, Functions, and Operations**
  - 3.3 Procedures**
  - 3.4 Records**



## *4.1 - 4.13 ICH GCP and the Investigator*

***An Investigator is defined as the person responsible for the conduct of the clinical trial at a trial site***

**The Guideline outlines the following:**

- 4.1 The Investigator's Qualifications and Agreements
- 4.2 What constitutes "Adequate Resources" to conduct a trial
- 4.3 Standards for providing "Medical Care of Trial Subjects"
- 4.4 Communications with the IRB
- 4.5 The need for "Compliance with the Protocol"
- 4.6 Handling of "Investigational Product(s)"

## *4.1 - 4.13 ICH GCP and the Investigator (Cont.)*

- 4.7 Randomization Procedures and Unblinding
- 4.8 Informed Consent of Trial Subjects
- 4.9 Responsibilities for “Records and Reports”
- 4.10 Need for “Progress Reports”
- 4.11 Responsibilities for “Safety Reporting”
- 4.12 What to do with “Premature Termination or Suspension of a Trial”
- 4.13 The “Final Report(s) by the Investigator”

## *Examples of GCP at the Site*

- **Investigator responsibilities**
- **Consent responsibilities**
- **IRB responsibilities**

## *Examples of GCP at the Site (Cont.)*

- **Protocol responsibilities**
- **Study File Maintenance**
- **Study Drug Accountability**

## *5.1 - 5.23 ICH GCP and the Sponsor*

**The Sponsor is responsible for a large number of issues including, but not limited to:**

- 5.1 Quality Assurance and Quality Control
- 5.4 Trial Design
- 5.5 Trial Management, Data Handling, and Record Keeping
- 5.14 Supplying and Handling Investigational Product(s)
- 5.18 Monitoring
- 5.19 Auditing

## *6.1 - 6.6 ICH GCP and Trial Protocols*

**Protocols should include the following:**

- 6.1 General information on the trial, including contact information
- 6.2 Background information on the specific trial
- 6.3 Trial objectives and purpose
- 6.4 The trial design
- 6.5 Inclusion/exclusion and discontinuation criteria of subjects

## *7.1 - 7.5 Investigator's Brochure*

### **Confidential Investigator's Brochure (CIB):**

***“A compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects...”***

# *The Essentials of Good Clinical Practice*

## ❖ The Essence of GCP:

1. Human subject protection
2. Data integrity and validity
3. Investigational product control and accountability



# *FDA GCP Inspections*

## ❖ FDA GCP Inspections:

- Fiscal 2005 Total: 646
  - CDER: 354
    1. Protocol violations
    2. Recordkeeping failures
    3. AE reporting failures
    4. Informed consent violations
    5. Drug accountability failures
  - CBER: 109
  - CDRH: 183



# *SOPs*

## ❖ Standard Operating Procedures:

- Detailed, written instructions that the research team follows to achieve uniformity of research procedures and ensure compliance with GCP and all FDA regulations and guidelines for clinical trials conducted at the investigative site.

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**Questions?**

**Thank you!**