Good Clinical Practice Regulations and Guidelines

Intro to Basics GCP 2012 Quality College
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Objectives

At the completion of this training session, you will be able to:

- Understand the requirements of GCP regulations as it relates to auditing
- Know where to find frequently used regulations
- Utilize selected guidance documents to enhance knowledge of GCPs
- Describe the term “Good Clinical Practice”.
Good Clinical Practices (GCPs)

“A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.” (ICH 1.24)
US Regulations and Guidelines Applicable to Clinical Trials

- Code of Federal Regulation (21 CFR)
- Good Manufacturing Practice (GMP)
- Good Laboratory Practices (GLP)
- ICH (International Conference on Harmonization) tripartite guideline: Guideline for Good Clinical Practice (GCP)
GCP - FDA 21 Code of Federal Regulations Chapters

- 21 CFR § 11  Electronic Medical Records
- 21 CFR § 50  Protection of Human Subjects
- 21 CFR § 54  Financial Disclosure by CIs
- 21 CFR § 56  Institutional Review Boards
- 21 CFR § 312  IND Application
- 21 CFR § 314  Applications for FDA Approval to Market a New Drug
Composition
- European Union, Japan, and United States.

Purpose
- To provide an opportunity for the harmonization of drug development regulatory requirements with input from both regulatory and industry representatives.

Goals
- To identify and reduce differences in technical requirements for drug development among member regulatory agencies.
- Develop common testing standards among industrialized nations.

International Conference on Harmonization (ICH) (1991)
13 Principals of ICH

2.1 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).

2.2 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.
13 Principals of ICH cont’d

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

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

2.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
13 Principals of ICH, cont’d.

2.6 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.

2.7 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.

2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
13 Principals of ICH cont’d

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 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).
13 Principals of ICH, final

2.12 Investigational products should be manufactured, handled, and stored in accordance with applicable 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.
Exercise

Which section of the CFR will you find references for the following findings?

- General responsibilities of PIs
- Refusal to approve an application
- Elements of Informed Consent
- IRB composition and processes
- Financial Disclosure for PIs and SubIs
- Validation of a computer system used for clinical trials
GCP Summary

Why
• To protect trial subject safety and data integrity

Who
• To assure society that in the prevention and treatment of diseases there can be an improved quality of life.

How
• Regulate the process through which evidence of safety and efficacy are developed.
FDA Web Links

- FDA Home
  - http://www.fda.gov/
- DHHS: Department of Health and Human Services
  - http://www.os.dhhs.gov/
- CDER: Center for Drug Evaluation and Research
  - http://www.fda.gov/cder/
- NIH: National Institutes of Health
  - http://www.nih.gov/
- OHRP: Office for Human Research Protection
  - http://ohrp.osophs.dhhs.gov/
- Belmont Report
- FDA Information Sheets for Institutional Review Boards and Clinical Investigators
  - http://www.fda.gov/oc/ohrt/irbs/
ICH Web Links

ICH: International Conference on Harmonization
  • http://www.ich.org/

Declaration of Helsinki
  • http://www.wma.net/e/policy/b3.htm
Spanish and French ICH

Bienvenido


Bonjour

EU Web Links

- European Agency for the Evaluation of Medicinal Products (EMEA)
  - http://www.emea.eu.int/
- European Union Council Directives and Regulations
  - http://europa.eu.int/index_en.htm
- European Forum for Good Clinical Practice (EFGCP)
- European Commission DG3-Pharmaceuticals and Cosmetics
  - http://dg3.eudra.org/F2/home.html
**Other Helpful Web Links**

- **CPGM: Compliance Program Guidance Manuals**
  - [http://www.fda.gov/ora/cpgm/default.htm](http://www.fda.gov/ora/cpgm/default.htm)

- **FDA Information Essential for Clinical Trials**
  - [http://www.mco.edu/research/fda.html](http://www.mco.edu/research/fda.html)

- **Regsource.com**

- **NLM: National Library of Medicine**

- **AAHRPP**
  - [http://www.aahrpp.org/learn/find-an-accredited-organization](http://www.aahrpp.org/learn/find-an-accredited-organization)
Discussion / Questions
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