

GOOD CLINICAL PRACTICES IN CLINICAL TRIALS: A COMPREHENSIVE PROGRAM ON THE ICH, EMA AND FDA GCP GUIDELINES



13th and 14th July 2010, 18.00 – 21.00h

Information

International Relations Office
Universidad CEU San Pablo
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Summary

These seminars provide an introduction to good clinical practices (GCP) in clinical research according to Food and Drug Administration (FDA) and European Medicine Agency (EMA) regulations and International Conference on Harmonization (ICH) guidelines. Topics include: conducting clinical trials in accordance with GCP; regulations established by local, U.S., and international regulatory bodies; the roles and responsibilities of investigators, sponsors, monitors, and auditors.

Participants will learn the principles and practices of clinical research that serve to protect the rights and safety of human research subjects, as mandated by the FDA, EMA and regulated by the International Conference on Harmonization (ICH) Guidelines. Good clinical practices also help assure the quality of the findings produced by a clinical trial.

Objectives

By the end of this course, you will be able to:

- Define the term GCP
- Describe the need for GCP
- Understand the Regulatory Landscape and Bodies pertaining to GCP
- List the members of a research team and describe their roles and responsibilities
- Describe ethical considerations of conducting clinical research
- Define common clinical research terms and acronyms.

Instructors

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Registration: 900 €

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COURSE CONTENTS

Unit 1 – Day 1

The Definition of GCP

- Introduction – Case Study on Fraud
- Historical Perspective - Review of Regulatory Milestones
- Review of Drug Development
- GCP as Mandated by the FDA
- GCP as Recommended by the ICH – A Brief History
- The U.S. FDA - Role and Responsibility
- Other (National and International) Governmental Regulation
- GCP inspections by AEMPS/EMA
 - + Introduction to AEMPS
 - + European Medicines Agencies Network
 - + AEMPS collaboration with EMA:
 - GCP inspections
 - Joint initiative on GCP inspections FDA/EMA (Pilot phase)

Unit 2 - Day 2

The Clinical Research Team

- An Introduction to the Clinical Research Team
- The role and responsibilities of the sponsor and monitor
- Historical Perspective - Review of Regulatory Milestones
- The Role And Responsibilities Of The Investigator
- The Role And Responsibilities Of The IRB
- Summary

