



*First Program  
In The Series*

# The Regulatory Context for Conducting Clinical Trials

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## **Course Introduction**

### **Regulatory Environment in the United States**

Introduction

Legislative Foundations

Center for Drug Evaluation and Research (CDER)

Center for Biologics Evaluation and Research (CBER)

Meetings with FDA: Pre-IND Meeting

FDA Time Frame for Reviews

FDA Time Frame for Reviews: FDA User Fee Act

### **International GCP Regulations**

Overview of International Regulations

GCP in Europe

International Conference on Harmonization (ICH)

### **Institutional Review Boards/Ethics Committees**

Introduction

Sources of Regulations

Membership

Functions and Operations

IRB Responsibilities

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