Applied Good Clinical Practice

Regulatory Environment in the United States
- Evolution of Drug Law in the United States
- Legislative Foundations
- FDA Responsibilities
- Center for Drug Evaluation & Research
- Meetings with FDA
- FDA Time Frame for Reviews
- User Fee Act
- US Regulatory Environment Quiz
- US Regulatory Environment Evaluation

International GCP Regulations
- Good Clinical Practices
- International GCP Laws
- International Conference on Harmonization
- Comparison of US and International GCP Regulations
- IRB/IEC Issues
- Informed Consent Regulations
- Adverse Event Reporting
- Access to Trial Records
- Tips for Conducting Global Studies
- International Regulations Quiz
- International Regulations Evaluation

IRBs/Independent Ethics Committees
- Membership
- Functions and Operations
- IRB/IEC Responsibilities
- IRB/IEC Quiz
- IRB/IEC Evaluation

Investigator Responsibilities
- Investigator Qualifications
- Statement of Investigator Form
- Adequate Resources
- Informed Consent
- Adverse Event Identification
- Drug Accountability
- Records and Reports
- Investigator Responsibilities Quiz
- Investigator Responsibilities Evaluation

Sponsor Responsibilities-Overview
- The Protocol
- Sponsor Obligations
- Monitoring Responsibilities
- Monitors & Their Responsibilities
- Site Initiation Visit
- Routine Monitoring Visits
- Final Monitoring Visit
- Changing CRFs
- Reporting Requirements
- Monitoring Reports
- Investigator Contact Report
- Monitoring Responsibilities Quiz

Clinical Quality Assurance Group
- Typical CQA Group
- CQA Audits
- GCP Audits
- Data Evaluation
- Investigator Site Audit
- Exercise
- Clinical Quality Assurance Group Quiz
- CQA Group Evaluation

FDA Inspections
- Noncompliance Issues
- Regulations Guiding Inspections
- What FDA Will Inspect
- Common Deficiencies
- Inspection Results
- FDA Inspections Quiz
- FDA Inspections Evaluation

Managing FDA Inspections
- Clinical Investigator Inspections
- For Cause Investigator Inspections
- IRB/IEC & CRO Inspections
- Sponsor/Monitor Inspections
- FDA Inspection Procedures
- Managing FDA Inspections Quiz
- Managing FDA Inspections Evaluation

Course Authors

Deirdre F. BeVard, RN
Executive Director, Clinical Research
HealthSouth

Michael Bruckheimer BS
Executive Director
Global Quality Operations
Novartis Pharmaceuticals Corporation

Edda L. Gomez-Panzani MD
Medical Director
Procter & Gamble Pharmaceuticals

Erich K. Jensen
Director, Worldwide Training Development Standards
Parke-Davis

Thomas J. Ott
Director, Worldwide Regulatory Compliance
Bristol-Myers Squibb

Cheryl J. Priest RN
Managing Partner and Executive Director
Falcon Consulting Group, LLC

Wayne A. Sadowski
Associate Director, Quality Systems
Clinical Research & Development
DuPont Pharmaceuticals

Joanne Spallone
Associate Director, Good Clinical Practices
Novartis Pharmaceuticals Corporation

Stan A. Szpindor MS Pharm
Associate Director R&D QA
Shire Pharmaceuticals