AGENDA DAY ONE

7:45-8:00 am - Registration and Continental Breakfast (provided)

8:00-9:00 am - Welcome and Expectations
- What is "good clinical practice"
- The "spirit" of the conference
- Great change in the Industry
- Pharma Industry overview/drug approval process

9:00-10:15 am - Good Clinical Practice: Obligations of the Sponsor and Monitor
- Basic Principals
- International Conference on Harmonization
- Investigator's Responsibilities
- Monitor's Responsibilities
- Company SOPs
- Record Retention

10:15-10:30 am - Break

10:30-11:45 am - Ethical Considerations
- Institutional Review Boards
- Informed Consents
- Financial Disclosure

11:45-12:45 pm - Lunch (provided)

12:45-2:00 pm - Investigator Recruitment and Selection
- Investigator Recruitment
- Potential Investigative Sites
- Investigator Selection Factors
- Site Selection Visits

2:00-3:45 pm - Study Start-Up and Site Initiation Activities  (Break - 2:45-3:00 pm)
- Essential Documents
- Site Initiation
- Subject Recruitment Planning

3:45-5:00 pm - Monitoring Activities and Site Visits
- Purpose
- Preparation
- On-site Document Review
- Visit Summary with Study Personnel
- Visit Report and Follow-up
- Monitoring Activities
AGENDA DAY TWO

8:15-8:30 am - Continental Breakfast (provided)

8:30-10:30 am - Monitoring Activities and Site Visits (continued)
• Case Studies
• Exercises

10:30-10:45 am - Break

10:45-12:00 pm - Risk Based Monitoring
• Budget and Contacts - The Basics
• Essential Documents
• Site Initiation
• Subject Recruitment Planning

12:00-1:00 pm - Lunch

1:00-2:00 pm - Risk Based Monitoring (continued)

2:00-3:00 pm - Quality Assurance Audit
• Difference between Auditing and Monitoring
• Sponsor Audits
• Preparing for an Audit
• FDA Inspections
• FDA Warning Letters
• QA Exercise

3:00-3:15 pm - Break

3:15-4:30 pm - Case Studies