

Important Topics for Clinical Research Professionals in these *Changing Times*

Join us!
Wednesday, August 18, 2010
Louisville, Kentucky



This class addresses critical topics Clinical Research Professionals must know. Topics are reviewed utilizing real world scenarios where class attendees learn industry best practices!

GCP COMPLIANCE: HOW SMALL MISTAKES CAN HAVE BIG CONSEQUENCES

- Identify the effects of errors/mistakes to the outcome of a clinical study
- Compare the term protocol non-compliance and waiver
- Describe methods to ensure consistent source documentation
- Identify the expectations regarding timely review of study-specific data
- Define appropriate delegation of study activities

ESSENTIAL DOCUMENTS: MAINTAINING THE REGULATORY BINDER

- Describe the importance of maintaining the Regulatory Binder during the research process
- Identify the contents of the regulation binder required for conducting a clinical trial
- Describe the maintenance of the regulatory binder during a clinical trial

UNDERSTANDING SITE MONITORING REPORTS AND FOLLOW-UP LETTERS

- Identify current practices utilized by Sponsors and CROs in documenting site monitoring visits
- Discuss common notations in monitoring follow-up letters and how these routinely translate into observations within a site monitoring report
- Compare and contrast the request-content of site monitoring reports as per ICH E6 Guidelines to those reports routinely performed by Sponsors and CROs
- Describe methods site and monitors can utilize to ensure transparency in site monitoring reporting practices

FDA INSPECTIONS: WHAT YOU CAN EXPECT IN AN AUDIT

- Define the phrase "FDA Audit", other audit terminology and expectations from FDA Audit
- Discuss differences between an audit and a routine monitoring visit
- Identify types of FDA audits and how to participate in an FDA Audit

Don't miss out! Register On-Line at www.AureusResearch.com

Contact Hours Earned: Total contact hours are pending. These contact hours of Continuing Nursing Education are provided by the Louisiana State University School of Nursing (LSUHSCSON) to those who complete the course in its entirety. LSUHSC School of Nursing is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's COA. LSBN Provider #6

Location: Norton Healthcare Pavilion
Cranmer Auditorium (Lower Level)
315 East Broadway
Louisville, Kentucky 40202

Time: 8:00 – 8:30 Registration
8:30 – 3:30 Class

Cost: \$199.00/per person

**This event is sponsored by
Norton University and Norton
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part of the Gear Program.**

For Additional Information

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