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Webinar on

4 Courses On Clinical Project Management And Quality Compliance

Webinar Description

This webinar bundle has recorded webinars which address approaches to regulatory affairs project management for the clinical trial, Good Laboratory Practice, GCP requirements, Clinical Trial Computer System Validation, Data quality, and compliance.

The webinar format is 1-1.5 hours of audio-visual presentation, including a brief Q&A session.

This webinar bundle includes below 4 recorded webinars:

Regulatory Affairs Project Management

Validation of GC/ GC-MS methodologies

FDA Compliance and Clinical Trial Computer System Validation

Monitoring a Quality Laboratory to Prevent Non-Compliance

Regulatory Affairs Project Management

Presented by Peggy J Berry

This program will address approaches to regulatory affairs project management for clinical trial applications, marketing authorization applications, and ongoing management of regulatory obligations. The information obtained will enable effective management and tracking of time and resources to complete the project objectives and ensure regulatory compliance.

Validation of GC/ GC-MS methodologies

Presented by John C Fetzer

Instrumental gas chromatography is an analysis is widely used to determine purity, the impurities, and the degradation products of pharmaceuticals. The focus of most validation work is on the methodology, the standard operating procedure (SOP). But validation of the instrumentation and other associated items of column, solvents, and other reagents and chemicals is also an area of focus in an audit.

To meet US EPA or FDA requirements, a method must meet many stringent requirements. The more important of these for specific analytical methods are method validation and instrument validation. To not do so is a non-compliance in which any data is not usable or reportable.

FDA Compliance and Clinical Trial Computer System Validation

Presented by Carolyn Troiano

The cost of adequately validating a clinical trial computer system can be high and must be weighed against system risk and usage. GAMP 5 system classification guidelines can help ensure that a clinical trial system is categorized appropriately, based on the type of system and technology involved. Along with risk, system classification can provide a clear-cut pathway for validating a system, based on the appropriate level of testing and validation effort. In this webinar, you will learn about FDA's expectations for classifying, assessing the risk, testing, and validating a computer system used in clinical trial work. You will learn in detail about the System Development Life Cycle (SDLC) methodology used to approach Computer System Validation (CSV), including all the phases, sequencing of events, deliverables, and documentation. Ongoing maintenance of the system in a validated state will be discussed, as well as governance, archival and retirement.

Monitoring a Quality Laboratory to Prevent Non-Compliance

Presented by John C Fetzer

Data quality and compliance with a required level of performance are measured by statistical tools. Usually, in compliance, there is a very heavy weighing towards only 3-sigma deviations. But statistics gives much more than that. There are other signs that being “out of control” is a building situation. These other statistical patterns can be used to trigger preventive actions without the dire consequence of a non-compliance.

Many problems that arise in an analysis result from causes that start small and grow over time. Others result from an unplanned change in a procedure or the performance of an instrument. These manifest themselves into changed patterns in certain measurable variables. The use of statistical methods to assess and monitor certain variables will be covered, highlighting the predictable patterns.

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