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Webinar on

6 Webinar Courses on Clinical Quality Control

Webinar Description

This webinar bundle consists of 6 webinar courses addressing areas like automating assays, applying BTD, sterilization design, QC for analytical materials, new requirements for trial master files, Instrumental liquid chromatography.

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

This webinar bundle includes below 6 recorded webinars:

Automating Assays for Clinical Diagnostics
How Successfully Apply for a Breakthrough Therapy Designation
Mathematics of Terminal Sterilization - Probability of Survival Approach -vs- Overkill Approach
Quality Control for Analytical Materials used in Microbiology Laboratories
Trial Master File – Clinical Data Systems
Method Validation of HPLC/ UPLC Methods

Automating Assays for Clinical Diagnostics

Presented by Todd Graham

With this webinar, you will be able to understand the steps needed to transfer, validate and maintain an automated assay in the laboratory. First, a key understanding of the various steps technicians performs on the bench is necessary, as certain methodologies are difficult to translate onto automation. Then the procedure must be made to work on the automation in a way that is reliable and repeatable. Validation studies must be performed and properly scaled to make sure that the automation works reliably, and that any issues involving the method of transfer have been properly resolved. Finally, developing a quality assurance plan in concert with both the assay team and the manufacturer of the automation equipment will be discussed, as quality methods must adapt to the new technology to maintain proper quality.

How Successfully Apply for a Breakthrough Therapy Designation

Presented by Carolyn Troiano

After attending this webinar, you will understand:

- How to identify the characteristics for eligibility of a BTD product and determine whether your organization has such new drug products in their portfolio
- The proper format, content, and structure of the BTD application to ensure you will meet all of the requirements and provide FDA with an easy-to-review document that is very well written
- The BTD process and when it is the best time and opportunity to submit your application; doing this too early or late will create issues that can be easily avoided
- The significance of getting your product on a track for BTD designation, especially in terms of the pros and cons, costs, benefits, and compliance issues
- The process for resubmission, should your BTD application be denied/rejected to make the appeal go more smoothly
- How, as an organization, you should communicate your BTD status to the public to maximize the benefit to your bottom line and reputation
- What the best practices are and potential pitfalls and how to avoid them to make your submission one that will have the highest chance of approval while keeping down cost and ensuring compliance

Mathematics of Terminal Sterilization - Probability of Survival Approach -vs- Overkill Approach

Presented by Jerry Dalfors

From the topics listed above the areas covered provide the mathematical means of developing and proving the sterilization process is effective and does not generate a problem for heat liable products.

- Survivor Curves to determine D-values and Z-values
- Linear Regression used to calculate the edge of failure
- Fraction Negative studies
- Correction factors associated with heating and cooling
- Cold spot determination - product and chamber - TD and HP
- Calculation of process lethality
- Biological Indicators to be used and how to make the selection
- Laboratory Studies needed to support Sterilizer Studies
- Identification of elements in the process that can affect D-value

Quality Control for Analytical Materials used in Microbiology Laboratories

Presented by Michael Brodsky

Upon completion of this session, attendees will learn:

- To understand intrinsic and extrinsic factors which can affect the performance of culture media, test kits, reagents and other analytical materials.
- To identify Control Points (CP) and Critical Control Points (CCP) in media quality assessment.
- To develop appropriate QC Practices and acceptability criteria to evaluate the performance of analytical materials for laboratory use.

Trial Master File – Clinical Data Systems

Presented by Carolyn Troiano

Companies engaged in the conduct of human clinical trials must adhere to specific government regulatory requirements. Certain documents, content and images related to a clinical trial must be stored and maintained, and depending on the regulatory jurisdiction, this body of information may be stored in a trial master file (TMF). This seminar will help you understand in detail the new requirements for trial master files.

- Trial Master File (TMF) background and rationale
- The essential documents to include in a TMF
- Organizing and maintaining a TMF
- Standard Operating Procedure required to support TMF
- Inspection of TMF records

Method Validation of HPLC/ UPLC Methods

Presented by John C Fetzer

Instrumental liquid chromatography, either as HPLC or UPLC, are common techniques in laboratories that do regulatory-compliance work. For Good Laboratory Practice (GLP) or for ISO 17025 compliance, such methods must meet certain requirements. This presentation will cover the key elements to have a compliant method.

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.

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