GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

4 Webinar Courses On FDA Compliance, Clinical Quality Control, Diagnostics, Clinical Data Systems And Computer System Validation

Webinar Description

This bundle of webinars will help you to understand the steps needed to transfer, validate and maintain an automated assay in the laboratory, heat sterilization is a PROBABILITY function dependent on heat exposure, the number of microorganisms, and the heat resistance of the microorganisms, the TMF includes all of the documentation that a sponsor must record to demonstrate that they have met their obligations for the conduct of a clinical trial, and understand how to leverage the vendor and other external resources to apply the best industry practices and avoid potential pitfalls when validating a clinical trial system.

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:

Automating Assays for Clinical Diagnostics

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

Trial Master File – Clinical Data Systems

FDA Compliance and Clinical Trial Computer System Validation

Automating Assays for Clinical Diagnostics

Presented by Todd Graham

Laboratories need to transition technologies all of the time. From new ways to perform assays to outdated technology, to new equipment pushes to the various needs of end users, assays need to switch between technologies on a regular basis. One needs to be able to easily and robustly transition assays from one technology to another. With this seminar, you will be able to fully understand how your essay is currently running and make note of what the new technology should be able to do. Then you will learn how to slowly get the new technology up and running, validating the quality system, equipment and the assay itself. You will learn what you need to understand in the process of transitioning old samples onto the new system and deal with any potential issues. Finally, you will develop a final validation plan that will allow you to embrace the new technology fearlessly. Assays performed by hand have a number of issues that may be assuaged by automation. One problem can be a simple lack of throughput, as a single worker, no matter how skilled, can only do so much work in a day. As technology progresses, there may be a need to automate a procedure so that a given laboratory may remain state-of-the-art. Finally, the automation of procedures may unlock key new capabilities that may enhance productivity in ways that may not be feasible using manual methods. That said, automating laboratory assays from manual methods is rarely as simple as bringing in equipment, programming the assay in and letting it run. A certain level of know-how is needed in order to understand the various pitfalls and issues that come with automating an assay.

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

Presented by Jerry Dalfors

Heat sterilization is a PROBABILITY function dependent on heat exposure, the number of microorganisms, and the heat resistance of the microorganisms. Current regulations expect the sterilization process to provide a level of assurance of at least 1 x 10-6 probability (fewer than one non-sterile unit per million units) of survival (non-sterility) for terminally sterilized parenteral and medical devices. Since Regulations require that we generate in our sterilization processes a PROBABILITY of a NON-STERILE UNIT (PNSU), how do we use D-values, Z-values, and Foto calculate the probability and determine that we have essentially zero risk in our products due to lack of sterility?

D-value is the term used to describe the amount of time required to kill or destroy a microorganism. Spores are much more difficult to kill than vegetative cells which is why we use spores as our Biological Indicator for the effectiveness monitor of our sterilization process. D121 tells us how many minutes it takes to kill an organism at 121oC (or 250oF) - note the "F". The D-value is the time required to reduce a population of microorganisms by one log at the process temperature. From 1x106 to 1x105 – from 1,000,000 to 100,000 organisms.

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. 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).

FDA Compliance and Clinical Trial Computer System Validation

Presented by Carolyn Troiano

The FDA governs the computer systems used to collect, analyze, transfer and report data that is in support of human clinical trials required for drug approval. FDA oversight is based on a Predicate Rule, known as “Good Clinical Practices,” or simply, “GCPs.” Computer systems subject to GCP requirements must be thoroughly and appropriately validated in accordance with FDA’s guidance on computer system validation. This involves a rigorous set of phases and steps to ensure that, in the language of FDA, “a system does what it purports to do.”

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 of 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.

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

www.grceducators.com
support@grceducators.com
740 870 0321