GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

10 Webinar Courses to Prepare and Manage FDA Inspection

Webinar Description

This webinar package gives you access to 10 webinar courses to brush up your knowledge on how to prepare and manage FDA Inspections. The instructors of these webinars will guide you with mock audits, SOPs, inspection process, 483 response process, FDA and EMA labelling guidelines, how to investigate deviations, the cleanroom behaviour, inspection pre-planning and preparation activities, documentation process, inspection Do's and Don’ts, batch record review, a complete guide to 21 CFR part 11, ISO 13485 Compliance, and how to write effective SOPs and work instructions.

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

This webinar bundle includes below 10 recorded webinars:

New FDA and EMA Labeling Requirements for Regulated Industries

The FDA Inspection: From SOP to 483

Best Practices for Investigating Deviations

Understanding Aseptic Technique and Cleanroom Behavior

Proper Management of Regulatory Agency Inspections

Batch Record Review and Product Release

21 CFR Part11 Compliance

Verification, Validation, Master Planning for U.S FDA and ISO 13485 Compliance

Writing Effective Standard Operating Procedures and Work Instructions

21 CFR Part 11 (Electronic Records/ Signatures) Compliance for Computer Systems Regulated by FDA

New FDA and EMA Labeling Requirements for Regulated Industries

Presented by Carolyn Troiano

This webinar will help you understand in detail the new requirements for labeling from FDA and EMA, including a set of rules for electronic submission of labeling content, and strategies and actions for meeting the new challenges posed.

Pharmaceutical companies must manage the process of designing and creating product labels that meet regulatory requirements. This includes product-labeling documents such as Packet Inserts (PIs), Summaries of Product Characteristics (SmPCs) and Core Data Sheets (CDSs). A large number of product strengths, dosage forms, and product presentations result in a large number of labeling records that must be maintained and kept synchronized.

The FDA Inspection: From SOP to 483

Presented by Jeff Kasoff

This is a detailed course designed to provide medical device/pharmaceutical professionals with the information they require to prepare for and manage FDA inspections. This course provides the rationale, strategies and flows on how to plan for an inspection, the inspection process and approach, and which company roles should be assigned for these types of inspections, among other related topics.

The FDA inspection is the most nerve-wracking event in the life of a regulatory professional - you're in charge of compliance, usually in the background, and NOW you're in the spotlight, and if your performance isn't good, it's not the show that may close, it's YOUR COMPANY! However, adequate planning, training, composure, and understanding should result in many encore presentations! This session will discuss how to prepare for the inspection, what to do during the inspection and the close-out interview, and how to respond to the inspection. Also contained in this session will be the limits of FDA's scope during an inspection, including what documents you are not required to show them, and the permissibility of photographs and affidavits.

Best Practices for Investigating Deviations

Presented by Danielle DeLucy

One of the most common FDA 483 and Warning Letter citations continues to be inadequate investigations. The FDA uses the investigation reports and investigation trends to identify potential quality problems in all areas of the company. Ultimately, inadequate investigations can lead to 483 citations, Warning Letters, a release of the sub-standard product, or product recall. Furthermore, costly and time-consuming system remediation may be required. Having a procedure on Deviation Investigations is not enough. It is the content and conclusions of the investigations themselves that truly count. Doing a proper root cause analysis, gathering evidence and ensuring a sustainable corrective action is a key to a proper deviation investigation. This webinar will help attendees understand the fundamental investigation steps and skill sets. A key focus will be placed on identification and initial reporting of deviations, fact/evidence gathering, and arriving at the correct root cause and CAPA. The importance of investigation planning, critical thinking skills, and effective preventative action plans will also be discussed.

Understanding Aseptic Technique and Cleanroom Behavior

Presented by Danielle DeLucy

Aseptic technique, in sterile compounding, contributes to preventing microbiological contamination. Aseptic technique is being used to provide safety, efficacy, and sterility to the products that are sterile in nature, especially when it comes to various patient injections. This course by expert speaker Danielle DeLucy will benefit those Aseptic operators, Aseptic sample handlers, personnel who work in a Biological Safety Cabinet (BSC) and their management and Quality Assurance counterparts, in highlighting how to operate in a clean room environment, proper facility design, proper personnel gowning, and the equipment needed to conduct environmental monitoring.

In sterile compounding, aseptic technique is contributing to the prevention of microbiological contamination. It is providing sterility, safety, and efficacy to the sterile product, especially various injections for patients. Cleaning, Gowning and proper methods of contamination control will be reviewed along with why clean rooms are designed the way they are.

Proper Management of Regulatory Agency Inspections

Presented by Danielle DeLucy

The purpose of the Regulatory inspection is an activity that should demonstrate that your company is operating according to the proper CFR requirements and maintaining a state of compliance. The key to a successful audit is being able to communicate how your quality systems assure this state of control. Many times, the arrival of a Regulatory Investigator is a daunting experience for some. This webinar, you will learn how to properly alert key members that an investigator has arrived, the proper protocol for setting up the Inspection room and any associated “war” rooms that will support the inspection, and how to manage requests from the investigators in a timely and accurate manner. This preparation minimizes stress and disorder during the inspections.

Batch Record Review and Product Release

Presented by Danielle DeLucy

Most Regulatory Agencies require firms to have written procedures in place to document production and process controls, better known as batch records. Additionally, there must be written procedures for a batch record review process that demonstrate compliance. A strong batch record review system is essential in order to properly document all critical processing parameters that go along with the production and manufacture of pharmaceuticals, biologics, medical devices, etc.

Upon completion of this session, attendees will learn the fundamentals for reviewing batch records in a pharmaceutical environment. They will hear about the proper training that must be demonstrated before one is considered a suitable reviewer of these critical documents and they will learn how to react to discrepancies found in these records.

21 CFR Part11 Compliance

Presented by Edwin Waldbusser

This Webinar will explain what 21 CFR Part 11 is, why it is important to FDA regulated companies and how conformance to Part 11 differs from just having good IT security. Procedures for controlling electronic signatures and electronic records will be explained. FDA regulated companies want to transition to electronic records for economy and efficiency. FDA, because of its concern for patient safety, wants to prevent electronic records from being compromised with possible resulting harm to the patient. FDA has set up regulations that address both data security and patient safety. We will show how 21 CFR part 11 considers both.

Companies want to transition to electronic records but are afraid of compromising their quality system and receiving 483's at their next inspection. Part of this fear originates from confusion. FDA originally published a rather severe 21 CFR Part 11. After industry complaints, the FDA acknowledged that the regulation, as written, would result in nobody attempting to convert to electronic records. But, instead of rewriting the regulation, FDA said it would "selectively enforce" sections of the regulation. This webinar will explain what all these means.

Verification, Validation, Master Planning for U.S FDA and ISO 13485 Compliance

Presented by John E Lincoln

How can companies address the U.S. FDA's tougher stance and product, process and QMS V&V? One major failing is the lack of sufficient or targeted risk-based V&V Master Planning. Why do companies need a Validation Master Plan? What is it? How is it structured? Supporting systems/documents? How should each individual V&V plan be structured? Clarification of validation terms. Device, product, process, equipment, QMS, software V&V. What are the key components in understandable language? How is it run? What are the "must have" elements from ISO 14971 and ICH Q9 for hazard analysis and product risk management? How can these be integrated into a company's QMS?

FDA Warning Letters and recent high-profile recalls indicate major cGMP deficiencies in big-name device and pharma companies. One major failing is lack of sufficient or targeted risk-based Verification and Validation planning and execution. Another is confusion over terminology. Why do companies need a Validation Master Plan? What is it? How is it structured? Supporting systems/documents? What are the "must have" elements from ISO 14971 and ICH Q9 for hazard analysis and product risk management? How can these be integrated into a company's QMS? How to meet the similar V&V requirements of ISO 13485. Eliminate the confusion over V&V terminology. Develop a repeatable and cGMP-compliant V&V system.

Writing Effective Standard Operating Procedures and Work Instructions

Presented by Charles H. Paul

Standard Operating Procedures and work instructions – the documentation required by regulation – is essential to the effective and compliant running of any regulated business. Unfortunately, many individuals in those businesses miss the valuable opportunities that properly developed Standard Operating Procedures/Work Instructions can provide. Regulated documentation can serve a variety of purposes other than meeting a regulatory requirement – as training materials, to standardize operations, to manage individual and group performance, to identify the sources of deviations, etc. The key is to know how to write those documents to properly meet those needs.

Writing effective Standard Operating Procedures and Work Instructions is not intuitive, it is not a skill that is often taught in our universities, and it can be a difficult and cumbersome task to execute. Knowing the most effective and efficient processes for gathering, organizing, and writing technical documentation is absolutely critical to providing significant value to a dreaded, avoided, and seemingly unimportant work task.

21 CFR Part 11 (Electronic Records/ Signatures) Compliance for Computer Systems Regulated by FDA

Presented by Carolyn Troiano

The Webinar will focus on the importance of ensuring that electronic record/electronic signature (ER/ES) capability built into FDA-regulated computer systems meets compliance with 21 CFR Part 11. This includes the development of a company philosophy and approach and incorporating it into the overall computer system validation program and plans for individual systems that have this capability.

FDA's 21 CFR Part 11 was enacted in the late 1990s and implementation success across the pharmaceutical and other regulated industries have been mixed. There are very specific limitations that arise when using ER/ES capability, such as the elimination of print capability to prevent users from making decisions based on a paper record as opposed to the electronic record. It also requires very specific identification of users that ensures the person signing the record is the same person whose credentials are being entered and verified by the system. The rule for changing passwords must be rigorously adhered to and the passwords must be kept secure.

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

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