GRC Online Training Hub
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Webinar on

3 Webinars to help you Prepare and Manage an FDA Inspection and Citations

Webinar Description

This webinar bundle consists of 3 webinars, which are designed to provide all FDA regulated industries with the information they require to prepare and manage an FDA inspection. The instructors of these webinars will take you through Mock Audits, SOP Inspections, 483 Response Process, and Behaviour during the inspection, several types of 510(K). This bundle will also teach you to prepare a submission to get FDA approval for a new product. It will also help you identify and explain the best types of formats that can be used to develop standard operating procedures 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 3 recorded webinars:

The FDA Inspection: From SOP to 483

Preparing a FDA 510(k) Submission

Writing Effective Standard Operating Procedures and Work Instructions

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.

Preparing a FDA 510(k) Submission

Presented by Edwin Waldbusser

We will explain what a 510(k) is and the procedure to prepare the submission. The several types of 510(k) will be explained. Each part of the submission will be explained. The very confusing concepts of predicate device and substantial equivalence will be discussed. How to find an acceptable predicate device will be taught. FDA places special emphasis on-device software. we will cover the requirements for software.

Preparing a submission to get FDA approval for a new product is time-consuming and confusing. The submission requirements refer to many unfamiliar concepts and terms. More than half of all submissions are rejected. We will teach you to prepare a submission meets all the FDA requirements.

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.

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