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Webinar on

5 Essential webinars on Documentation, SOP and Labelling Standards

Webinar Description

This webinar bundle has webinars addressing the best practices for documentation, FDA, and EMA labeling requirements, generation of controlled documents, investigating deviations, batch record review, and SOP and documenting 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 5 recorded webinars:

New FDA and EMA Labeling Requirements for Regulated Industries
Generation of Controlled Documents and Related Training
Best Practices for Investigating Deviations
Batch Record Review and Product Release
Writing Effective Standard Operating Procedures and Work Instructions

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.

Generation of Controlled Documents and Related Training

Presented by Mr. Jerry Dalfors

The purpose of this webinar is to provide the topics and basic instructions needed to establish the documentation practices needed to meet or exceed compliance expectations expected by regulatory agencies (FDA/EPA and ISO) to generate and ensure objective and technically accurate data entry for quality related systems and production operations. Good Documentation Practice (GDP) is a term in the pharmaceutical industry to describe standards by which data entry and related documents are created and maintained. While not law, authorities will inspect against these guidelines and cGMP expectations in addition to the legal requirements and make comments or observations if compliance with GDP is not part of the company's quality systems performance.

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.

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.

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 knowing 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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