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Webinar on

Generation Of Controlled Documents And Related Training

This webinar is intended to provide the needed documentation practices associated with documentation creation, document approval, handwritten entries, copies of documents, document maintenance and document modification.

PRESENTED BY:

Mr. Jerry Dalfors has extensive (40+ years) of business administration, consultative, technical and managerial experience in the development and manufacture of highly regulated biopharmaceutical products including injectables, biologics, medical devices and oral dosages. Jerry is considered an expert in almost all aspects of the biopharmaceutical and medical device industry and has trained many FDA field inspectors on a variety of topics.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

This presentation is intended to provide the needed documentation practices associated with documentation creation, document approval, handwritten entries, copies of documents, document maintenance and document modification. This document details the minimum documentation requirements for MEDIn still personnel, contractors and consultants completing cGMP documents. Specific operational procedures using more detailed instruction sets may have additional documentation requirements which may go beyond the principles of this guideline.

The requirements apply to the following documentation in:

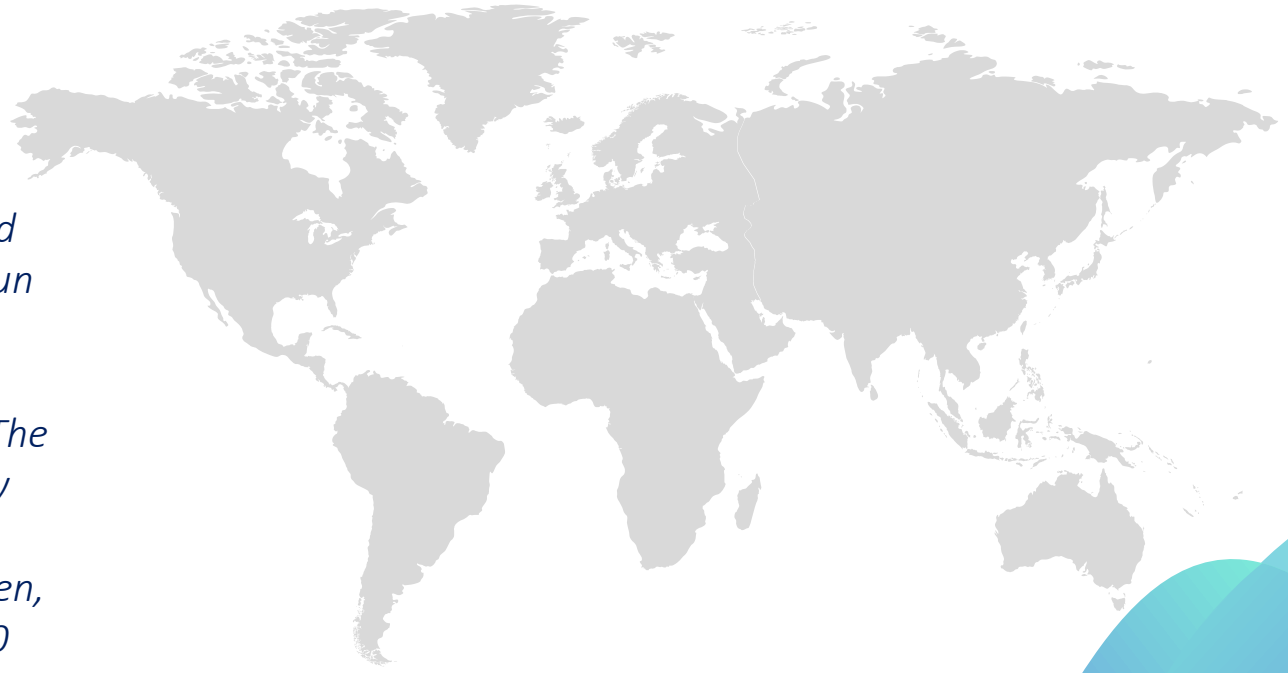
- Controlled Documents and related Data Sheets
- Controlled Logbooks
- Instrumentation Charts
- Laboratory Notebooks
- Bound Record Books
- Manufacturing Batch Records
- Validation/Qualification Protocols and Reports

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.

Why Should Attend ?

Will you be prepared when required to write a standard operating procedure (SOP), Batch Production Record (BPR) or Device History Record (DHR)? Writing these controlled documents in a way that will allow anyone to be able to read the instructions and execute the activities without error or run to run variation and provide the required objective evidence that each step in the execution of the instructions was conducted as required and the data recorded immediately. The purpose of these controlled documents is to ensure accuracy and repeatability when executing a task which is needed to demonstrate a successful quality system. When poorly written, these documents are of limited value. Using the following 10 guidelines, you can create a successful SOP document as well as batch production records and device history records (BPRs and DHRs). Following the recommended steps in the generation of controlled documents within the framework of the company's policies, practices, and guidelines, the procedural related documents we have just discussed will help document authors deliver more accurate documents, with shorter review cycles and the elimination of operator errors.



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