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Webinar on

3 Valuable Webinars To Describe A Compliant Program, Aspectic Techniques And Human Factor Validation Of FDA

Webinar Description

This webinar package gives you access to 3 webinar courses to brush up your knowledge on Qualification of Suppliers and Contract Manufacturing Organizations, Understanding Aseptic Technique and Cleanroom Behavior, Method Validation of HPLC/ UPLC Methods.

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:

Qualification of Suppliers and Contract Manufacturing Organizations

Understanding Aseptic Technique and Cleanroom Behavior

Method Validation of HPLC/ UPLC Method

Qualification of Suppliers and Contract Manufacturing Organizations

Presented by Edwin Waldbusser

Suppliers and CMO’s must be selected following a rigorous formalized procedure. This webinar will describe a compliant program based on regulatory requirements. Phases of supplier and CMO selection from initial telephone inquiry to the quality survey to qualification audit will be explained. The qualification audit will be described with key points to evaluate explained. How to deal with uncooperative suppliers will be explained.

Understanding Aseptic Technique and Cleanroom Behavior

Presented by Danielle DeLucy

Aseptic technique, in sterile compounding, contributes to prevent 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.

Cleaning, Gowning and proper methods of contamination control will be reviewed along with why clean rooms are designed the way they are. In addition, this course will review how Quality Systems help define requirements for aseptic technique and clean rooms and how to properly maintain these environments.

Method Validation of HPLC/ UPLC Methods

Presented by John C Fetzer

Instrumental liquid chromatography, either as HPLC or UPLC, are common techniques in laboratories that do regulatory-compliance work. For Good Laboratory Practice (GLP) or for ISO 17025 compliance, such methods must meet certain requirements. This presentation will cover the key elements to have a compliant method.

Instrumental liquid chromatography is an analysis is widely used to determine purity, the impurities, and the degradation products of pharmaceuticals. The focus of most validation work is on the methodology, the standard operating procedure (SOP). But validation of the instrumentation and other associated items of column, solvents, and other reagents and chemicals is also an area of focus in an audit.

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