ASTM 2500: Lessons Learned Through a Decade of Implementation

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Organizer : WCS

Venue : online

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Overview

Regulatory bodies; such as, the FDA and EMEA place a high level of scrutiny on a firm's validation program during GMP compliance inspections. Therefore, it is essential to an organization's success to implement a robust, compliant validation approach.

One of the most critical factors in manufacturing pharmaceuticals and medical devices is ensuring that equipment used for production is properly validated. Validation is required to demonstrate that equipment is fit for its intended use.

In recent years, there have been several standards and guidance documents created to discuss best practices for commissioning, qualification, and validation. One of these documents is the ASTM E2500 standard guide. Unfortunately, some of these documents are too vague and lack the details needed to provide adequate guidance and direction to the industry.

This webinar discusses the concepts found in ASTM E2500 in sufficient detail to help industry professionals understand how to implement a validation program based on the ASTM 2500 Approach.

Why an attendee will pay for this training?

This course provides detailed guidance on the concepts of ASTM 2500 and how to implement a validation program based on that approach.

With limited guidance and experience, industry has been left to interpret how to adequately comply with the regulations. This course provides a comprehensive overview of the regulatory

authority requirements and expectations for a compliant validation program and demonstrates how ASTM 2500 complies with those requirements.
Because of the tremendous effort expended in conducting validation studies, efficiency and documentation will be stressed throughout the discussion.
This course will provide a thorough review of regulatory guidelines on validation. Each element required to have a complete and thorough validation will be discussed in detail to ensure course attendees have a clear understanding of each requirement.

Session Highlights
• **Regulatory Requirements for a Compliant Validation Program**
o FDA
o EU
o ICH Q7
o ICH Q8: Pharmaceutical Development
o ICH Q9: Quality Risk Management
o Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach
• **What is ASTM 2500**
o Definition
o Concept
o Requirements
o Differences from traditional validation approach
• **Real World Examples of ASTM 2500 Implementation**
o Lessons Learned

Who Will Benefit

- Operations
- Quality Assurance
- Quality Engineering
- Validation
- Engineering

Event Categories :