FDA COMPLIANCE AND CLINICAL TRIAL COMPUTER SYSTEM VALIDATION CORE REQUIREMENTS, EXPECTATIONS AND CHALLENGES

FACULTY
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Award winning FDA Compliance Expert for Validation, 21 CFR Part 11 (Electronic Records/Signatures) and Data Integrity.
My experience includes 34+ years in IT/ Business, Marketing & Compliance leadership and management roles at a variety of Fortune 100 companies, across multiple industries.

WHO WILL BENEFIT

- Data “Owners”
- Data “Stewards”
- Information Technology Analysts
- Information Technology Developers and Testers
- QC/QA Managers and Analysts
- Clinical Data Managers and Scientists
- Analytical Chemists
- Compliance and Audit Managers
- Laboratory Managers
- Automation Analysts
- Computer System Validation Specialists
- GMP Training Specialists
- Business Stakeholders/Subject Matter Experts
- Business System/Application Testers

OVERVIEW

The FDA governs the computer systems used to collect, analyze, transfer and report data that is in support of human clinical trials required for drug approval. FDA oversight is based on a Predicate Rule, known as "Good Clinical Practices," or simply, "GCPs." Computer systems subject to GCP requirements must be thoroughly and appropriately validated in accordance with FDA's guidance on computer system validation. This involves a rigorous set of phases and steps to ensure that, in the language of FDA, "a system does what it purports to do."
The cost of adequately validating a clinical trial computer system can be high, and must be weighed against system risk and usage. GAMP 5 system classification guidelines can help ensure that a clinical trial system is categorized appropriately, based on the type of system and technology involved. Along with risk, system classification can provide a clear-cut pathway for validating a system, based on the appropriate level of testing and validation effort.

LEARNING OBJECTIVES

- Understand FDA requirements for clinical trial Computer System Validation (CSV)
- Understand the System Development Life Cycle (SDLC) approach to validation
- Utilize GAMP 5 system classification and risk methodologies for categorizing systems and developing a validation pathway
- Understand how to build a complete validation strategy and program for clinical trial systems
- Know how to manage the validation process and create FDA-compliant documentation
- Know how to monitor a clinical trial system that is in production, governing the data and system through retirement
- Understand the roles and responsibilities required to validate a clinical trial system
- Know how to measure cost vs. compliance risk for a clinical trial system

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AGENDA DAY 01

FDA oversight of computer systems used in regulated industries
- "GxPs" defined
- Focus on "GCPs"

Introduction to Clinical Data Systems (CDS)
- Defining the types of systems
- System evaluation, scoring and selection process overview

Introduction to Computer System Validation (CSV)
- FDA's Guidance for Computerized System Validation (1983)
- Evolution of validation

System Development Life Cycle (SDLC) framework and validation
- SDLC phases (requirements, design, testing, implementation, acceptance, release to production, change control, retirement)
- SDLC deliverables, timing, and documentation

GAMP 5 and system classification
- GAMP 5 system categories and criteria
- Using GAMP 5 to develop an approach to CSV for a clinical data system

System risk assessment and managemen
- Clinical data system inventory
- Risk assessment, mitigation and prioritization

Building a solid project management plan to corral a clinical data system validation effort
- Validation strategy and planning
- Clinical data system implementation and validation execution

Incorporating business process re-engineering principles into the clinical data system validation effort
- Clinical process mapping
- Seeking opportunities for improvement

Incorporating Organizational Change Management (OCM) principles into the clinical data system validation effort

Much More.....

AGENDA DAY 02

Example – implementing and validating a clinical data system
- Situation overview
- Building a strategy
- Managing the project using the CSV principles, SDLC methodology and good project management practices
- SDLC phases, deliverables and templates
- Incorporating BPR and OCM practices

Ongoing monitoring and management of a clinical data system in a validated state throughout the SDLC
- Operations and maintenance
- System and data backup and archival
- Change control board and best practices (high on FDA's list for scrutiny)
- Periodic review and assessment for revalidation
- Policies and procedures (IT and user)

Ongoing training and OCM
- Disaster Recovery (DR) planning and execution
- Business Continuity Planning (BCP) and execution

System and Data Governance Board
- Board Charter
- Sponsorship
- Roles and responsibilities
- Meetings and status reporting

FDA's strategy and direction – the "swinging pendulum"
- Recent trends in FDA findings related to clinical data systems
- Factors influencing FDA audit and inspection
- What does the future look like?

Wrap-up/ Q&A

FDA Compliance and Clinical Trial Computer System Validation Core Requirements, Expectations and Challenges

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