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FDA Trends for Computer System Validation (CSV) Compliance and Enforcement

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Event URL : http://www.BostonEventsList.com/events/fda-trends-for-computer-system-validation-csv-compliance-and-enforcement

Organizer : GlobalCompliancePanel

Venue :

Location : Four Points by Sheraton Boston Logan Airport,
Revere, MA, US, ZIP: 02151

FDA Trends for Computer System Validation (CSV) Compliance and Enforcement

This Seminar will focus on the key areas that are most important for protecting the validity of data that is regulated by FDA, and is typically housed electronically in computer systems. This includes how to properly validate an FDA-regulated computer system in order to ensure security and data integrity objectives are met. Implementing and following the System Development Life Cycle (SDLC) methodology is the best approach for Computer System Validation (CSV) and maintaining the system in a validated state throughout its life.

The SDLC approach takes all aspects of validation into account throughout the life of the system and protects the data that it houses through its retention period. The data is a key asset for any FDA-regulated company and must be protected. If data becomes invalid, based on improperly validating and maintaining the system that houses it in a validated state, the work related to the data would need to be repeated. This could result in a devastating loss to any company's bottom line.

We will discuss the key areas that are most important during inspection and audit, including

security, data integrity, validation, training, and documentation.

Why You should Attend:

FDA requires that all computer systems that handle data regulated by the Agency be validated in accordance with their guidance on computerized systems. This guidance was first issued in 1983, and the main points of focus remain consistent today, despite the number of years that have passed and the technology changes that have taken place.

The guidance was revisited for its application to the medical device industry in the 1990s, as the first issuance addressed pharmaceuticals only. In 1997, 21 CFR Part 11 was issued to address electronic records and signatures, as many FDA-regulated organizations began seeking ways to move into a paperless environment. This guidance has been modified over the years to make it more palatable to industry, and this includes discretionary enforcement measures, but still remains somewhat confusing. The intent was to avoid creating a huge regulatory compliance cost to industry that was initially preventing companies from embracing the technology.

This session will provide some insight into current trends in compliance and FDA enforcement. Some are based on technology changes, and these will continue to have an impact as new innovations come into use in the industry. Others are based on factors including economics, social media, new diseases, politics, and a host of other influences.

Areas Covered in the Session:

- Computer System Validation (CSV)
- System Development Life Cycle (SDLC) Methodology
- "GxP" - Good Manufacturing, Laboratory and Clinical Practices (GMPs, GLPs, GCPs)
- 21 CFR Part 11, Electronic Records/Electronic Signatures (ER/ES)
- Data Retention/Archival to ensure security, integrity and compliance
- Validation Strategy/Planning that will take into account the system risk assessment and system categorization (GAMP V) processes
- Policies and Procedures
- Critical Training and Organizational Change Management (OCM)
- FDA Regulatory Trends
- FDA Response to Change
- Recent FDA findings for companies in regulated industries
- Recent trends in technology that need to be addressed in the CSV approach
- Industry Best Practices
- Q&A

Who Will Benefit:

Personnel in the following roles will benefit:

- Information Technology Analysts
- Information Technology Managers
- QC/QA Managers
- QC/QA Analysts
- Clinical Data Managers
- Clinical Data Scientists
- Analytical Chemists
- Compliance Managers
- Laboratory Managers
- Automation Analysts
- Manufacturing Managers
- Manufacturing Supervisors
- Supply Chain Specialists
- Computer System Validation Specialists
- GMP Training Specialists
- Business Stakeholders responsible for computer system validation planning, execution, reporting, compliance, maintenance and audit
- Consultants working in the life sciences industry who are involved in computer system implementation, validation and compliance
- Auditors engaged in internal inspection

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Event Categories :