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Maintaining your laboratory in a state of control – The data integrity challenge

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Abstract

Analytical laboratories are considered high risk systems because they perform the last control step before products are released to market or data are submitted to the FDA for pre-market approval. Subsequently, laboratory systems are on the radar screen of FDA and other regulatory agencies. All regulations have strict requirements for electronic raw data and other e-records to ensure accuracy, integrity, authenticity, security and availability of records from generation to deletion. Laboratory best practices for meeting regulatory and compendial requirements are changing to meet FDA's emerging expectations on data integrity. The ISPE GAMP Good Practice Guide for Validation of Laboratory Computerized Systems (CSV) has provided industry with new ways to approach laboratory compliance. In addition, USP Informational Chapter <1058> on analytical instrument qualification (AIQ) is being discussed by USP all across industry based on the results of a stimulus paper suggesting better alignment of AIQ and CSV. In addition to regulations required to qualify instruments and validate systems, today's laboratories also face a significant challenge to quickly and easily implement an instrument interface to collect and aggregate data. Automation via a LIMS system that is validated, controlled and monitored can improve your compliance by implementing the systematic procedures necessary for regulatory compliance and management of compendial requirements. Documentation of this overall approach can be set forth in a Laboratory Data Integrity Strategy outlining the informatics with control points that can be routinely monitored and audited to put your lab in the best defensible position.

Biography

Jacqueline McCulloch, RAC, is a Senior Consultant with Clarkston Consulting and has over 25 years of experience working in quality systems compliance, regulatory submissions & strategy. She has experience leading projects for regulatory submissions and quality systems. She is experienced in working under remediation and consent decree.

Courtney Woodson is a consultant with Clarkston Consulting. He has over 10 years of information systems experience, with the last 6 years focused on leading technical projects for Life Sciences industry clients. Mr. Woodson has experience in Title 21 CFR Part 11 validated manufacturing systems development, compliance, and management. He is a skilled analytical thinker who is highly organized and possesses the ability to interact with individuals at all levels of the organization.