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Enabling Efficiency, Cost Reduction and Compliance Using a Validation Lifecycle Management System

By Ivan Soto Feb 28, 2018 8:00 am PST

Validation is a critical regulatory requirement for the Pharmaceutical industry. Validation is an important element of the 3-stage lifecycle approach described in the FDA Process Validation guidance document published in January 2011. The 3-stage approach includes Stage I Process Design, Stage 2 Qualification and Stage 3 Continued Process Verification. The lifecycle approach promotes the integration of the 3-stages where information and data are readily available during the entire process. The data generated during the entire lifecycle can be used to reduce the amount of validation and revalidation activities.

During the validation process companies generate a significant amount of data and information related to the lifecycle of GMP regulated systems. The traditional validation process is executed using paper-based records such as Validation Plans, System Specifications, Risk Assessments, Protocols and Validation Summary Reports. During the lifecycle of GMP systems a significant amount of paper-based records is generated that require storage and archival. Unfortunately, the cost of document storage and archival is very high during the entire lifecycle. The traditional validation process is quite inefficient and cost effective due the significant amount of inefficiencies related to manual activities such as printing, scanning, executing, and routing documents for review and approval.

This whitepaper summarizes the challenges found in the traditional validation process and the benefits achieved by implementing Validation Lifecycle Management Systems (VLMS).

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Ivan Soto
Ivan Soto has more than 20 years of pharmaceutical industry experience in multiple pharmaceutical and consulting companies. His expertise includes Validation, IT Compliance, Quality Control and Quality Assurance. In...
View Author Bio

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