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Diverting from traditional validation approaches – Beefing up and speeding up validation, while minimizing vulnerabilities to new regulatory inspection foci

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Abstract

Traditional validation increased the risk-based approach to Computer Software Validation (CSV), whether the software operates independently or controls scientific equipment. However, companies did little to change the validation documentation approach. Modular testing may seem the easier or fastest method, yet it prolongs the validation process many ways. Furthermore, that approach contributes to the industry's ongoing uncertainty of "how much is enough" for justification of more limited (or expanded) protocol tests.

Since the U.S. Food and Drug Administration (FDA) announced additional inspection foci (July 2010), several patterns of validation weaknesses have been identified across the industry, contributing toward a surge of 483 warning letters.

One critical weakness is using spreadsheets without validation. One spreadsheet requires the same validation documentation as an in-house built software application, which may seem overwhelming and frivolous. Another key weakness is the "lack of following through." Multiple types of Periodic Reviews are required, risk mitigation measures must be implemented, protocol deviations resolved with a temporary workaround must have the original problem fixed and the workaround removed. This paper lays out a new validation approach to streamline the risk-based CSV and spreadsheet validation processes; consolidate documentation while limiting overlapping issues; identify all required Periodic Reviews; establish a standardized status check for each review (synchronizing some), reduce tasks sometimes assigned to revenue-producing scientific workers, and provide end users a more complete Study Environment immediately upon system release.

Financial gains come from using revenue-producing workers less during validations, having immediate training materials with known reproducible results, potentially reducing future Change Control actions, saving some time presenting documents requested during regulatory audits and inspections, and providing more user spreadsheets immediately with software system release to users.