Life Sciences Case Study

PROJECT OVERVIEW

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Computer System Validation to Computer System Assurance Assessment

Clarkston recently completed an outside-in perspective to identify opportunities for computer system validation (CSV) simplification and alignment to the anticipated computer system assurance (CSA) guidance document from the FDA for a pharmaceutical company.

The client's Technical Operations group and, more specifically, Quality Assurance, were interested in identifying opportunities to simplify the current compliant processes to reduce the complexity and timeline for computer system validation projects. This project was important not just for process simplification, but also to support a project to move to a paperless validation solution.

For the paperless validation solution to deliver the effective and efficient process improvements promised, the current process needed to be re-evaluated to ensure that fewer documents would be used and that templates could be multipurpose. Once the templates were set up in the new system, it would be difficult to reengineer the process; possible, but more difficult and disruptive.

The first phase of the process was an objective assessment of the company's readiness to move to CSA. Clarkston leveraged a proprietary assessment tool to jointly score the company's readiness and overall process. The focus of this engagement was on U.S.-centric processes and alignment with the industry standard for the computer system lifecycle.

Throughout the project, the team noted opportunities for improvement beyond the process simplification and readiness for CSA. Documents to be combined were identified, content changes for clarity and understanding were shared, and strategies working with both global and local systems were explored.

A more streamlined approach with few documents to be written, reviewed, and approved were identified as a key component to reducing the overall project timelines.

This outsider perspective of a process that has been in place for many years allowed the client to consider the recommendations to add process maps to documents, to simplify content, and to combine documents for a more simplified approach to CSV, which would support both moving to a paperless validation solution and quick adoption of the highly anticipated CSA guidance document from the FDA.

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INDUSTRY:

Life Sciences

PRODUCTS AND SERVICES :

Discovery, development, and commercialization of therapeutic drugs

PRIMARY OBJECTIVES:

- Evaluate existing CSV environment to identify areas of opportunity to simplify processes and ensure alignment to leading GxP industry practices, including Computer Software Assurance (CSA) principles.
- Understand the key processes being used today to analyze how different resources interact across the organization and to define areas of opportunity as the client embarks on incorporating CSA concepts and a new paperless validation solution.
- Provide an in-depth evaluation of the client's current CSV state, including a gap analysis relative to industry best practices and a roadmap of the necessary steps to get to the desired future state.

RESOLUTION:

- Reviewed all global documents (policy, SOP, work instructions, templates) to create both local and global process maps
- Compared global to local processes, identifying inconsistencies and areas of confusion lacking alignment
- Proposed ways to mitigate gaps in the computer system lifecycle
- Recommended documents to be combined, deleted, rewritten, or written for a more simplified compliant process
- Identified processes that should not be imbedded in CSV
- Compared existing CSV and CSA state against industry best practices

KEY BENEFITS:

- Recommendations to simplify the CSV process prior to starting a project to move to a paperless validation solution
- Gained alignment around areas to focus on, including effective and efficient processes, implementation for paperless validation solution, and timelines
- Furthered Technical Operations' understanding of challenges and opportunities of CSA transition

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KPI'S

Implementing recommendations will reduce local CSV documents in Quality Management System by more than 25%

Deepened Technical Operations and Quality Assurance's understanding of key challenges and opportunities to streamline CSV processes and ready the organization for CSA

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