

Global Computer Systems Validation Process for Research

The Situation: Global companies can often act like smaller independent companies by failing to leverage their resources and processes. This global pharmaceutical company evolved to a different computer systems validation process at each major research site in North America and Europe. As sharing of validated systems, data, research and reporting drove projects together, computer systems validation (CSV) led to rework of the validation effort before meaningful research could be achieved. Without a common CSV process, global research and quality assurance could not be leveraged, costing the Company in terms of resource and systems utilization and ultimately time-to-market for new drug applications.

The Solution: The Company decided that a fresh, outside perspective was required to bring all sites together in their endeavor to support a single global CSV standard. The ultimate test would be that each site could readily accept work performed and validated at other sites. ResultWorks was contracted to lead this effort employing their proven facilitation skills and methodology.

ResultWorks laid out a plan to assess the CSV approach at each site by engaging with key stakeholders. Interviews with dozens of people yielded an evolving picture of significantly different processes which were designed and executed toward the same objective. ResultWorks consultants found very strong processes, documentation, and management at each site. While there were significant differences, best practices, and strengths surfaced.

The core stakeholder team was assembled for a tightly executed two-day Result SessionSM in Europe. ResultWorks created working materials for the Result SessionSM to facilitate discussion, analysis, and decision making by the core team. On day one, the team reviewed the detailed processes of each site along with supporting documents and procedures. They challenged these processes and tools compared with the underlying FDA requirements.

On day two, ResultWorks shared a proposed future process which leveraged the best practices of all sites into a single streamlined CSV process. ResultWorks facilitated discussion, objections, and brainstorming to arrive at an emerging process that all sites could support.

Critical to the success of the CSV effort was the consideration of tools to be used for each process step. ResultWorks analyzed all of the tools, documents, and forms, and found a great deal of commonality. Many documents had similar purposes however, key terminology was often inconsistent. During the Result SessionSM, ResultWorks presented a consolidated mapping of tools and terminology used by each site for each process step and offered strawman recommendations for standards. Choices were evaluated, alternatives considered and decisions were made by the core team leading to a process with existing best-in-class supporting tools.

ResultWorks assimilated all of the decisions into a consolidated CSV process document within one month of the Result SessionSM. The global CSV process has since been adopted and new global system projects are realizing the benefits.

Key Benefits:

1. **Global Process:** One global CSV process supports global system implementations. Global quality assurance of systems is now a reality.
2. **Improved Return-on-Investment:** New global CSV process is expected to cut 2-6 months from comparable global implementation efforts.



One global computer systems validation process now supports global system implementations.