

5 Steps to More Efficient Computer System Validation

For biopharma and life sciences companies, computer system validation (CSV) is an essential process to ensure all computer systems work as intended as part of the manufacturing process. Without the right strategy, processes, and technology in place, companies can open themselves up to regulatory issues, defects, time-consuming and costly re-work, and ultimately patient risks.

Companies that prioritize adequate planning, preparation, and innovation will gain efficiencies to scale and flex with the ever-changing industry. Below are five ways to make your CSV processes more scalable and effective.

1. Put a Strategy in Place

Before starting any type of CSV project, it's important to create a strategic plan. The plan should detail the goals and objectives of the validation, include a business and workflow analysis, and define the necessary functional and user requirements. These requirements should be clear, specific, and reflect your unique environment to ensure the system will work as intended.

2. Develop a Validation Plan

A crucial next step is to develop a plan for the validation processes. This plan should include an explanation of how you will achieve continuous validation throughout the software development life cycle (SDLC) and compliance with regulatory requirements and industry best practices.

The validation plan should also include the scope of the project, the approach to testing, a list of all team members as well as their roles and responsibilities, and the requirements necessary for the system to be validated.

3. Implement a Risk-based CSV Approach

One of the best ways to improve CSV efficiency, save time, and reduce costs is to follow a GAMP® 5 approach that uses a formal risk-based assessment.

Consider scenarios in which the system would not work properly or fail, the likelihood the system would require downtime, and what the overall impact would be should the system not function properly.

Then, document how your team will respond, identify appropriate controls, and validate that they were applied successfully.

Keep in mind, however, that not every computer system will need full revalidated. To save time, identify the types of changes that will not alter how the system works. Then create documented procedures in the QMS that outline how these changes will be managed.



4. Create Detailed Documentation

The most successful CSV projects are comprised of structured knowledge and clear documentation about standards, processes, and logistics. This approach enables well-informed decisions, leaves no room for error, and ensures all team members are working together in an efficient way.

Your documentation should include a clear definition of the approach, address redundancies or conflicting information, match with the high-level guidance, and prioritize teamwork. It's also important to include potential challenges, obstacles, and what-if scenarios — and guidance for how they will be addressed.

5. Embrace Automation and Efficient Technologies

More complex technologies are being added to labs and manufacturing suites to increase efficiencies and safety. Cloud-based technologies such as infrastructure as a service, platform as a service, and software as a service can help reduce costs, improve flexibility, boost scalability, and quicken responsiveness to changing business needs.

Keep in mind, however, that each type of technology requires a different validation strategy to accommodate for server and application qualification and data validation.

On the CSV side, digital solutions that offer validation automation help to reduce errors and risks while driving efficiency. Companies that embrace technology innovation and automation from all angles will be best positioned for efficiency gains.

The Efficient Approach to CSV

Technology alone won't solve your validation inefficiencies. Find an experienced partner with a proven grasp on computer system validation for the constantly changing biopharma and life sciences manufacturing field. Together, you can develop a proactive plan that prioritizes accountability, saves time, and reduces costs.



About ICQ Consultants

ICQ (Integrated Commissioning & Qualification Corporation) partners with the world's largest biopharmaceutical manufacturers and emerging life sciences companies to provide comprehensive commissioning, qualification, and validation services that accelerate the delivery of medications and therapies to patients in need.

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