

Azure DevOps for computer system validation (CSV) compliance – The why & how of it



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Abstract

As the life sciences industry faces increasing regulatory demands and the need for rapid innovation, Azure DevOps (ADO) offers a comprehensive toolset that enhances efficiency, traceability, and compliance across all SDLC stages of computerized systems. By integrating various capabilities of ADO, organizations can streamline development, reduce manual errors, and maintain regulatory adherence, ultimately accelerating time-to-market and enhancing product quality. Gain a deeper understanding of Azure DevOps and how it can be used as a single-point solution for Computer System Validation (CSV).



Table of Contents

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■ Abstract	1
■ CSV Innovation: A tipping point in pharma?	3
■ Exploring traditional CSV further	3
■ Roadblocks in traditional CSV approaches	4
■ Azure DevOps: A closer look into key capabilities	5
■ How to use ADO as a CSV repository?	5
■ A clear roadmap to CSV journey with ADO	6
■ Best practices for using Azure DevOps for CSV compliance	7
■ Embracing innovations in CSV with ADO	9
■ References	10



CSV innovation: A tipping point in pharma?

With the evolution of the pharmaceutical industry, the skepticism surrounding the use of computerized systems has transformed into widespread reliance. In the early 1990s, regulatory frameworks such as the EU GMP Annex 11 expressed concerns about replacing human operators with computer systems, fearing a loss of quality and oversight.

However, this perspective has since shifted. Today, from bioprocessing to packaging and quality control, computerized systems are integral to delivering consistent, data-driven results.

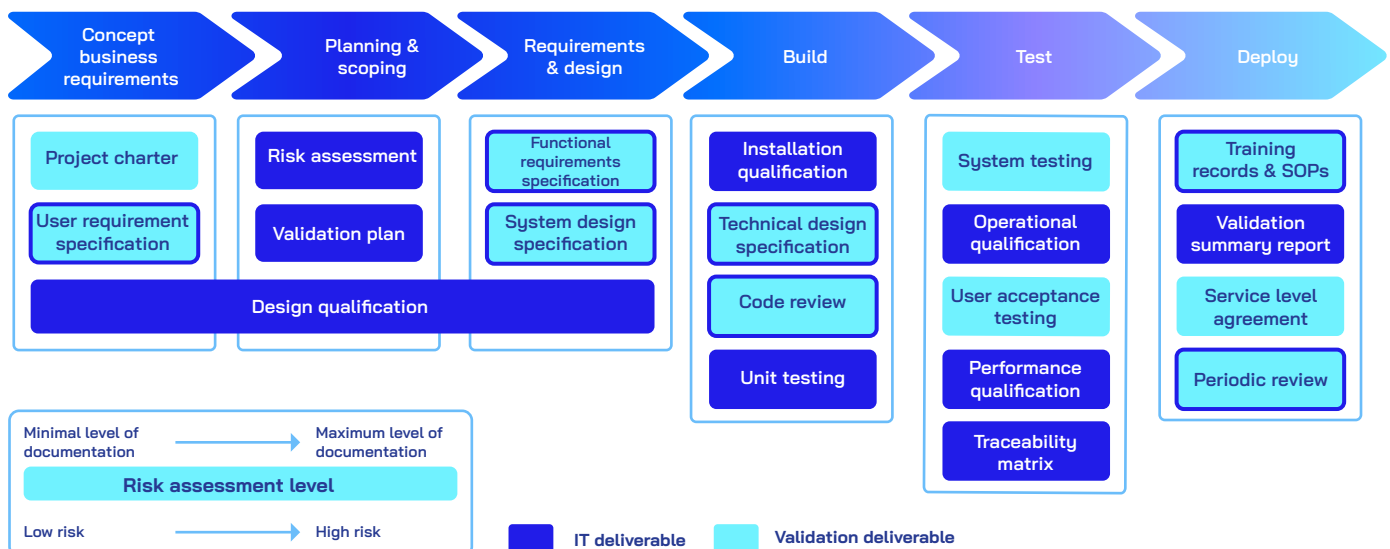
Nonetheless, strict regulations remain essential to ensure that computerized systems meet rigorous compliance standards. The CSV market is expected to reach \$7.33 billion⁽¹⁾ by 2030. The increasing technological adoption has driven the demand for CSV services. Yet, traditional CSV approaches often struggle to keep up with the speed and complexity of modern software development.

Enter Azure DevOps (ADO)—a digital-first toolset that transforms how organizations manage CSV. By integrating development, testing, and deployment into a single, streamlined process, ADO helps to ensure compliance and accelerates development timelines.

Exploring traditional CSV further

CSV is an ongoing compliance process that covers every stage of a system's lifecycle, from its development and implementation to its use, maintenance, and retirement. It ensures that computerized systems used in production, testing, or distribution meet predefined quality and standards. It is mandated by regulatory bodies like the Food and Drug Administration (FDA) and European Medicines Agency (EMA) to ensure patient safety, product quality, and data integrity.

Computer System Validation (CSV) SDLC Process



Roadblocks in traditional CSV approaches

The FDA has always promoted the least burdensome approach in all areas of medical device regulation. However, even after 20 years, CSV is still too complex. Organizations struggle with CSV in terms of resources, time, and cost, as well as the inability to implement modern technologies. As a result, overall project costs are higher using a traditional CSV approach. Let us dive deeper into the existing problems.

1. Testing bottlenecks

This involves manual execution and the development of lengthy test cases that demand hours of labor, often requiring screenshots, downloading documents, and compiling extensive reports—an old-school approach. Reliance on such methods is error-prone, and in a regulated environment, even minor errors can be fatal.

2. Regulatory compliance complexity

Regulatory standards, such as 21 CFR Part 11⁽²⁾, GxP⁽³⁾, and Annex 11⁽⁴⁾ introduce complexity at every stage of the validation process. Additionally, keeping up with evolving regulatory guidelines across different regions complicates the validation process, as systems must be validated to meet specific regional requirements.

3. Evolving technology landscape

As life sciences organizations increasingly adopt cutting-edge technologies like cloud computing, AI, and ML, their systems are becoming more dynamic and sophisticated. It is difficult to ensure compliance by using the same validation methods designed for simpler, on-premise systems.

4. Data integrity and cyber security concerns

Manually managing vast amounts of data can lead to mistakes, data breaches, or tampering, which could compromise data integrity and the entire validation process. Additionally, the rise in cyber threats poses new risks to data security.

5. Resource constraints

Conducting validation testing, documenting results, and maintaining compliance demands significant resources. The traditional approach to CSV exacerbates these resource challenges because of its reliance on manual testing and documentation.

6. Change management challenges

Managing system updates, software patches, or any organizational changes is difficult to streamline as it requires extensive documentation, impact assessments, and



collaboration across multiple teams. Implementing changes to validated systems often requires a revalidation process to ensure ongoing compliance.

7. Governance and accountability

In traditional CSV processes, responsibilities are often fragmented across various departments—quality assurance, IT, and regulatory teams—leading to gaps in accountability. Without clear governance, ensuring that all systems remain in a validated state can be difficult, especially as organizational complexity grows.

8. Vendor selection and management

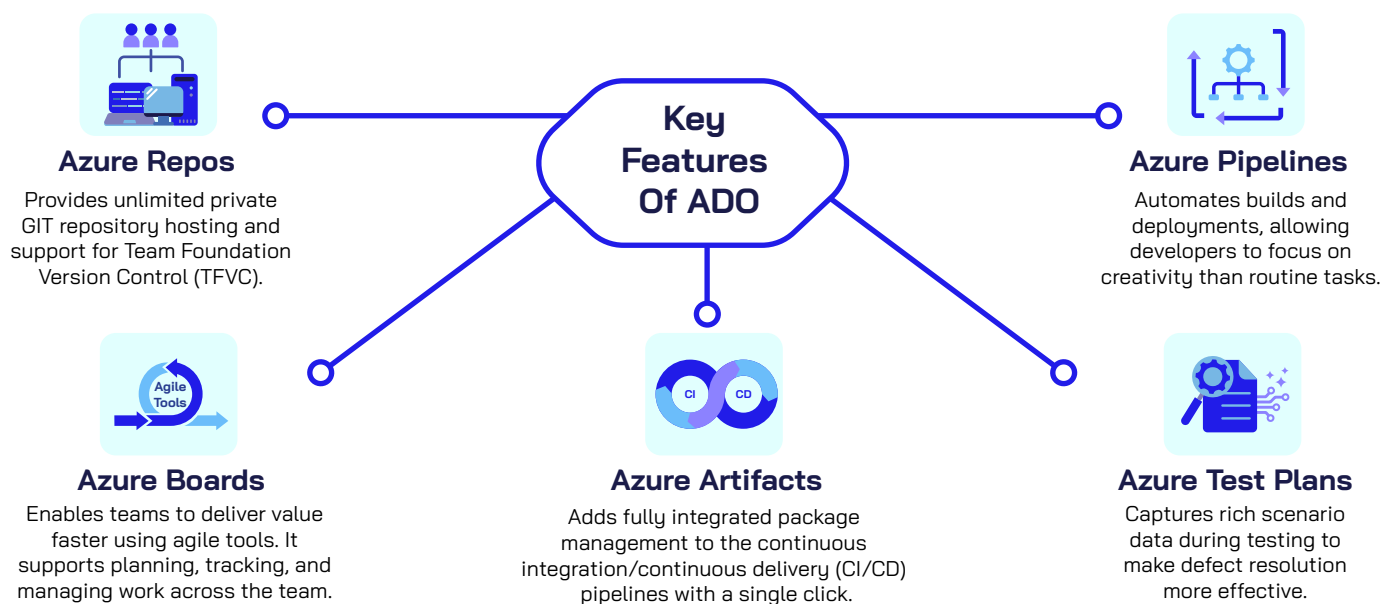
For pharmaceutical companies relying on third-party platforms, managing the validation of off-the-shelf and cloud-based solutions introduces another layer of complexity. Ensuring that vendor-supplied systems meet regulatory, and validation standards often requires rigorous auditing and documentation.

Pharma companies can easily overload staff, waste resources, and affect their sustainability practices with traditional CSV processes. Transitioning to modern tools and methodologies is essential to overcoming these hurdles and ensuring that validation processes are efficient, sustainable, compliant, and secure.

How can we move ahead with a less rigorous, economical, and faster validation methodology? The answer lies with ADO.

Azure DevOps: A closer look into key capabilities

ADO is a comprehensive tool that allows project teams a place to plan work, collaborate on code development, and manage the build and deployment of applications. It supports a set of processes that brings project managers, developers, and other contributors together to complete software development and software implementations.



How to use ADO as a CSV repository?

It's time to move forward with a fully automated, compliant, and quality-based CSV. ADO can be the foundation for employing new technologies to meet the FDA evolving regulatory requirements. Here are some components of the standard CSV methodology that could work well in ADO:

■ System Risk Assessment (SRA)

SRA is the first deliverable in the CSV process. It can be created in ADO as a new work item with standard assessment questions on system complexity, GxP impact, regulatory applicability, and 21 CFR Part 11 applicability. Using Microsoft Power Automate with ADO, the answers to the questions can automatically return results, such as whether the system should be validated, the overall risk level of the system, and a list of the validation documents that should be delivered as part of the CSV effort. The SRA results are then routed for automatic approval within ADO, removing all manual paper tasks.

■ User Requirements Specification (URS)

Without a solid URS, an organization cannot provide documented evidence that a system works as intended. Requirements are usually gathered in an analysis phase within traditional projects. This would not change; however, the difference is that requirements specific to the industry can be pre-loaded into ADO as a work item. The time now spent in the analysis phase would be reviewing the pre-loaded processes and requirements, removing what is irrelevant, and adding more client-specific nuances. Approval of the URS also is documented in ADO.

■ Functional Requirements Specification (FRS)

The FRS is produced during a design and development phase and should document all configurations and any customizations, integrations, and/or data migration. Several work items, used together, would comprise the total FRS. Each of these items is traced back to a user requirement (predecessor), and the FRS ADO work item would be the successor to the appropriate OQ test scripts, saving effort in building an independent Requirements Trace Matrix (RTM).

■ Operational Qualification (OQ)

The OQ test scripts can be developed as part of Conference Room Pilot (CRP) events using Microsoft's Regression Suite Automation Tool (RSAT) with appropriate test prerequisites and data inputs. When executed, these tests would provide documented evidence that the associated user requires and that the FRS items function as intended. Once the test scripts are created, they can be used repeatedly for future revalidation change control efforts, such as patch releases and upgrades.



A clear roadmap to CSV journey with ADO

Moving from traditional CSV to ADO will ensure sustainability and provide pharmaceuticals with the ability to leverage an automated process. ADO streamlines documentation and emphasizes risk management, data integrity, and quality assurance, helping the organization keep up with their regulatory efforts. Here, we will dive deeper into CSV processes and where ADO features can be used to support SDLC phases.

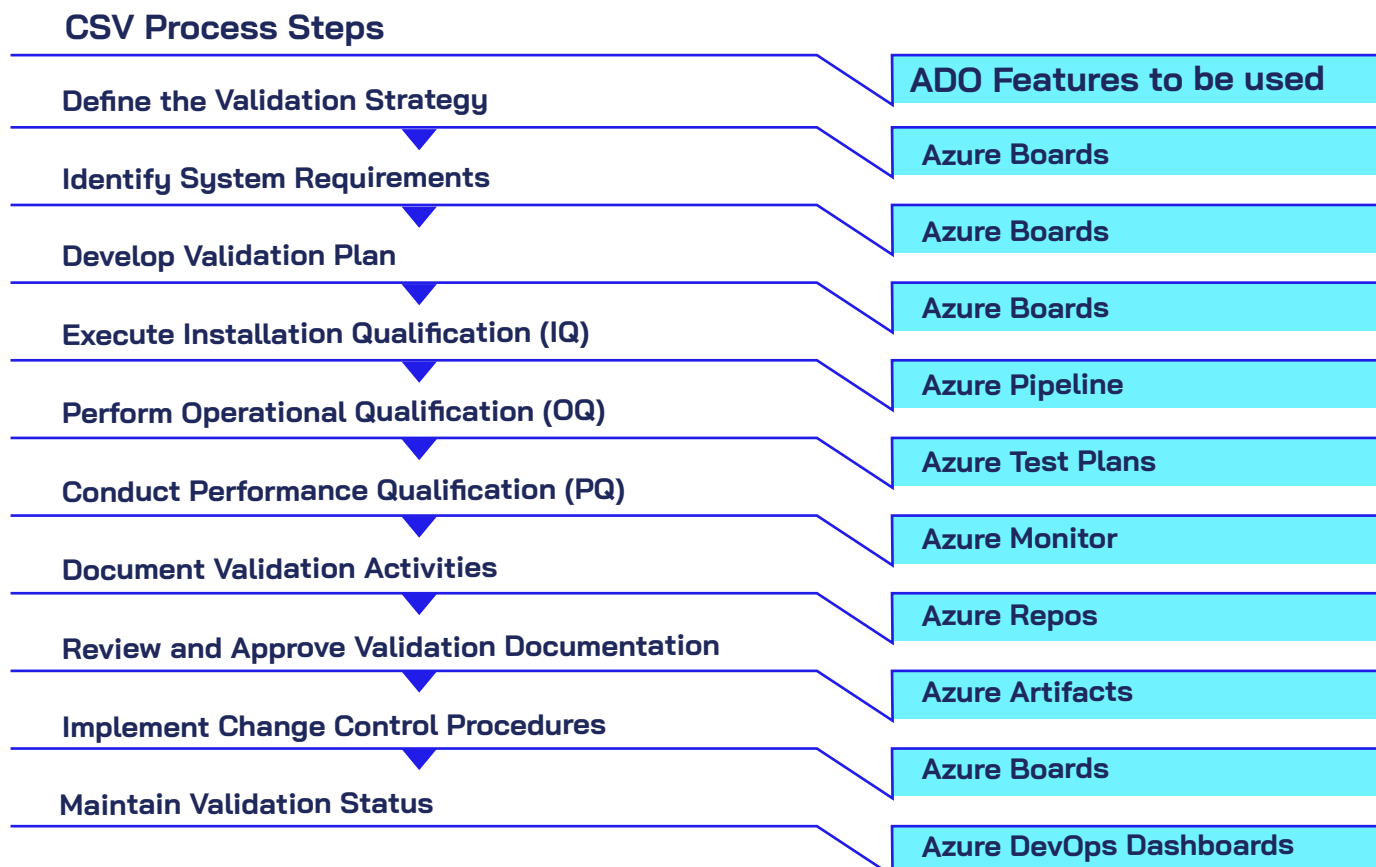


Exhibit 2: CSV process steps and corresponding ADO features to be used.

1. Requirements and collaboration

Azure Boards can capture and manage system requirements with work items such as user stories, features, and tasks. It offers full traceability between requirements and associated artifacts like test cases and code, ensuring that development aligns with business objectives. Additionally, it can integrate with communication platforms such as Microsoft Teams and Slack.

2. Version control

Git in ADO can provide robust version control, ensuring changes in codes, rereleases, and even sprints. Git tags can be used to mark these versions, making it easier to track and

3. Automated build systems

With Azure Pipelines, teams can implement automated CI/CD (Continuous Integration and Continuous Delivery/Deployment) pipelines to build, test, and validate code changes. This feature supports multiple platforms, programming languages, and build systems, allowing a unified workflow across diverse environments.

4. Coding and development

Azure Repos offers robust source code management capabilities, with version control using Git or Team Foundation Version Control (TFVC). Teams can implement branching strategies for collaborative coding and merging changes. With its powerful search functionality, developers can quickly locate and navigate code within repositories.

5. Testing and quality assurance

With Azure Test Plans, create, manage, and execute test cases, including manual and automated testing. The tool seamlessly integrates with test automation frameworks to enhance the testing process, and automatic objective evidence capture add-ins streamline script creation and test execution. Without such tools, the organizations will be stuck when new updates keep coming.

6. Deployment

Azure Pipelines supports automated deployments, allowing for the rapid and consistent delivery of applications. Integration with Azure services for cloud deployment speeds the process up. At the same time, integration with Docker and Kubernetes supports container-based workflows.

7. Artifact management and packaging

robust versioning and tracking capabilities. Supporting popular package formats such as NuGet and Maven, this feature ensures that teams maintain consistency across different development environments and projects.

8. Monitoring and analytics

By integrating with Azure Monitor and Azure Application Insights, teams can gain real-time visibility into application performance and gather telemetry data to assess system health. In addition, the customizable dashboards and widgets allow for seamless project tracking. It can also use Power BI for advanced reporting and visualization.



9. Security and compliance

With Role-Based Access Control (RBAC) and Azure Security, teams can set up fine-grained access controls to protect sensitive data. Built-in compliance auditing capabilities help teams maintain audit trails, ensuring that projects meet regulatory requirements. Furthermore, integration with security tools aids in identifying code vulnerabilities, helping teams comply with security standards.

Best practices for using Azure DevOps for CSV compliance

Properly setting up ADO environments is crucial for any SDLC project's success. Here are some of the ADO best practices to meet all the CSV regulatory requirements:

- Plan sprints effectively by defining goals, prioritizing activities, estimating efforts, tracking tasks, and creating sprint backlogs in ADO. After each sprint, analyze the activities and plan for the next one.
- Create a centralized knowledge base to improve collaboration and communication between team members.
- Implement continuous integration/continuous delivery (CI/CD) to enhance automation, collaboration, and feedback.
- Ensure continuous implementation of security practices in DevOps.
- Continuously monitor software performance and progress using burn-down and burn-up charts.
- Set up dashboards in ADO to track key project execution metrics. Switch to microservices to ensure greater agility and scalability.

Embracing innovations in CSV with ADO

In today's regulatory landscape, CSV is a must. Digitalization can revolutionize how organizations approach it and give them the confidence to face audits. It can automate key processes, enhance collaboration, and provide centralized platforms for managing CSV.

A future-proofed CSV approach with AI/ML and GenAI integration that enhances the validation process with automated script and test case generation. New developments like validation 4.0, risk-based prioritization, AI/ML automation tools, cloud-based solutions, global harmonization approaches, and a focus on user experience are reshaping the current CSV scenario in pharma.

By embracing these advancements and digitalization tools like ADO, organizations can stay ahead of regulatory changes while continuing to innovate with confidence in their systems and processes.

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