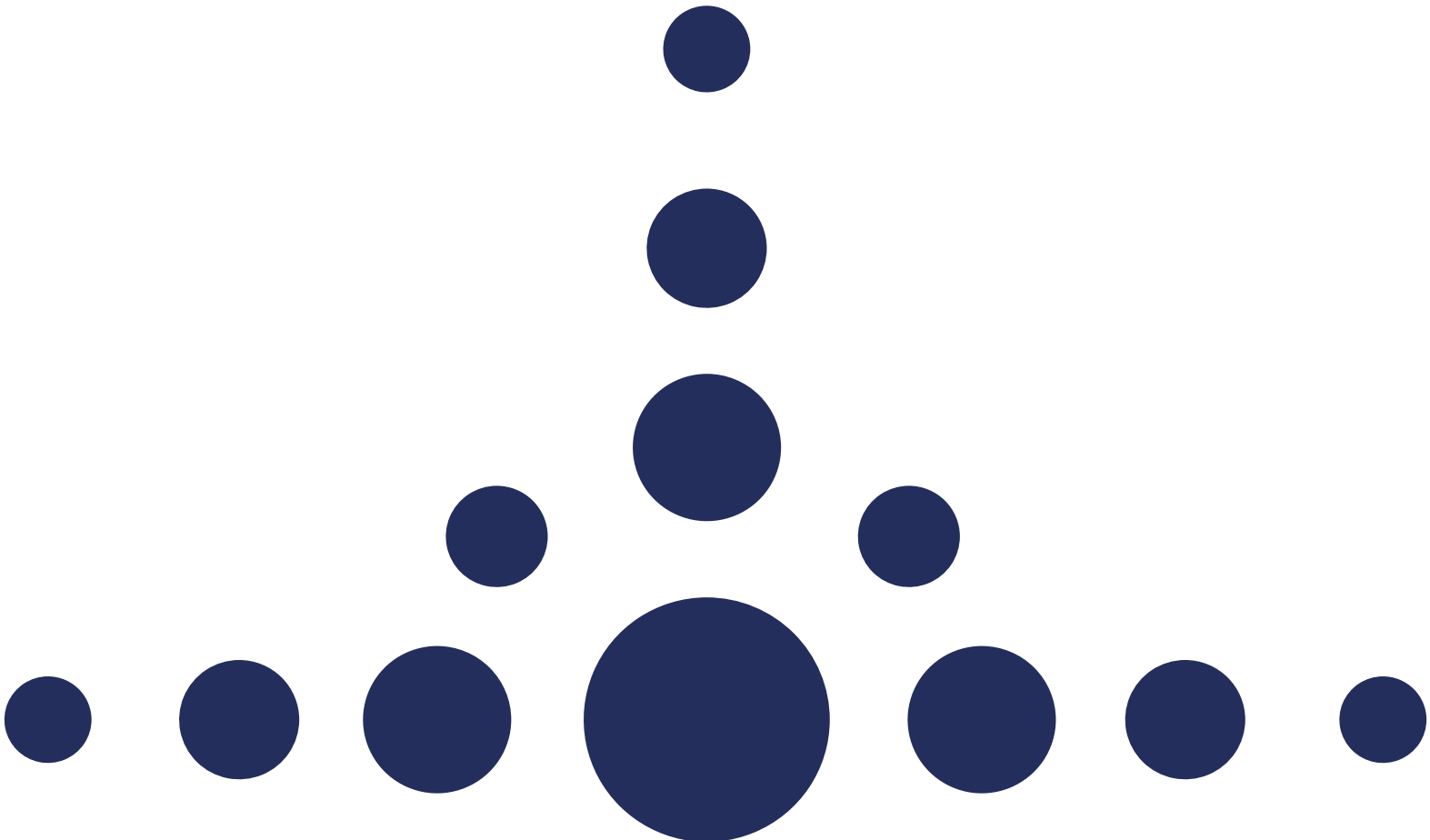




Automate Validation Across Your Tech Stack

Achieve Continuous Compliance with USDM Cloud Assurance™



Introduction

Validation ensures that your technology systems, software, and processes consistently fulfill their intended use and meet user needs. Audits confirm that you have established the controls required to validate your systems and keep them validated.

Unfortunately, validation can be burdensome. Over-validating can easily exceed the cost of implementation. Even a risk-based approach can be time-consuming when you have different interpretations of the regulations between technical, compliance, and business teams. As your organization's IT infrastructure becomes more sophisticated, you need more controls around network, storage, and database services.

*The FDA defines computer system validation (CSV) as "confirmation by examination and provision of objective evidence that **software specifications** conform to **user needs and intended uses**, and that the particular requirements implemented through software can be consistently fulfilled."*



Cloud Compliance

While cloud vendors take on more infrastructure management, your life sciences company is ultimately responsible for the quality of your system. You need an appropriate service level agreement (SLA) and risk mitigation for changes introduced by your cloud vendor. How will your teams gain visibility into their change process?

Cloud computing and the speed of product development present new challenges to validation in the cloud. Simply following your traditional change control processes might make it difficult to keep up with change-impact assessments and identify the right amount of regression testing. Beyond that, regression verification must be executed in a timely manner. Do your internal teams have the time and the expertise to evaluate and accommodate these changes?

Consider Outsourcing Validation

Taking on the responsibility of vendor qualification can be overwhelming. Navigating global regulatory requirements is complicated. Constant changes and countless interpretations create significant challenges and organizational inconsistencies when aligning Quality and IT business goals. Finding new employees and getting them up to speed with each of your vendors can be arduous. Retaining staff is vitally important to preserve the industry, product, and organizational knowledge. While it is important, what is the cost of your team spending time on vendor qualification instead of innovative priorities that return greater value? Offload your cloud vendor qualification and maintenance and give that time back to your team.

USDM Life Sciences' approach to compliance and technology is to simplify your ability to meet regulations, optimize and automate your GxP processes, and maximize the return on investment (ROI) of your technology. By taking a holistic approach to your people, processes, and technology, we can help you harmonize compliance across your organization and create a scalable strategy for radical innovation.

Modernize Your Approach with Computer Software Assurance

Computer Software Assurance (CSA) is a revised framework designed to help drug and device manufacturers get clarity to efficiently achieve Computer System Validation (CSV).

The U.S. Food and Drug Administration (FDA)'s highly anticipated draft guidance will spell out a true risk-based approach to validation. The CSA methodology has been championed for years by the FDA, and USDM has been implementing it for customers for more than two years. As the FDA emphasizes quality, they encourage the use of automation and new cloud technologies.



USDM Cloud Assurance

USDM's Cloud Assurance™ is a managed service subscription that offloads the initial qualification or validation of an IT system and maintains ongoing release management. It includes an annual vendor audit that customers can leverage as objective evidence of their system's compliant state.

Cloud Assurance is an automated, compliant digital platform for GxP cloud-based technologies of any size or complexity. Whether you have a single cloud application needing continuous validation or a multi-cloud system portfolio, Cloud Assurance scales to meet your needs and delivers a harmonized compliance framework that decreases your time investment and overall cost to maintain compliance.



USDM can manage your entire CSV or CSA process, achieve continuous maintenance of all your cloud vendor releases, and:

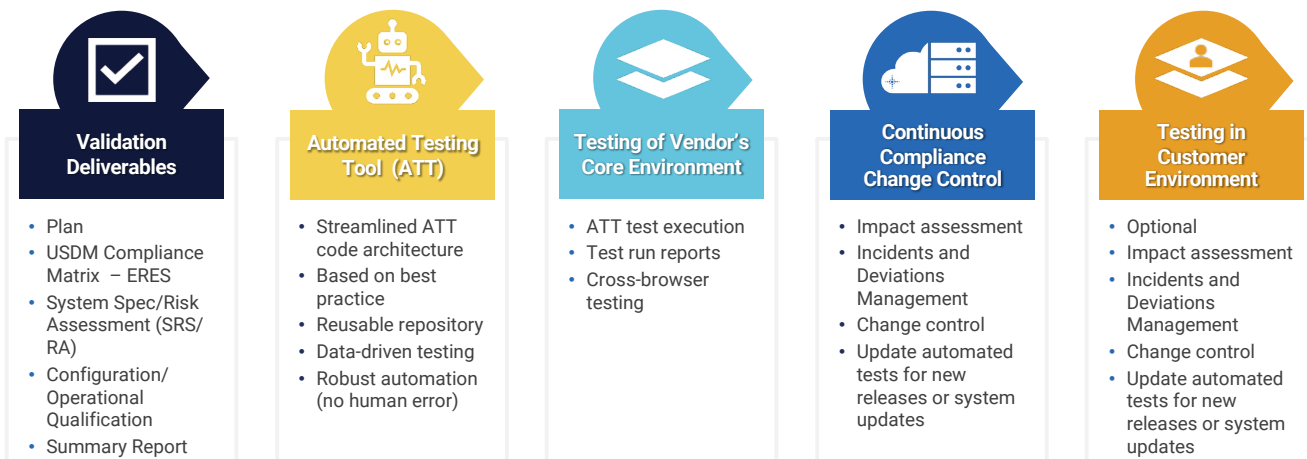
- Assist with cloud vendor selection and the Request for Proposal (RFP) process
- Manage cloud vendor assurance, vendor qualification, and maintenance of new releases
- Leverage automated regression testing
- Assess your IS efficiency and cloud compliance maturity and help build a strategic IT roadmap

USDM is on the cutting edge of technology and compliance. Our progressive solutions are based on more than 20 years of industry experience.

Automated Compliance

There is a time and place for manual testing, but in most cases, automated testing is the faster, more accurate, and most efficient way to keep pace with applications on rapid release cycles.

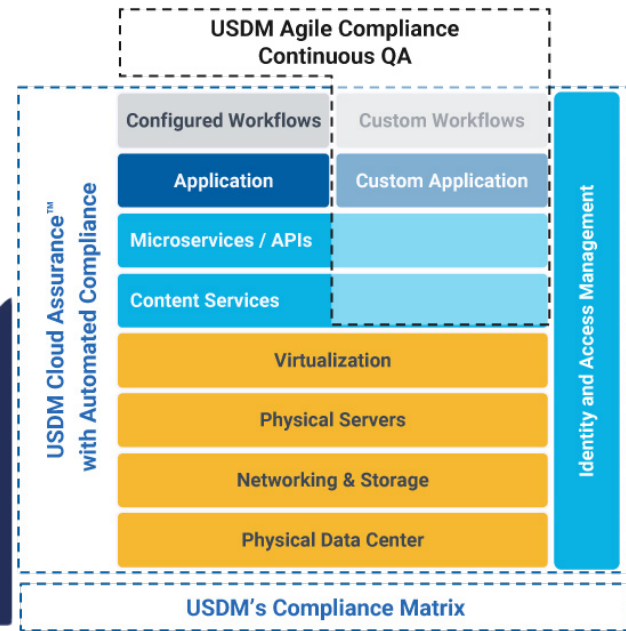
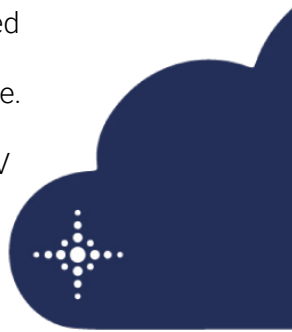
In addition to exceeding minimum testing requirements, automated testing saves significant time and money when you don't have to manually test things like operational qualification (OQ), and minimizes human error. The framework is aligned with the CSA methodology and leverages the technology vendor's testing assets where appropriate to prevent repetitive, low-risk testing. The following graphic illustrates USDM's automated compliance framework.



Evolve Your Infrastructure

Originally defined in the International Society for Pharmaceutical Engineering (ISPE) GAMP Good Practice Guide: IT Infrastructure Control & Compliance, the USDM Cloud Assurance building-block approach qualifies individual or combinations of services and microservices to maximize the opportunity for re-use. These qualified services and microservices are then used to build the infrastructure, platform, and support service layers to support the GxP application's use.

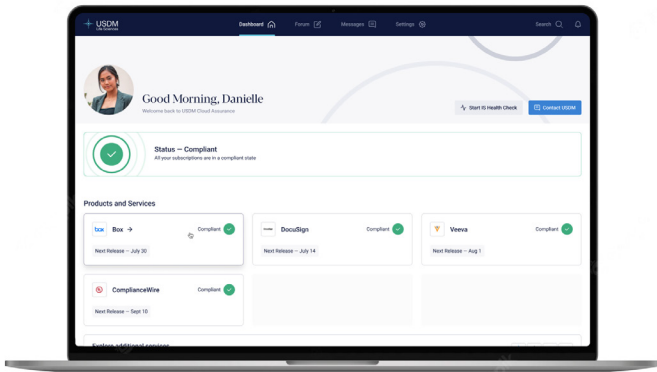
This building-block approach can be used for CSV and CSA and reduces your overall effort across your tech stack—you can qualify one instance of a building block and trust that all the other instances will perform the same way. Future use of these building blocks is focused on verifying the configuration and end-to-end intended use.



You don't have to choose between compliance and innovation. Cloud Assurance enables you to turn IT compliance into an innovation hub so you can get ahead and stay ahead of your competitors. Integration support across all departments ensures that you remain in compliance as your organization grows, and you have greater opportunities to unlock the value of your data with artificial intelligence (AI) and machine learning capabilities.

Cloud Assurance Web Application

To further simplify your compliance needs, USDM built a Cloud Assurance web application (web app) for always-on transparency and access to all of your system reports. From your Cloud Assurance online dashboard, you can track notifications and subscription activities and download the Annual Vendor Audit and assurance reports that you can leverage as objective evidence for the FDA and other global regulatory agencies. The web app capabilities and knowledge base will evolve to accommodate new knowledge, i.e., best practices, industry insights, and product information. You will also be able to engage with USDM subject matter experts and other product users. You'll move from simple awareness and control to communications and intelligent insights.



Cloud Assurance Certified Partners

With more than 300 life sciences companies subscribed, USDM Cloud Assurance has become the industry standard for continuous compliance in the cloud. We are strengthening this trust with a new Cloud Assurance Certified program that recognizes technology vendors that meet the quality and compliance demands of the life sciences industry. Cloud Assurance Certified technologies must undergo a rigorous compliance, security, and data integrity assessment by USDM and demonstrate their compliance with global health authority statutory and regulatory requirements. It is THE badge of trust for GxP functionality and signifies the technology partners' commitment to advancing pharma, biotech, and medical device companies.



Conclusion

From methodology development through end-user training, USDM ensures that your systems are compliant. We have two decades of focused expertise and have created proprietary templates, methodologies, and accelerators to help you simplify compliance. We have the tools to determine the global regulatory requirements, standards, and guidelines that govern your quality management practices and assess your compliance with them, and we help you implement the necessary technical and procedural controls. You don't have to choose between regulation and innovation we can show you how to simplify compliance to make it a strategic, competitive advantage.

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