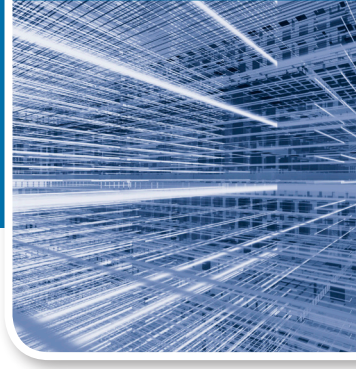
Atos | Syntel



Optimize Performance by Harmonizing Computer System Validation

Computer system validation (CSV) is an integral process for pharmaceutical, biotech and medical device companies. As new technologies such as cloud, mHealth and automated testing tools pave their way in the life science industry, the backend infrastructure becomes more complicated making CSV more complex.

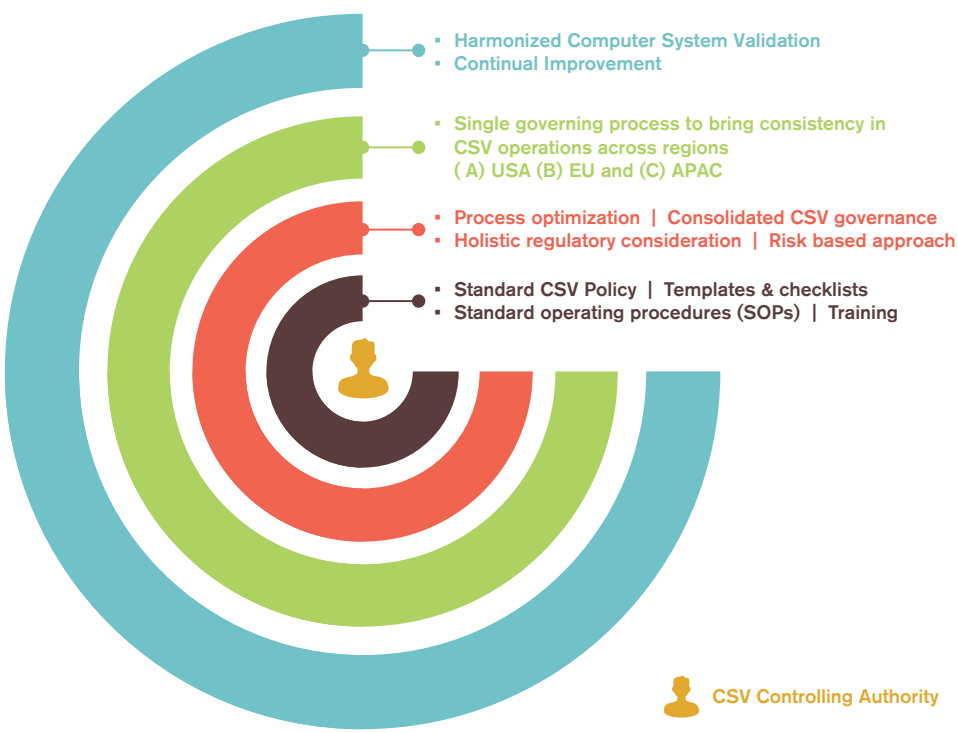
In most of the life science organizations, validation of systems is performed by business users and IT teams in a decentralized manner, as they work in silos across geographies. This results in increased time due to rework and a waste of resources. Overlapping standards and inconsistent documentation pose another major challenge for organizations already facing increased regulatory pressures. Further, FDA and other regulatory bodies such as EMEA, MHRA and MHLW are encouraging organizations to adopt a risk-based approach for validation of computerized systems.

Atos Syntel's Solution

To tackle these industry-wide challenges, Atos Syntel proposes a **Harmonization process framework** for CSV which operates on a factory-based model for validation and verification. The framework provides a centralized knowledge repository and governance model to measure performance across the validation process leading to harmonization.

Our dedicated team of domain and technical experts supports our life sciences customers with solutions on a harmonized CSV process, a central repository of knowledge gained from different engagements, with details on projects, best practices, processes and metrics.

This clarifies the role of each team member leading to a focused approach to executing the activity with quick turnaround. In addition to this, the framework is supplemented by a variety of in-house tools and accelerators to assess your systems and mitigate risks. This framework delivers end-to-end validation solutions and regulatory compliance.



ATOS SYNTEL'S CSV CoE

Atos Syntel's Computer System Validation Center of Excellence (CoE) facilitates a speedy validation process with our matured compliance procedures, templates and artifacts. Our experts aim at delivering efficiency gains through reusability and process optimization. Industry-best practices are woven into client policies and procedures to deliver a customized validation package.

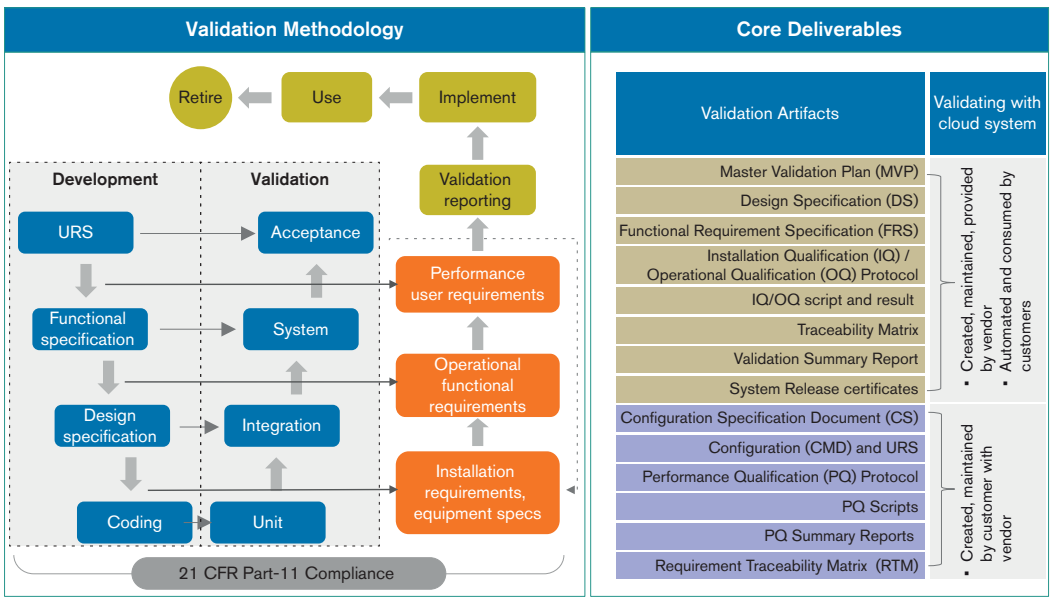
BUSINESS BENEFITS

- Up to 20% reduction in effort due to improved efficiency
- Up to 25% reduction in client expenditure by implementing holistic standards, procedures, templates, checklists and performance metrics
- Improved service levels and transparency by implementing clear roles and responsibilities using the responsibility, accountability, consult, inform (RACI) model and governance
- Rapid induction and training programs with secured knowledge retention across activities
- Optimized efforts through faster collaboration by adopting LEAN and automating repetitive tasks

Harmonized Data Center – Validation and Verification on Cloud

Newer technologies such as cloud have been adopted for cost-effective global systems and business processes. This makes it imperative to conduct validation across new technologies and processes to adhere to regulatory requirements.

Atos Syntel's cloud validating services help organizations and their vendors align their operating standards with predefined regulations. Our hybrid agile and traditional SDLC approach for validation strikes the right balance between agility with compliance.



The 'V-Model' is the backbone for any CSV testing performed at Atos Syntel CoE

Delivering Excellence

Deployed Centralized CSV for a Leading Pharmaceutical Company

Challenges

- CSV activity in silos for 250 applications, leading to excessive rework for the validation team
- Inadequate system inventory
- Decentralized system and overlapping of standards and procedures

Solution

- Conducted gap assessment, communication, management and consolidated CSV, benchmarking governance across different geographical locations
- Improved compliance with global computerized systems
- Used Atos Syntel's validation accelerator for global e-compliance
- Streamlined processes across locations
- Enhanced inventory management with proper segregation
- Trained client counterpart on CSV regulations and guidelines

Value Delivered

- 25% saving in efforts by optimizing resource utilization
- 30% increase in effectiveness by reducing cost of rework and quality of documentation
- Improved efficiency and reduced turnaround time
- Ensure uniform high quality and regulatory compliance landscape
- Successful United States Food and Drug Administration (USFDA) and Medicine and Healthcare Regulatory Agency (MHRA) audits