

## Will increased integration of AI in CSV really boost efficiency and profitability?

### Introduction

As life science companies brace themselves for business volatility in 2025, optimising process efficiencies and reducing costs is a key driver for increased adoption of Artificial Intelligence (AI) in Computer Systems Validation (CSV). It is expected that investments by life science companies in AI could lead to cost savings of up to 12% of total revenue. <sup>1</sup>

CSV, traditionally a manual, resource-intensive process, requiring extensive documentation, testing, and ongoing validation to satisfy regulatory bodies, can realise major efficiencies and cost savings by effectively integrating AI and Machine Learning (ML).

Compared to traditional strategy, AI can process data quicker, can evaluate complex data and identify trends. These technologies play a pivotal role in automating many business processes and activities that humans usually do and are being quickly adopted by the life science industry. AI/ML offer the potential to streamline validation processes, improve data accuracy, reduce human error, and accelerate time-to-market. There are challenges to effectively implementing AI/ML in CSV before any cost savings or improved efficiencies can be realised. Let's look at how AI can bring efficiencies to CSV and if the effort in overcoming the associated challenges is really worth it?

### The Role of AI/ML in Transforming CSV

While the traditional approach to CSV is proven and effective, this manual approach is time-consuming, resource-intensive, and subject to human error. AI/ML technologies are being adopted to streamline and optimise the traditional CSV process including through the automation of manual processes, the enhancement of the effectiveness of CSV and increasing compliance with regulatory requirements (Figure 1).

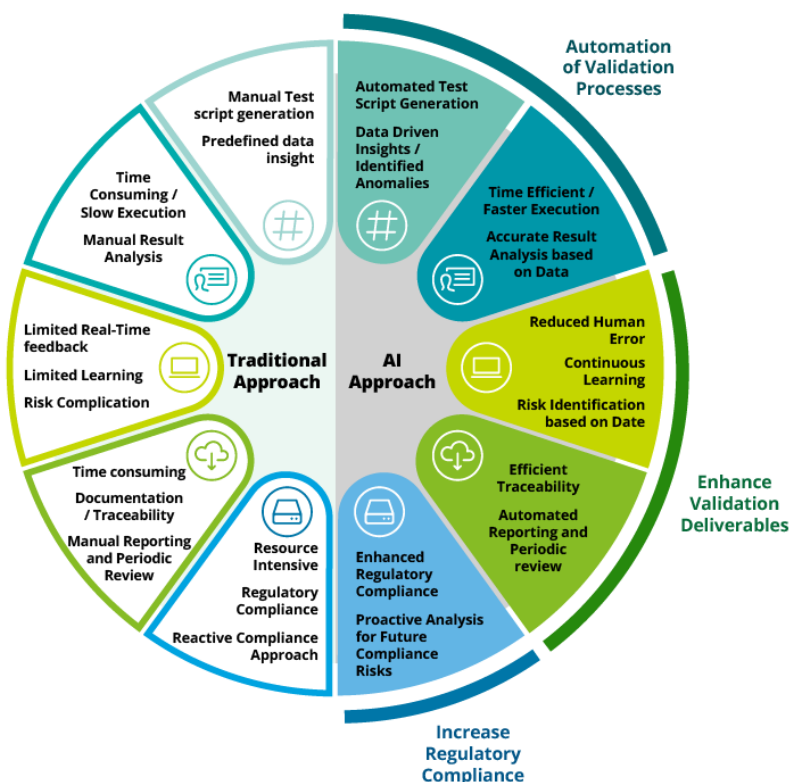


Figure: 1 – Benefits of AI over Traditional approach to CSV

### **Automation of Validation Processes**

Traditional validation requires human input to develop test cases, execute scripts, and analyse results. AI/ML can automate many of these tasks, allowing for faster, more efficient validation. For example, AI-powered tools can generate and execute test cases based on system specifications, perform regression testing, and identify anomalies with far greater speed and accuracy than manual processes.

Machine Learning models can analyse historical data from previous validation efforts, identifying patterns that could indicate potential risks or system failures. These models can also continuously monitor system performance, identifying potential issues before they escalate, helping to prevent system downtime or defects and increase compliance with regulatory standards.

### **Enhance Validation Deliverables**

Validation in the life sciences industry is heavily documentation driven. AI/ML can be used to both improve the quality of and speed up the generation of CSV deliverables. AI/ML can generate accurate validation documents by analysing input data, eliminating human errors, and providing valuable insights, identifying patterns, and providing recommendations in existing deliverables.

AI/ML can also help to automate compliance processes such as traceability, risk assessments, periodic reviews, audits, and reporting. The risk identification capabilities of AI/ML tools can be used to identify potential compliance risks by analysing data from various sources such as financial reports, customer complaints and regulatory filings. Combining risk identification with predictive analytics, AI/ML can be used to identify potential compliance risks and provide recommendations for mitigating those risks.

### **Increase Regulatory Compliance**

AI/ML are not only used to automate the process but also to enhance compliance with regulatory standards, achieved by acquiring and processing information from applicable regulations. AI/ML systems can be trained on rules and regulations that are applicable to the life sciences industry. This enables AI/ML to ensure that the CSV deliverables are completed in line with regulatory requirements and to identify and eliminate possible discrepancies, compliance gaps, or non-compliance with regulatory standards.

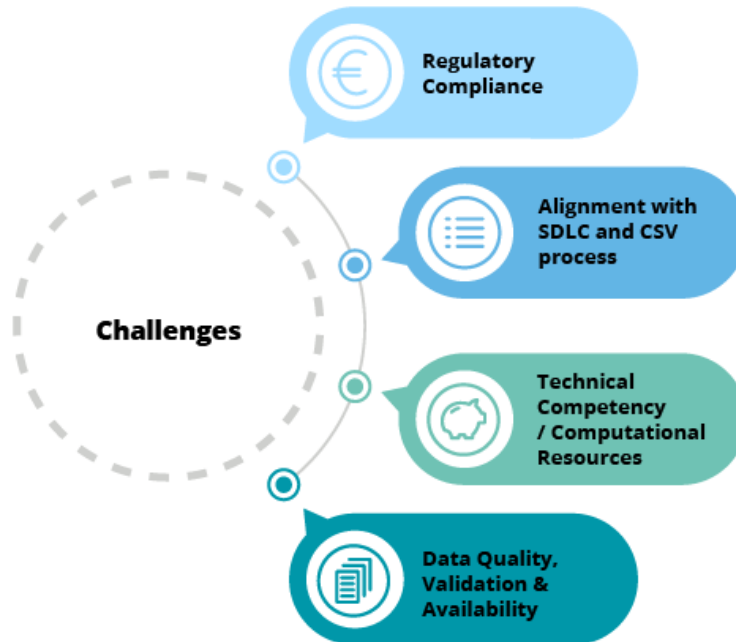
### **Challenges and Considerations in Implementing AI/ML**

While AI/ML offer significant advantages in automating and enhancing CSV as outlined above, their adoption comes with certain challenges.

One of the primary hurdles is ensuring that AI/ML applications align with regulatory requirements. Life sciences organisations must ensure that their use of AI/ML in CSV complies with their own Software Development Lifecycle (SDLC) and CSV processes and with current industry regulations and guidelines.

AI/ML algorithms depend on high-quality, accurate data to make reliable predictions. If the data input into these models is inaccurate or incomplete, the resulting analysis may be flawed. Organisations must invest in data governance and ensure that the data feeding into AI/ML models is validated and secure.

The integration of AI/ML into CSV workflows requires specialised skills and knowledge. Life sciences companies need to invest in training their employees or engaging experts with the necessary technical competencies to manage these technologies and ensure their proper implementation.



**Figure: 2 AI implementation challenges**

### **Conclusion**

Advancements in AI and other digital technologies is transforming how CSV is delivered, but are improved efficiencies and increased cost savings really achievable in CSV? It is clear that efficiencies and cost savings do not come without challenges. The adoption of these technologies must be done carefully, ensuring compliance with regulatory requirements, maintaining data integrity, and addressing the need for specialised expertise. However, the effort involved in overcoming any challenges associated with effective integrating of AI into the CSV process will almost certainly ensure significant cost savings for an organisation.

As AI/ML continue to evolve, they will undoubtedly become essential tools in modernising CSV practices, helping life sciences companies stay competitive while maintaining the highest standards of product quality, patient safety, and data integrity.

### **Reference:**

1. <https://www2.deloitte.com/us/en/insights/industry/health-care/life-sciences-and-health-care-industry-outlooks/2025-life-sciences-executive-outlook.html>