

# SaaS Validation using Automation 2024:

Three insights that define how new testing technologies will help transform GMP validation

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# SaaS Application Support through automated Testing

SaaS Application insights and growth trends in Life Sciences that system owners should consider and how to leverage this transformative technology to save time.

The transition to SaaS offers numerous benefits for biotech and pharmaceutical companies, including scalability, cost efficiency, and the ability to quickly adapt to changing business requirements.

Validation activities for a hosted system also require software owners to reevaluate their organization's current validation procedures. The SaaS model shifts much responsibility for system maintenance and security to the software service provider, but the **accountability for ensuring regulatory compliance always remains** with your organization.

This shift has led to the development of **new validation strategies** that are collaborative, risk-based, **continuous**, and adaptive to cloud-based solutions. IT Validation Managers must ensure that their SaaS solutions meet the same rigorous standards as their on-premises predecessors.

Advances in automated, continuous validation technology contribute to the high market adoption and growth rate projections for automated testing over the next decade.

# 17%

# CAGR

The market has achieved a significant valuation of USD 18.3 billion in 2022 and is forecasted to pursue an impressive CAGR of 17% through 2028, reaching USD 49.29 billion.

**-GLOBE NEWSWIRE**

# Forecasting 2024: Trends

Adopting automation in your validation testing toolbox enhances enterprise value across the board by **increasing test efficiency, simplifying, and standardizing** testing strategies.

In 2024, we are already seeing a surge in automation testing activity. Robotic Process Automation (RPA) and AI initiatives are also being introduced to streamline user management, data entry, and test case creation.

Standardized continuous testing features and cloud platform consolidation ensures consistency. Faster bug detection and reduced hosting and testing costs lead to quicker fixes, and overall higher quality state of an application.

**Automation empowers businesses**, but human expertise remains crucial for strategy and complex tasks.



# INSIGHTS - Supporting SaaS & Implementing Testing Automation

## 1 Adoption of Enterprise SaaS software Strategies & Regulatory Compliance

Adopting SaaS offers significant benefits in scalability and cost for our life science partners. To maximizing advantages while ensuring compliant applications, requires strategic planning in data security, regulatory adherence, vendor management, and system integration.

## 2 Leveraging Automated Testing for Efficient Validation

Automated testing significantly simplifies SaaS validation for GXP applications. Having a suite of automated regression test scripts, for example decreases compliance risk by allowing more comprehensive testing, while shortening system validation project timelines and reducing costs.

## 3 Preparing for the Future: Trends and Innovations

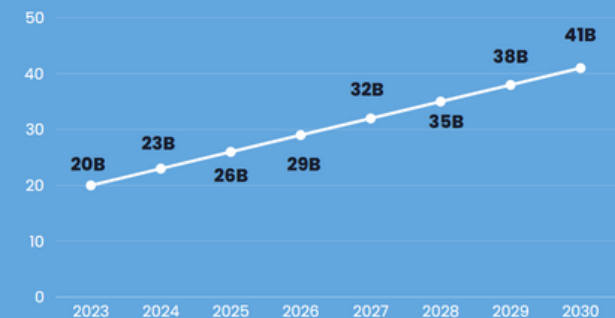
The future state of computer system validation for leading life science companies will have most of their applications hosted externally. These systems will be in a state of continuous validation via automated testing and reporting. In this CSA model analysts will only maintain the testing suite, and have more time to focus on opportunities to perform enhancements to reduce risk to patient safety, product quality and data integrity.

Testing is a major, time-consuming exercise. It perhaps offers the **greatest opportunity** for efficiency savings.

- ISPE GAMP5 Revision 2 Guidance

### Automation Testing Growth

Projected Growth based on current CAGR values



# Adoption of Enterprise SaaS software Strategies

Navigating the Cloud: Strategic SaaS Solutions for Biotech and Pharma Growth

## The SaaS Advantage

**Scalability:** SaaS provides unmatched scalability, enabling life science firms to adjust IT resources with minimal upfront costs and lower operational costs.

**Affordability:** By leveraging cloud-based services, companies can significantly reduce upfront capital spend. Subscription-based models spread costs over time and eliminate the need for full time infrastructure staff.

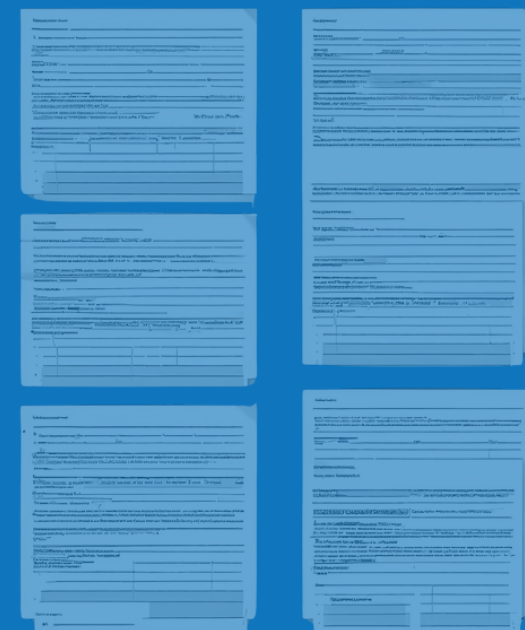
**Continuous Updates and Maintenance:** SaaS providers manage updates and maintenance, keeping the latest features and security up-to-date. Improving performance while reducing risk.

## Strategic Considerations

**Data Security and Privacy:** Service level agreements (SLA) are more critical in a SaaS model. Clients must ensure providers will comply with industry-standard for security and data integrity.

**Regulatory Compliance:** Validation standards (GCP, GLP, GMP, etc.) must be adapted to the cloud-based nature of SaaS. System owners must have a process in place for scheduled updates that are outside their control.

**Risk Mitigation:** Compliance documentation from software vendors (if it exists) often only covers core package functionality. A suite of scheduled regression tests is an excellent substitute for subjective risk assessments.



## Insight #2

# Leveraging Automated Testing for Efficient Validation

Enhancing Efficiency: The Power of Automated Testing in Validation Processes

## The Role of Automated Testing in Validation:

### Consistency:

Automated testing tools can execute predefined test cases faster and more consistently than manual testing, significantly reducing the validation cycle time. This consistency ensures that every functional aspect of the SaaS solution is tested under the same conditions every time.

### Coverage:

Automation allows for extensive test coverage, including regression, user, performance, and security testing, without an increase in time or cost. As SaaS solutions evolve, automated tests can be easily scaled or modified to cover new features and functionalities.

### Error Reduction:

Automated testing eliminates human error, ensuring that validation processes are accurate and reliable. This is particularly important for extensive regression or other repetitive testing.

## Strategies for Implementing Automated Testing and AI:

### Selecting the Right Tools:

Select automation and testing tools that are compatible with your SaaS solution and can be integrated into your existing validation framework. Consider tools that offer flexibility, scalability, and comprehensive reporting capabilities. Often Selenium java platform can be used to great affect (includes ALM integration)

### Developing a Skilled Team:

Ensure your team has the necessary skills to implement and manage automated testing and AI technologies. This may involve uptraining current staff or hiring specialists with experience in these areas.

### Continuous Learning and Adaptation:

Leaders must stay informed on the current state and advancements in automated testing and AI technologies. Regularly review and update your validation processes to leverage new tools and techniques that can improve your processes.

“The use of appropriate tools and automation to support IT process, infrastructure, SDLC management... can bring significant efficiency improvements while also increasing quality and **lowering risk.**”

- ISPE GAMP5 Revision 2 Guidance



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# Preparing for the Future: Trends and Innovations

Strategies for Navigating Emerging & Future Trends

## Introduction to 5 Future Trends and their Impact on SaaS and Validation

### 1 Artificial Intelligence (AI) and Machine Learning:

- Impact: Streamlines validation by automating data analysis and predictions.
- Preparation: Train your team and invest in AI tools.

### 2 Blockchain for Data Integrity:

- Impact: Provides a secure, unchangeable record system.
- Preparation: Look into blockchain for secure data management.

### 3 Internet of Things (IoT) in Labs and Manufacturing:

- Impact: Automates data collection for real-time insights.
- Preparation: Use IoT to enhance data accuracy and management.

### 4 Regulatory Technology (RegTech) for Compliance:

- Impact: Automates compliance and regulatory reporting.
- Preparation: Implement RegTech for up-to-date compliance.

### 5 Cloud Computing Advancements:

- Impact: Boosts SaaS capabilities and efficiency.
- Preparation: Keep up with cloud advancements to improve validation strategy.

To stay relevant, engage in continuous education, form strategic partnerships, and implement agile validation processes. This allows for quick strategy adjustments when new technological or regulatory changes are implemented.

# Conclusion

**A culture emphasizing compliance and continuous improvement technology drives progress in life sciences.**

The life sciences industry is moving toward the SaaS systems model for compliance, security, and cost benefits. The previous paradigm of creating independent test scripts and manual testing is being replaced by comprehensive testing strategies and automated testing.

By committing to **leadership engagement**, training, proactive risk management, and the strategic use of technology, organizations can establish efficient automated computer system compliance strategies into their corporate DNA.

# Resources & Citations

1

[YAHOO Finance \(CAGR\)](#)

2

[GAMP5 CSV Manual](#)

3

[FDA-2022-D-0795 \(CSA\)](#)