Changing Realities in Your GxP Lab with SaaS

Benefits of Software-as-a-Service for regulated industries and what to expect from your software vendor

Scientists frequently question what software validation activities are needed for (Software-as-a-Service) SaaS in GxP or regulated environments. This paper explores how to address GxP and validation requirements while also gaining the benefits of SaaS solutions.

Software providers take on a range of responsibilities in administrating SaaS solutions, including. validation activities, data security, authentication, disaster recovery, ISO maintenance, and documentation. Revvity Signals SaaS solutions address all of these. Additionally, our solutions transform the traditional burden of software updates to the SaaS benefits of the latest features and functionality. SaaS is rapidly changing dated perceptions in the lab.

GxP and the Importance of Validation

GxP regulations were created to ensure that products from regulated industries are safe, meet their intended use, and adhere to quality processes during various stages of product development and manufacturing. "Good practice" regulations apply to a range of activities in such industries as pharmaceutical, food, cosmetics, and medical devices. These include manufacturing (GMP), clinical (GCP), laboratory (GLP), and documentation (GDP).

GxP can also be thought of as a combination of functionality that helps scientists in regulated environments work more efficiently and confidently (i.e., software features that assist in day-to-day lab activities), and capabilities that help enforce compliance with regulations.

Signals Notebook is a cloud-native electronic laboratory notebook (ELN) that is validation ready and can be used in GxP regulated environments following validation. Revvity Signals supports a comprehensive set of scientific use cases including biology, chemistry, formulations, analysis, and more. It also continues to add functionality for GxP regulated work, improving productivity and data transparency through enhanced collaboration, workflows, and lab automation.

Figure 1. GxP: FDA's good practice quality guidelines and regulations for various stages of product development and manufacturing.

Shared testing and validation responsibilities

To confirm the delivered software works according to requirements, Revvity Signals software development process verifies our software was built based on stated requirements and is tested to ensure the functionality meets them. This process assures customers that they received the right product and that it is maintained in a compliant-ready state.

In GxP industries, however, it is the customer's responsibility to validate a compliant-ready system provided by the vendor. Several regulatory bodies, including the FDA, the European Commission, and the International Society for Pharmaceutical Engineering (ISPE) offer recommendations for companies to validate their software systems.

For example, the ISPE's Good Automated Manufacturing Practice (GAMP) guidelines are a key reference used by pharmaceutical, medical device and other life sciences companies, as well as energy agencies and consumer product industries. The ISPE GAMP for regulated spaces explains the necessary steps to validate software and meet regulatory expectations. The guidelines include a management model specifically focused on SaaS solutions. This details what a software supplier is responsible for, what they should own, and what customers can expect from them.

Traditional On-Premise Software vs SaaS: What to Expect

SaaS systems are becoming increasingly popular among organizations searching for functionality, versatility, and accessibility. In the traditional IT model, the customer company is responsible for everything from application infrastructure to the platform, data security, and software itself.

They also must have a disaster recovery plan, backup procedures and appropriate testing in place.

With SaaS, however, the vendor provides the infrastructure needed to run applications, apart from the users' laptops and network connections, relieving customers of these responsibilities. Validating a SaaS solution is significantly less burdensome than with on-premise applications. SaaS solutions can relieve the customer from creating and managing their platform, application, or webpage, on their own. SaaS solutions minimize platform maintenance and management, freeing software developers, IT operators (DevOps) and security operations engineers (SecOps) to focus on higher value activities.

More responsibility on the vendor for SaaS applications translates to less of a burden in validation effort and cost for the customer, leading to more efficient workflows and happier scientists. What's more, SaaS streamlines validation and increases its predictability. For example, reducing code increments and only validating the delta, makes resource use more predictable and easier to plan. Users also benefit from frequent updates. This allows them to adopt new features faster without the lengthy work software updates require in a traditional IT model.

Eliminating software update delays

Customers no longer need to delay software updates in order to meet other priorities, and risk losing critical features, functionality, or reinforced security. Timely security updates are vital to prevent data breaches. SaaS solutions free the customer from time-consuming, cumbersome update work.

Vendor Responsibilities vs. Customer Responsibilities

SaaS solutions are faster to implement because the vendor takes over most of the responsibility for servers, networking, and the application itself. The vendor manages the application's infrastructure and its security. Revvity Signals sets up the system using cloud-native architecture, creates the environment, and handles its maintenance. This includes data backups and security updates. Our experts test the application before it's deployed, allowing the customer to focus on testing based on their specific configurations.

Installation, operational, and performance qualifications

Revvity Signals performs installation qualifications (IQ) and operational qualifications (OQ). This confirms that deployment, application versions, and all the services and functionalities are on the correct instance and version. It's important to note that these are out-of-the-box, non-configured testing workflows.

Next, the Revvity Signals team can be engaged to configure the system to meet the customer's business needs (intended use). Typically, configurations may include adding user groups, defining user rights and privileges, or defining templates. In a validated instance, these configurations require User Requirement Specification (URS) documentation according to the customer's documentation process, then go under change control. Performance qualification (PQ) or User Acceptance Testing (UAT) follows, using the URS to confirm and provide objective evidence that the system is correctly configured. Revvity Signals professional services team can help develop and execute PQ/UAT test scripts following the customer's documentation processes.

SaaS solutions bring customers the greatest value by eliminating most of the upfront work of setting up a system or managing its maintenance and security. The vendor owns management, maintenance, disaster recovery, initial deployment testing, and updates, as well as baseline workflows and application functionality. This frees the customer to focus on "How do we want to use the software? How do we configure it for our specific needs?"

SaaS solutions remove much of the burden IT groups encounter in a regulated industry. Customers need only supplement the testing Revvity Signals provides with testing specific to their own configuration and workflows.

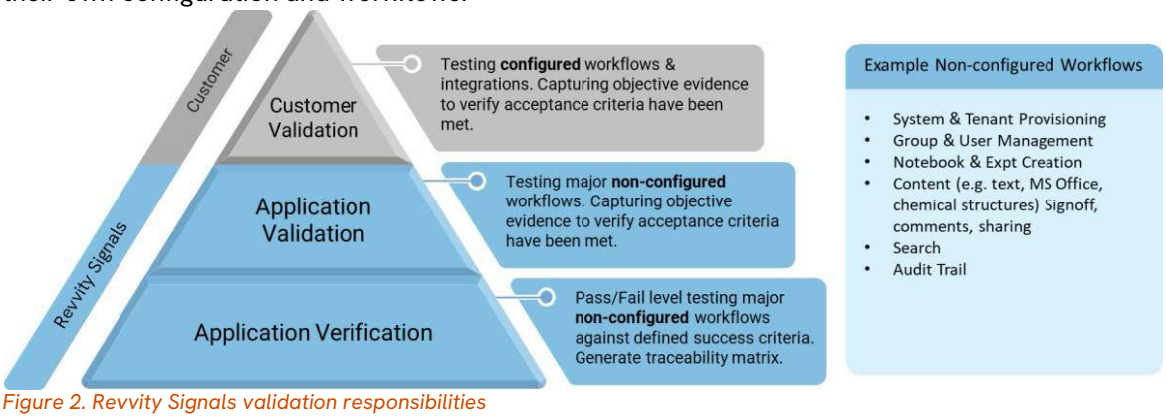

Figure 2. Revvity Signals validation responsibilities

Revvity Signals delivers Signals Notebook Enhanced Enterprise Edition (E3) and Signals Notebook Private Cloud to support validation. Once the customer has documented their processes and completed their validation activities, these SaaS solutions are considered validated. Revvity Signals:

- Runs verification on every standard release for each deferred release (there are multiple standard releases within each deferred release that are delivered to E3 and Private Cloud customers on the deferred release cycle)
- Runs verification on the deferred release itself
- Runs IQ (and provides customers with a report of each successful IQ)
- Runs OQ covering baseline out-of-the-box, non-configured workflows
- Produces documentation to assist customer validation documentation

Revvity Signals Professional Services for Implementation and Validation Support

In addition to these important services, Revvity Signals also supports configuration documentation and validation. More than 150 informatics Service Specialists partner with our customers to implement, monitor, support, and adopt their SaaS solutions. The vendor-customer team multiplies resources to reach end goals quickly and completely.

Conclusion

GxP is an important standard for compliance-related industries to ensure product safety. It not only guides capabilities to meet regulatory compliance, but also reinforces the functionalities scientists need to work in these settings. Likewise, it's crucial for both vendors and customers to properly implement and validate the software.

Revvity Signals partners with customers, bringing access to SaaS expertise for regulated industries. These solutions accelerate and strengthen system set up, maintenance, security, and appropriate authentication. Our solutions enable audit trails to safeguard customer data and information and provide the documentation and data packages customers need for regulatory accreditation in GxP environments.

Quality, Testing, Compliance Notes:

Certifications and Attestations of Testing and Quality Earned by Revvity Signals

- ISO 9001: 2015 – Certifies Revvity Signals' quality system and demonstrates, by third party audits, that the business follows defined processes for its determined scope (design, development, testing, support).
- ISO 27001: 2013 – Certifies Revvity Signals' information management system and demonstrates that the business follows defined IT security processes.
- SOC 2 Type 2 attestations – Attests that Revvity Signals has controls in place to assure that the business complies with three of the five trust service principles of security, availability, and confidentiality

Interpretation of 21 CFR Part 11 Compliance

The FDA's Code of Federal Regulations Title 21 contains a section (21 CFR Part 11) describing standards that must be followed when using electronic signatures in electronic records submitted to the FDA, such as new drug applications. In the past, these were paper applications, typically consisting of hundreds of binders of data and proof. Now, with electronic submission being possible, it's a much more efficient system, but it's also easier to manipulate electronic data without a proper audit trail and verified electronic signatures.

To address this issue of data security, the FDA created the 21 CFR Part 11 regulations on how to deal with electronic

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