Signals Validation Readiness





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# At a Glance

In a regulated industry, you need an electronic laboratory notebook (ELN) that ensures data integrity while streamlining validation. The validation-ready Signals Notebook Enhanced Enterprise Edition (E3) does just that. As Software-as-a-Service (SaaS) solution, Signals shifts more responsibility for software maintenance and validation to the provider, reducing the burden for your local IT team. With updates rolled out on predictable schedules and supported by full documentation, maintaining validation is stress-free. Gain peace of mind for yourGxP workspace with Signals Notebook.

## **Benefits**

- Ensure user compliance through controlled access, electronic signatures, and complete audit trails, in accordance with 21 CFR Part 11 and Annex 11.
- Lighten your IT burden with a SaaS solution. Revvity handles the bulk of the responsibility for servers, networking, maintenance, disaster recovery, deployment testing, security, and updates.
- Streamline implementation with personalized support for configuration—adding user groups, defining user rights and privileges, or defining templates.
- Get performance qualification support from the Revvity Signals' professional services team to develop and execute performance qualification (PQ) and user acceptance testing (UAT) test scripts.
- Control the rollout of updates to the validated environment through three tenants sandbox, staging, and production.
- Plan validation work with predictable product release cycles, three times a year. Gain early access to updates in the sandbox environment.



- Fully test updates before deployment to the validated workspace with production environment updates scheduled a month after rollouts to the staging tenant.
- Validate updates with ease, supported by clear, detailed validation documentation for every update, so that you only need to validate what has changed.

#### **Key Features**

- Support for Configuration, PQ, and UAT. The Revvity Signals team can be engaged to configure the system—adding user groups, defining user rights and privileges, or defining templates—and to develop and execute test scripts for performance qualification (PQ) and user acceptance testing (UAT).
- Predictable, scheduled updates. The precise dates for updates are announced up to nine months in advance. Updates to the Staging environments occur on the first Fridays of February, June, and October. Updates to the Production environments occur on the first Saturdays of March, July, and November, except when this falls on a major US public holiday.
- Multiple Tenants and Deferred Release Cadence Facilitate Validation. The Signals Notebook Enhanced Enterprise Edition (E3) includes three tenants—a sandbox tenant, a staging tenant, and a production tenant.
- Two different release cadences to facilitate validation activities. The "Agile Release" cadence, for the Sandbox environment, provides first access to new capabilities. The Deferred Release cadence, for the staging and production environments, facilitates validation planning and rollout.
- Full Release Documentation. Delta Validation documents for every release include IQ-OQ test results, a Validation Summary Report, a Verification Summary Report, and Signals Notebook Validation release notes.
- Professional services available for implementation and validation support, to enable customers to reach end goals quickly and completely.

## A SaaS ELN Will Reduce Your IT Burden

Deploying a SaaS ELN solution like Revvity Signals lightens the load of your IT team. In the traditional IT model, your company is responsible for everything from application infrastructure to the platform, data security, and software itself, as well as disaster recovery and backup.

As a SaaS solution, Revvity takes over most of the responsibility for servers, networking, and the application itself, and manages the application's infrastructure and security. Including data backups and security updates. This frees up your IT team to focus on higher-value activities.



**Revvity Signals Facilitates Validation** 

As a SaaS solution, Signals streamlines validation. Our experts test the application before it's deployed, performing installation qualification (IQ) and operational qualification (OQ). Customers need only supplement the testing Revvity provides with testing specific to their own configuration and workflows.

We Can Support Configuration and Performance Qualification (PQ)

The Revvity Signals team can be engaged to configure the system to meet your business needs (intended use). Typical configurations include adding user groups, defining user rights and privileges, or defining templates. The team can then support the documentation of User Requirement Specifications (URS) and the development and execution of Performance Qualification (PQ) or User Acceptance Testing (UAT).

Multiple Tenants and Deferred Release Cadence Facilitate Validation

The validation-ready Signals Notebook Enhanced Enterprise Edition (E3) includes three tenants a sandbox tenant, a staging tenant, and a production tenant—with two different release cadences, Agile and Deferred. This setup facilitates validation activities.

The Sandbox tenant, updated on the "Agile Release" cadence, provides early access to new capabilities. The Sandbox tenant is normally used to determine the utility of a given capability, and to plan validation activities related to implementing that feature.

The Staging tenant is updated on a Deferred Release cadence, updated three times per year, at the beginning of February, June, and October. The Deferred Releases combine all updates made during the previous four months. This tenant is used to execute the activities needed to take the validation-ready offering to a fully validated state.

The Production tenant, used by an organization's end users, is also updated on a Deferred Release cadence, at the beginning of March, July, and November. Production tenant updates are timed to happen one month after the staging tenant updates. This time difference allows completion of validation activities so the Production tenant remains validated.

Agile and Deferred Release Documentation

Signals Notebook customers receive documents to facilitate their validation activities for every release. New functionality is described on the What's New webpage whenever the Sandbox tenant is updated. This content makes it easy to plan validation activities and gives two to six months' advance notice of features anticipated for the Deferred Release.

Delta Validation documents are delivered in every release as a single zip file. These include IQ-OQ test results, a Validation Summary Report, a Verification Summary Report, and Signals Notebook Validation release notes.

Revvity Signals Professional Services Provide Implementation and Validation Support

Revvity Signals supports configuration, validation, and documentation. More than 150 informatics Service Specialists partner with customers to implement, monitor, and validate their Signals solutions.

Visit us to <u>learn more</u>.

#### Frequently Asked Questions (FAQs)

Which version of Signals Notebook is best for a GxP environment?

The Signals Notebook Enhanced Enterprise Edition (E3) is validation ready. The Signals Notebook Private Cloud edition is also offered in a validation-ready option.

Is there a Private Cloud option for Revvity Signals that is validation-ready?

Yes. The Signals Notebook Private Cloud edition is also offered in a validation-ready option. Customers using the Private Cloud edition have one Sandbox tenant plus three Staging Tenants and three Production Tenants. As in the E3 edition, updates for the Sandbox environment are on the Agile schedule. But in Private Cloud, customers can choose whether to follow the Agile or Deferred schedule for the staging and production environments. Private Cloud customers can also switch between the Agile and Deferred schedules.

What certifications and attestations have been earned by Revvity Signals?

Revvity Signals' quality management system (QMS) is ISO 9001:2015 certified, which demonstrates, by third party audits, that the business follows defined processes for its determined scope (design, development, testing, support). Signals also has SOC 2 Type 2 attestations that attest that Revvity Signals has controls in place to ensure that the business complies with three of the five trust service principles of security, availability, and confidentiality.



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