



Discovering the Ease of Maintaining GxP Validation in a Cloud-Based ELN

While cloud-based software brings significant improvements in speed, agility, collaboration, and more, organizations in regulated industries may think their validation requirements put those gains out of reach. Roche Diagnostics, however, implemented validation-ready, cloud-native Signals Notebook from Revvity Signals across all of its R&D labs, from core labs to molecular PCR, and is expanding into manufacturing support and quality engineering. These teams now work on a global, fully GxP-validated ELN, while being able to take advantage of new features and capabilities that are released according to a planned, agile program.

The Roche implementation is an excellent illustration of a regulated organization experiencing a smooth transition to agile software practices, including GxP validation. Since the initial pilot with 60 scientists using Signals Notebook Enhanced Enterprise Edition (E3), the ELN was next rolled out to more than 1,500 users across multiple locations – with roughly 1,000 previously using paper lab notebooks and 500 moving from a legacy ELN – and today stands at over 3,100 users and growing.

Success stems, in part, from the release cadence of Signals Notebook, with its staggered schedule that provides plenty of time for teams to evaluate, plan, and execute validation activities around the new releases. Signals Notebook delivers evolving ELN capabilities to Roche scientists while making it easy to securely maintain a constant state of validation.

Success Factors for Employing Agile Practices in a Validated GxP Environment

In its deployment of Signals Notebook E3, the Roche IT team has relied on several success factors. These factors have not only helped ensure successful implementation, but perhaps equally important, have also helped everyone get comfortable with the transition to agile processes in a GxP setting.

The first is what they refer to as “built-in quality and validation.” That means that leaders from the Quality and Validation organizations are embedded in the IT team, where they consult on the GxP relevance and validation approach for every new software release, right from the beginning. These dedicated staff stay abreast of important topics, learn about all updates early, and oversee validation activities. In this way, the IT, Quality, and Validation teams are in constant dialogue.

The second success factor is a risk-based approach to validation testing. By following a risk-based approach, the Roche staff know they don’t need to conduct full validation testing on every detail of each software update, because many changes will not have any GxP impact. As they review releases, they determine which elements require full validation and for which aspects informal testing is sufficient. With this prioritization, they focus on the testing that matters.

A third factor is their modular training concept. This approach makes a big difference when releasing new features that require user training, because they can quickly get small training modules in place.

Harnessing the Multiple Tenants of Signals Notebook E3 to Support Validated Delivery

To facilitate validation activities, Signals Notebook E3 edition customers receive three tenants: a Sandbox Tenant, a Staging Tenant, and a Production Tenant. Updates are released to these three environments according to a staggered timeline, allowing time for exploration, planning, and validation.

The Sandbox Tenant is updated on the Agile cadence, offering the first access to new capabilities as they become available, so Roche staff can explore features and plan validation.

The Staging Tenant is updated on the Deferred Release cadence. Releases to the Staging Tenant combine all updates made to the Sandbox during a four-month period. This tenant is used to execute the activities needed to take the validation-ready offering to a fully validated state.

The Production Tenant is used by an organization’s end users. This tenant is also updated on the Deferred Release cadence, but not until one month after updates are released to the Staging Tenant. This staggered schedule allows time to complete validation before rollout to the Production Tenant, so that the Production Tenant always remains validated.



Roche customized the use of these Signals Notebook tenants. In addition to Signals Notebook E3, Roche also has Signals Notebook Standard, which comes with one tenant that is updated on the Agile Release cadence. The Roche IT team uses this tenant on Signals Notebook Standard for its sandbox activities. Then, in Signals Notebook E3, the Roche team keeps its staging tenant strictly controlled, so that it is always in a validated state. Only the technical and testing teams are allowed in the staging environment. Roche likes this approach because it means the organization is “release ready” at all times. With this setup, they choose to limit their “playground” work to the Signals Notebook Standard Tenant.

The Roche team uses another of its three tenants in Signals Notebook E3 for user training and onboarding. Power users also maintain accounts there, to try out new features early. They also use this environment to test integrations with external software and data sources.

The Training Tenant is where users get comfortable with the solution and its updates.

“We have this self-contained world of not only the product strategy and all the documentation that you would normally have with the validated system, but it also allows us to have an agile delivery with user stories and releases. So that was a huge win for us.”

– Jen Kraljevich, Product Manager, Roche Diagnostics

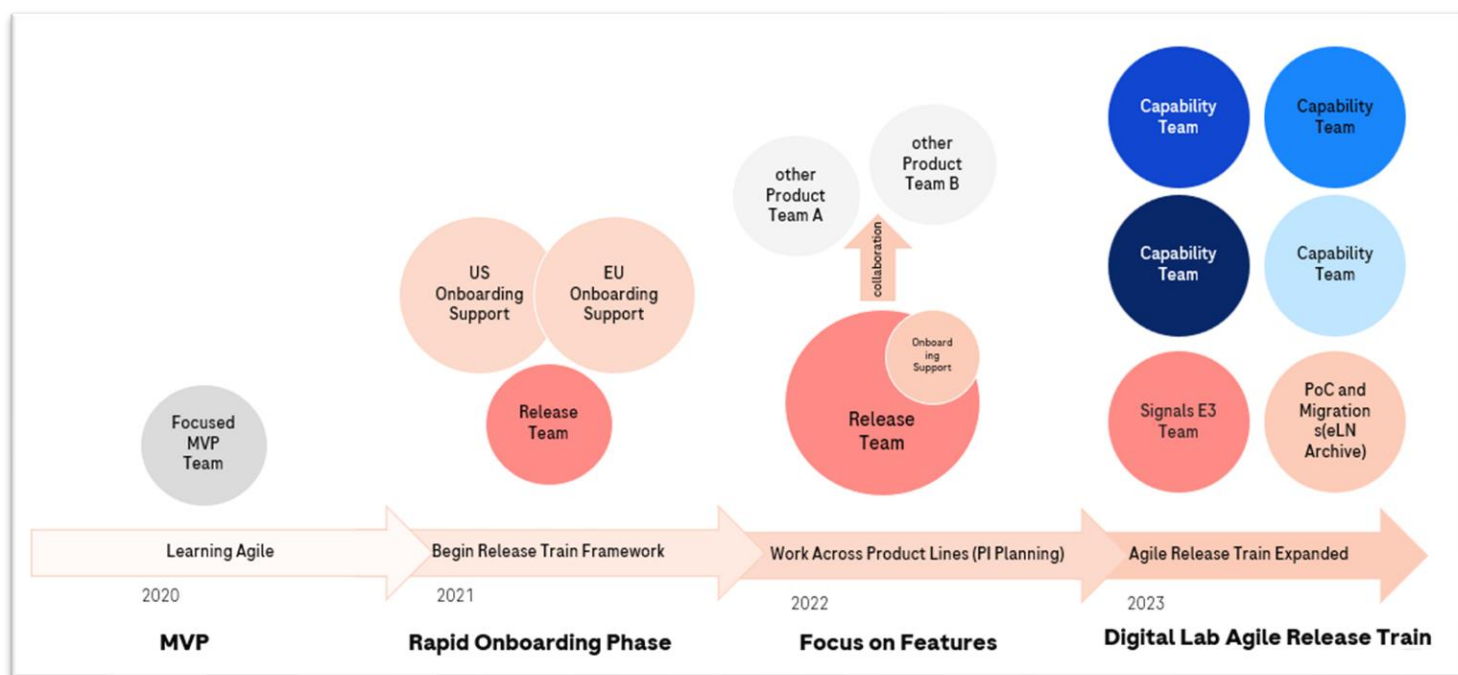


Figure 1: Evolution of the team structure as it adapted to meet the differing requirements throughout the implementation of Signals Notebook at Roche.

Orderly Steps for Assessing New Releases—and Keeping Everyone Comfortable

The Signals Notebook release cadence, with its staggered schedule from sandbox to staging to production, is designed to provide a controlled, orderly rollout of new features and capabilities. Teams know what is coming and when, and have time to test and validate.

With this staggered release cadence, the Roche IT team has found it easy to be successful in maintaining a validated ELN while working in an agile framework. In addition, the Roche team follows an organized series of steps to assess new releases. These best practices help everyone in the organization remain comfortable throughout the agile process.

The first step is holding regular roadmap meetings with Revvity Signals staff. With these meetings, the Roche team knows what's coming six to nine months down the road. As soon as they learn about new features in the works, the team starts planning.

Then, they monitor standard release notes from Revvity Signals. The Roche staff plug this information into a spreadsheet, organize it for themselves, and make notes to each other about how they will organize their testing, validation, rollout, and training.

Next, Roche business analysts (BAs) conduct an initial assessment of each release. These BAs are subject-matter experts for various aspects of the business and Signals Notebook, so they provide early insight into the details.

The work of the BAs is followed by an impact assessment with the business, validation and test leads, along with organizational change management staff. During this process, they ask questions:

- Will this release impact any business processes?
- Is this new capability big enough that we want to address it in a user story that becomes part of the documentation of what the solution does?
- If so, do we need to test it? Does it meet the threshold for the test rigor to be active or passive?
- Will we need training?
- Should this particular feature get highlighted in communications to users?

Throughout the assessment process, the Roche team considers the option to delay deployment of a new feature, when appropriate. They might make this decision if the team is particularly busy with integrations or staff onboardings. They might also hold off on a feature until they can develop some illustrative use cases. In these situations, they keep the feature in the backlog, and roll it out when they are ready.

Once the assessment is complete, the Roche team prepares for deployment. They know which features they will prepare user stories for, what validation testing needs to be done, and the timing involved. They proceed according to plan, and when it's time to release the update into the Production Tenant, all changes are fully validated, ensuring a smooth rollout. The production environment remains in its fully validated state, and users can begin enjoying new capabilities and features.

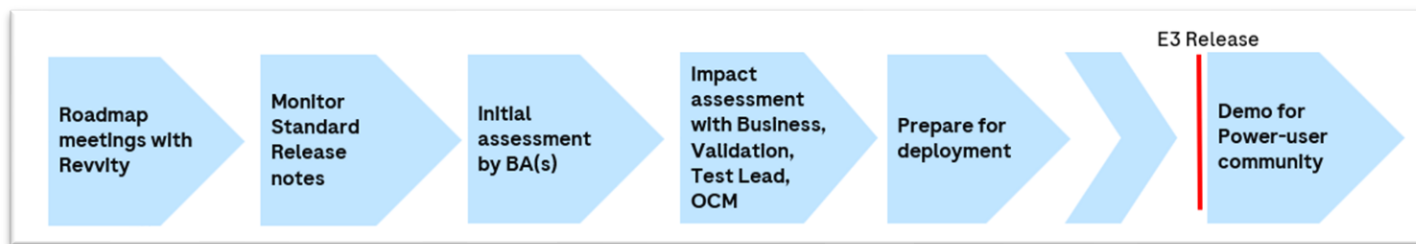


Figure 2: Process deployed by Roche for the implementation of Signals Notebook.

Conclusion: Enjoying the Benefits of Software Advances in a Validated State

As the Roche Diagnostics case illustrates, organizations working in validated GxP environments can reap the benefits of a cloud-based electronic laboratory notebook like Signals Notebook E3. The Signals Notebook release cadence, with its staggered schedule, gives teams plenty of time to evaluate, plan, and execute validation activities. In this way, agile practices mesh smoothly with controlled, orderly updates. With a validation-ready, cloud-based ELN like Signals Notebook, GxP organizations can take advantage of evolving ELN capabilities while securely maintaining a constant state of validation.