Eli Lilly: Implementing and Maintaining a Cloud ELN in a GxP Environment

Eli Lilly and Company needed a new electronic laboratory notebook (ELN) for its research and development operations. The new solution needed to be GxP validation-ready and capable of meeting the evolving scientific and business needs of an organization with staff around the globe. The new ELN also needed to support the software integrations used in the existing platform while adding robust GxP compliance features. Eli Lilly needed a user-friendly platform interface to ensure easy adoption while reducing demands on internal IT staff and allowing for scalability. Without this, any changes to project requirements could disrupt operations.

Eli Lilly chose Signals Notebook, a secure, cloud-native, validation-ready ELN from Revvity Signals that enables users to capture, organize, and customize their data while adhering to GxP regulations. Signals Notebook offers automated compliance workflows, ensuring that GxP regulations are seamlessly integrated into daily R&D operations. It provides comprehensive audit trails, sign/close/witness workflows, and the ability to capture reasons for changes, as required for 21 CFR part 11 compliance. The platform's data integrity assurance features, including robust security measures and access controls, maintain the accuracy and reliability of research data that are crucial for GxP compliance.

Under managed permissions, colleagues from any of Eli Lilly's global locations can collaborate and share insights effortlessly, leveraging real-time collaboration tools that enhance the efficiency of research initiatives globally.

Initial Implementation: Using Five Environments to Test and Validate the New ELN

For its initial rollout and validation of Signals Notebook, Eli Lilly harnessed five work environments:

- Sandbox: The sandbox allowed Eli Lilly's IT team to explore how features and configurations could fit into the workflows of various user groups.
- Development: The team drafted test scripts and carried out informal testing in the development environment.
- Quality Assurance (QA): Formal testing was performed in the QA environment.
- Production: Once formal testing was complete and fully approved, the formal configuration was rolled out to users in the production environment.
- Training: The training environment provided a safe space for users to learn the system.

This structure allowed for an orderly, controlled process for evaluation, testing, validation, and rollout of Signals Notebook.

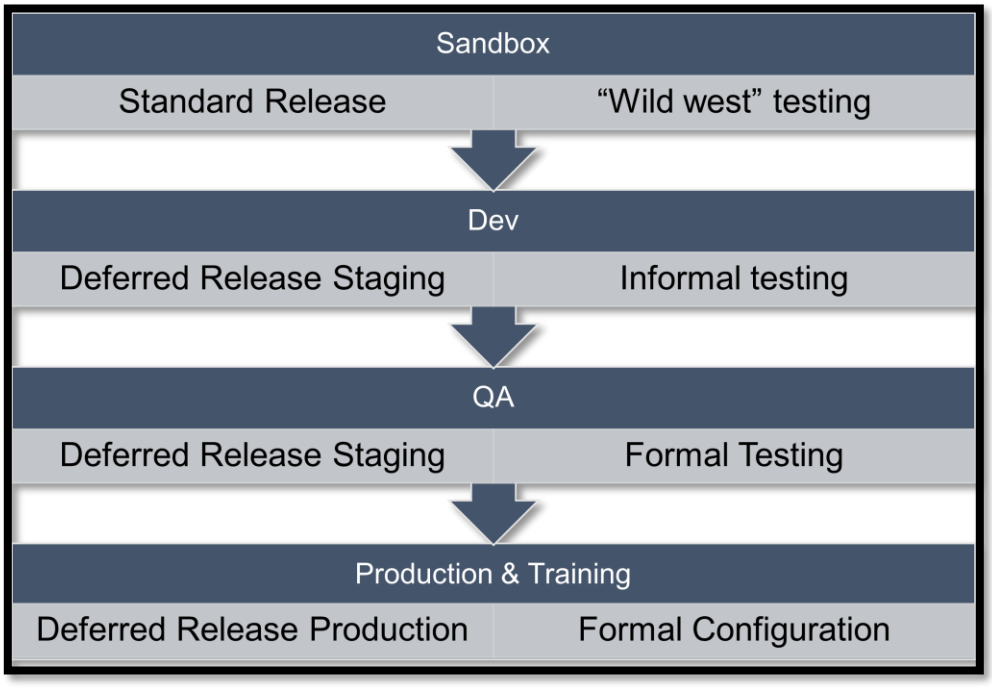

Figure 1: Five environments used in the validation process during the implementation of Signals Notebook at Eli Lilly.

Four Major Benefits from the New ELN

Implementing Signals Notebook has brought many benefits to Eli Lilly, from reducing IT workload to streamlining validation. In particular, four major advantages stood out.

1. Help Desk Requests Decreased Nearly 90% With its previous ELN, the Eli Lilly IT team received more than 90 help desk requests a month. After moving to Signals Notebook—an intuitive, user-friendly system—the monthly average dropped to 10, a decrease of almost 90%. This change has freed Eli Lilly's IT team for higher-value work.

2. Easy Notebook Access with a SaaS Cloud Solution With its previous ELN, which was installed on individual laptops, creating a notebook for a new user or laptop was a multistep process requiring IT support. With Signals Notebook, a cloud-based software-as-a-service (SaaS) solution, Eli Lilly users can access the ELN from a browser on a desktop computer, laptop, or even a tablet, and create new notebook entries themselves.

3. Streamlined Change Management With its previous, on-premises ELN, the vendor issued updates infrequently, in major releases. These large updates required extensive testing and often took a year or longer to be rolled out. With the cloud-based Signals Notebook, it's easy to manage the validation of updates, which are issued by Revvity Signals under two different release schedules: Agile and Deferred.

Updates—to provide new features or address evolving security needs—are released by Revvity Signals into the sandbox environment as they are ready. This is the "Agile Release" schedule. Then, every four months, all recent changes are bundled into a Deferred Release, which is issued first into staging environments—like the development and QA environments at Eli Lilly—and then, a month later, to production environments.

With this cadence, the Eli Lilly IT team has time to organize its validation work. First, they evaluate changes as they are released into the sandbox, consulting with stakeholders. Then, they plan and conduct testing and validation activities, first in their development and QA environments, and then in the production and training environments.

4. Easy Scheduling of Customization Work The Revvity Signals update cadence also allows time for customization, through what the Eli Lilly IT team calls a "post deferred release" cycle. If a user or group submits a request for a configuration change or template update, the IT team can easily schedule the work to follow the rollout of a deferred release.

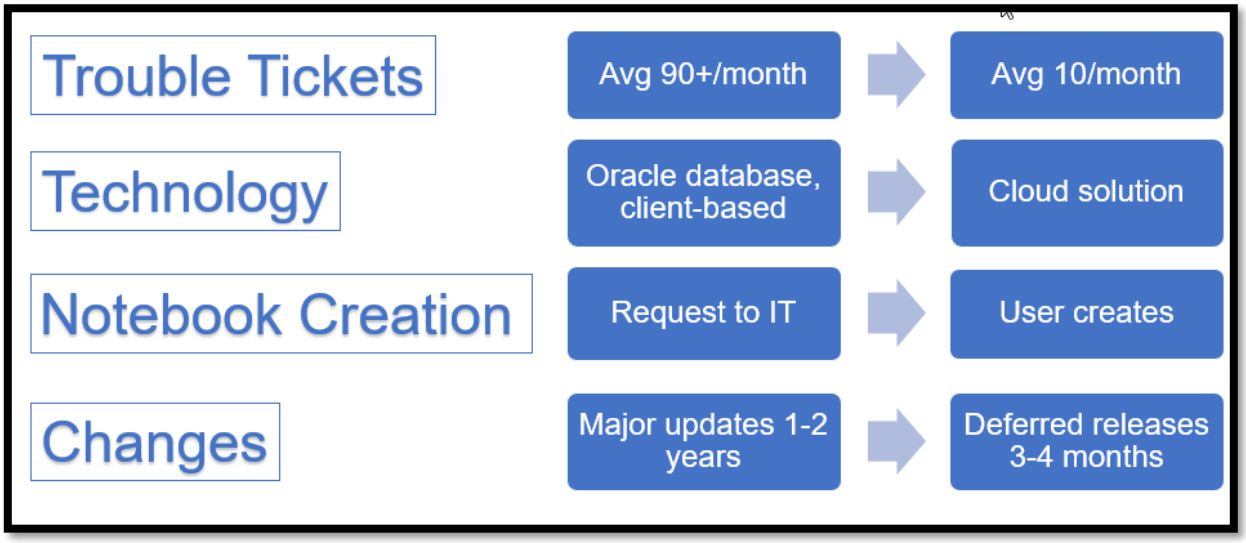

Figure 2: Results post-implementation of Signals Notebook at Eli Lily.

On our old [ELN] system, we were averaging about more than 90 tickets a month. And when we moved into our Signals Notebook, we saw a decrease to about an average of 10 tickets a month. That really spoke to having a solution that was more intuitive for our users. And that helped free up that capacity for our IT support by having less tickets. Alycia Hargraves, IT-Manager, Eli Lilly

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Five Learnings for Implementing Signals Notebook in a GxP Environment

The Eli Lilly team distilled five key learnings from its process of deploying Signals Notebook in a regulated environment.

1. Conduct Early Evaluations and Testing - Conducting early evaluations and testing of updates has been a key component to Eli Lilly's success keeping its ELN in a validated state. By the time a deferred release arrives, the team has been preparing for months, and is ready for rollout.

2. Communicate Often - As updates are received in the sandbox environment, the Eli Lilly IT team seeks input from staff in quality, validation, security, and legal functions, to ensure the full impact has been assessed.

3. Prioritize - Although it sounds simple, the Eli Lilly team knows the power of prioritizing. As features are offered, the team considers which are high priority and which are less critical. They may also choose not to enable some features. This prioritization helps them plan work and assign resources.

4. Build a Support Space and Harness Power Users - A support space, such as an internal website providing a user forum and answers to common questions, is valuable for building a user community and reducing the need for IT intervention. The Eli Lilly IT team also designates some tech-loving users in each local group as power users, who serve as a first tier of support.

5. Have a Backup Plan - Even with good planning, validation can deviate from schedule—if a document is not approved in time, or if testing runs longer than expected. By consulting with the legal, quality, and security departments, the IT team determines how to handle these situations. They may briefly disable a non-essential feature or shut off user access for a few hours or even a day. With a backup plan in place, the team knows how to respond.

Summary: Streamlined Validation and Continued Access to the Latest Features

By replacing a dated ELN with Signals Notebook, Eli Lilly has reduced demands on its IT staff. With this intuitive cloud-based system, help desk requests have dropped nearly 90%. More importantly, through the predictable cadence of updates, validation is now streamlined and controlled. Users have ongoing access to the latest features while the system maintains a constant state of validation.

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