Axxam CRO Transforms Quality Operations with an ELN for Data Integrity



By Revvity Signals

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Introduction

Paper record-keeping poses significant challenges in early-stage drug discovery, including compliance and data integrity risks, inefficiency and resource intensity, and limited real-time visibility and traceability of experimental data.

Transitioning from paper records to an electronic laboratory notebook (ELN) can mitigate these challenges, improving quality processes by offering enhanced accuracy, efficiency, and compliance. ELNs strengthen the audit trail, data integrity, searchability of archived data, and collaboration between internal and external teams.

Axxam, a contract research organization (CRO) with headquarters in Milan, Italy, chose to address these challenges by implementing Signals Notebook from Revvity Signals. The company has seen advancements in digitalization, improved data integrity, and adherence to ISO standards.

The Challenges of Paper Records

Axxam provides integrated drug discovery services in the life sciences industry, from target assessment and hit identification to lead optimization, with an emphasis on bioactive molecules across all therapeutic areas. The CRO employs almost 120 scientists in early drug discovery, offering services like assay development, high-throughput screening, and induced pluripotent stem cell (iPSC) research.

Axxam chose to install a GLP-based quality management system in 2006, even though it was not a requirement to conform to certification standards, to better control facilities and manage experimental data. It knew that its processes needed to be fully digitalized—since more than 3000 paper notebooks, accumulated over 20 years, hindered rapid access to data, traceability, and regulatory compliance. Axxam extended quality activities beyond lab operations to all company processes replacing paper records with an ELN. Its ability to manage and secure the large amounts of produced data assures clients of their confidentiality. Axxam's implementation of ISO standards, ISO 9001 and ISO 27001, underscores its commitment to quality and data integrity, values that are especially important in drug discovery.

Axxam chose Signals Notebook, a Cloud-native, validation-ready ELN, to record, archive, and customize data from diverse workflows, collaborate between internal teams, and ensure compliance with ISO certification processes to implement the quality system.

Collaborative Implementation and Configuration of Signals Notebook

Revvity Signals provided extensive support throughout implementation, hosting weekly meetings with a representative from each of the 12 different groups at Axxam—including chemists, biologists, and data sciences—to understand each team's needs. The inclusion of a representative from each group ensured widespread dissemination of information required by the ELN. Revvity Signals also supported the analysis of Axxam's historical paper notebooks to identify the types of essential information scientists were storing. Together they streamlined the process, creating templates to standardize data input across teams for ease of storage and retrieval.

Benefits of Digitalization with Signals Notebook

1. Workflow optimization and scalability

Inefficient use of resources and lack of real-time access to data was replaced with digitalized processes that led to data mobility. This allowed the rapid integration of new facilities and technologies into the flow of data, thus fostering seamless collaboration across departments and Axxam's global facilities. For example, a cellular biologist can now quickly access Cell Factory team data within Signals Notebook, eliminating the need for additional requests and saving valuable time and resources while enhancing collaboration and data reliability. Axxam has already onboarded 115 users and integrated 12 departments into this digitalized record-keeping process.

2. Standardized processes improve quality

An unforeseen benefit was the incorporation in Signals Notebook of processes that weren't even being recorded in paper records. A prime example is the Compound Management team, which prepares compounds (e.g., dilutions, plates) internally for other groups and also for clients. Now, with Signals Notebook, Compound Management is included in the electronic flow of information at Axxam, greatly enhancing data integrity and quality.

3. Enhanced quality standards

Axxam achieved ISO 9001 and ISO 27001 certifications in July 2024, and, using Signals Notebook, extended quality standards to all processes and ensured IT system security and data integrity. Signals Notebook is in compliance with Axxam's quality processes and helps safeguard the vast amounts of data produced, benefiting both clients and internal operations.

4. Better management of diverse biology workflows

Axxam is following the trend in drug discovery to combine the activities of medicinal chemistry and biology, smoothing the way for scientists to collaborate more closely. While chemists adapted easily to ELNs for recording reactions and procedures, biologists faced challenges due to the collaborative nature of their work that were solved by shared templates and coordinated communication. Axxam's biology team, which includes more than 110 scientists, uses Signals Notebook to track its experiments. They can now easily add data to a template, using dropdown menus, thus saving time, reducing errors, and improving traceability.

5. Integrations with other Revvity Signals applications

Axxam relies on critical components native to Signals Notebook:

- <u>ChemDraw</u>: Chemists use Revvity Signals chemical communication program for management, reporting, and presentation.
- <u>Inventory</u>: Axxam has completed real-time visibility of all materials, making it more efficient to track dangerous reagents (e.g., carcinogens) or control the storage and delivery of cell lines. This is definitely an added value for monitoring the safety and health of all scientists.
- Task and Request: Revvity Signals configured task and request workflows for Axxam service groups to collaborate with other groups, via Signals Notebook.
- Instrumentation Database: Axxam has added a laboratory instrumentation database that allows scientists to describe their protocols in more detail, also precisely reporting which instrument was used.

6. Training for ongoing use and development

Once the templates were designed and tested, Revvity Signals trained administrators and scientists on how to fill each template and how to enter data. Axxam administrators are now capable of modifying existing templates or creating new ones.

7. Collaborating with clients

Signals Notebook simplifies the generation of client reports by replacing paper records with searchable digital files. Users can quickly access project data, even from closed projects, and create a PDF for clients.



"The Revvity Signals teams have been invaluable in helping us implement Signals Notebook. Their support has been crucial from the beginning of the project to the present day. The ELN has significantly improved our data integrity, traceability, and overall quality management system, which is very important for our clients."

~ Beatrice Bellanti, Quality Assurance Manager

Axxam



Conclusion

This project of replacing paper with an ELN for experimental data registration is continuously evolving as Axxam always strives, thanks to Signal Notebook, to meet the needs of its scientists in their daily work.

Axxam's adoption of Signals Notebook has revolutionized its operations, enhancing data integrity, collaboration, and compliance. By digitalizing workflows, this CRO has streamlined processes, achieved important ISO certifications, and empowered its teams with efficient, scalable tools that support cutting-edge drug discovery.



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