Global CDMO Flamma Enhances Collaboration
Using Signals Notebook as Centralized ELN Solution

By Revvity Signals

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Introduction

Flamma Group is a contract development and manufacturing organization (CDMO) that provides a variety of pharmaceutical services including current Good Manufacturing Practice (cGMP) manufacturing of active pharmaceutical ingredients (APIs), regulated starting materials (RSMs), and new chemical entities (NCEs). The Italian family-owned and operated company was founded 75 years ago to make amino acids, which it still produces along with associated variants and derivatives. The company has expanded to almost 1000 employees and four research and development (R&D) and manufacturing facilities, with two in Italy as well as one in the US and one in China.

To efficiently handle the increasing complexity of developing custom API processes for different clients, the CDMO wanted to digitalize its R&D and manufacturing records using an electronic lab notebook (ELN). Flamma chose the Signals Notebook from Revvity Signals, which met its needs for flexibly structured documentational tools along with advanced user and project access controls, among other features. The validation-ready, cloud-native Signals Notebook created a centralized solution that resulted in improved collaboration and efficiency across the company's global sites.

The Need for Data Visibility and Access

Flamma needed real-time insights into its data to be able to make quick decisions. Before implementing Signals Notebook, a lack of ready access to data from its four sites in different regions made it difficult to respond rapidly to find solutions to problems. This data visibility issue was related to the use of paper-based records and varying documentation practices across its four sites.

Flamma wanted to create a standardized documentation approach in an ELN. It was critical that the ELN have a user-friendly interface and that the scientists be able to quickly enter the large quantity of information required in their experiments, while maintaining high data quality and integrity. Access to customer-specific data would need to be carefully protected. It was also vital that the ELN be integrated with the company's systems, including a legacy ELN and an existing project management system. After screening the ELNs available on the market, Flamma concluded that the Signals Notebook was the best fit.

Robust Controls Protect Customer Data

As a key part of the implementation of Signals Notebook, Flamma integrated the ELN with an existing project management system (PMS) used to manage all its projects. Information in the PMS about the resources and people assigned to each project was transferred into Signals Notebook, such that each user's workspace now accurately reflects, in real-time, their current assignments. In addition, data from Signals Notebook is extracted into the PMS, creating a real-time project dashboard where managers can view resource allocation. This secure, bidirectional flow of documentation eliminates manual tagging and reduces errors.

Customer-specific data is protected, because a user can only see the projects to which they are assigned. A role-based permission system governs who can view, edit, or approve an experiment. In addition, access is secured via multifactor authentication.
Robust lifecycle control ensures data integrity. Experiments must be signed and reviewed within a certain period of time. If an experiment needs to be reopened, an explanation must be provided. A locked-down audit trail records each review and each reopening, ensuring compliance and traceability.

> *An aspect we consider of highest importance is the ability to rapidly enter information without losing any important information associated with our experiments, so we have implemented a standardized experiment template.*
>
> **Marco Ferrara**
> R&D Team Leader, Flamma SpA

Customized Templates and Automated Imports

Signals Notebook offers templates and other features that can be customized so that a company can implement a standardized format fit for their purposes. Flamma employed an experiment template so that all necessary information can be recorded quickly and uniformly across all its sites and R&D teams. This standardized template improves searchability. Drop-down menus and structured fields were used wherever possible to minimize free-text entries, further enhancing searchability.

> *Our focus is process chemistry, and we need to describe with a high level of detail how each operation is performed. We found snippets quite useful to help harmonize and at the same time speed up the description of lab operations.*
>
> **Marco Ferrara**
> R&D Team Leader, Flamma SpA

In addition, predefined text templates called "snippets" can be defined by a company for commonly used phrases. At Flamma, snippets helped scientists save time by quickly filling in detailed operation descriptions, as well as helping ensure that important details were not missed and descriptions were harmonized.
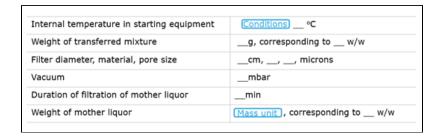
Internal temperature in starting equipment	Conditions __ ºC
Weight of transferred mixture	__g, corresponding to __ w/w
Filter diameter, material, pore size	__cm, __, __, microns
Vacuum	__mbar
Duration of filtration of mother liquor	__min
Weight of mother liquor	Mass unit , corresponding to __ w/w

Figure 1. Predefined text templates simplify protocol writing using standard descriptions and fields that can be easily completed.

Another feature Flamma found valuable was the integration of the Reagents Material Library in Signals Notebook with PubChem, to allow users to pull material data from the PubChem library. This automated import saves time and reduces errors.

With access to high quality, searchable data, Flamma's teams can now quickly search data to find solutions to issues that arise at any site, enabling them to respond rapidly

Implementation Journey

For Flamma, one of the keys to successful implementation of Signals Notebook was involving test-users across all four of its sites and across different roles—both in the early evaluation and identification phase as well as during configuration and implementation. The Revvity Signals team supported Flamma through all the stages of its journey. Even after implementation, monthly updates from Revvity Signals ensure that Signals Notebook continuously evolves with feature enhancements and fixes. This ongoing refinement of the solution supports Flamma's strategy of continuous improvement.

Conclusion

A Centralized Solution for Global Collaboration

The centralized solution of Signals Notebook helped Flamma achieve its goals of improved consistency and quality of its experimental records, along with faster and better data access that allowed the CDMO to collaborate globally across its sites. The integrated communication tools in the solution have allowed faster feedback and issue resolution. Cross-department collaboration has also improved, as departments synchronize their efforts more effectively. In addition, enhanced traceability has led to faster identification of process inefficiencies, allowing cost savings. Most importantly, the solution has allowed robust control for a high level of data integrity and protection of client intellectual property.

With ongoing feedback from its users and support from the Revvity Signals team, Flamma continues to customize Signals Notebook to enable continuous improvement of response time and provide a competitive edge to its CDMO business.

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