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CASE STUDY

Skills Transfer during QMS Implementation to Ensure Long-Term Cost Control

With half a century of innovations serving the health and nuclear medicine sectors, the IRE is recognized as the world leader in radioisotope production. Its subsidiary, ELiT Radiopharma, is a laboratory of ideas and actions dedicated to radiopharmaceutical innovation. Together, the two organizations have a total of 250 employees, primarily operating in:

- The production of radioisotopes, raw material for the radiopharmaceutical industry
- Research, development, and production of radiopharmaceuticals for diagnosis and treatment in hospitals
- Analysis and control of radioactivity

Dual Operations Prompt a Challenging Quality Project

The IRE's operations are at the crossroads of two areas of regulatory requirements, that of pharmaceutical and nuclear activities. The IRE is therefore subject to numerous and diverse regulations; the institute must apply good manufacturing practices (GMP), ISO standards (9001, 17025, 14001), Eudralex and FDA guidelines, and those of the nuclear industry. For example, a non-conformity of a substance may require a nuclear safety analysis. Ensuring the safety of patients and staff, the IRE's mission statement, requires the deployment of a highly reliable quality manager system.

The quality management system has two major objectives: ensure the safety of patients and staff, as well as foolproof reliability. It is this robustness that the institute was looking for when it launched its call for tenders for the management of documents and quality processes for 250 users.

Ennov was the natural choice for several reasons, among them: Ennov's repute and expertise in the industry. Secondly, the Ennov platform's flexible configuration allowed it to meet not only the requirements of the pharmaceutical industry but also those of the nuclear sector, in which Ennov has notable references. Thirdly, the transparent approach of both the sales representatives and the project team laid the foundation for a trustful and long-lasting working relationship.

Valued Autonomous Operations, Made Possible by Skill Transfer

The first phase of the project to deploy a quality Document Management System (DMS) with the IRE was distinguished by a particularly successful transfer of skills.

The document management deployment phase was led by the IRE quality department along with active support from the IRE's IT department. The IRE team was able to rely on the methodology and experience of Ennov consultants, who guided them towards the best practices. This support allowed the quality department to gain confidence during their first implementation project. Operational routines were quickly established.

The IRE quickly realized that beyond the project phase, the success of the solution would be long-term. The solution would have to adapt to the inevitable changing requirements linked to modifications in purpose, organization, standards and scope. In order to control its costs, the IRE wanted to be autonomous in order to evolve its solution without relying on the editor or a third party. Ennov was an integral part of this strategy, providing a complete transfer of skills.

The Mechanism for Skill Transfer

The document management deployment project was led by the business team along with active support from the IRE's information systems department. The team was able to rely on the methodology and experience of the Ennov team to achieve the project goals.

- **Training:** The training of the quality department prior to the design/implementation sprints allowed them to immediately share the same project terminology and to adopt an approach in line with the Ennov platform.
- **An Iterative Approach:** The configuration of the document management system was built iteratively between the IRE and Ennov consisting of «practical work» sessions, which led to increased competence for each sprint (design workshop, presentation, tests).
- **Documentation and Availability:** The IRE appreciated the quality of the documentation provided by Ennov, which was clear and educational. The quality department also regularly asked the Ennov project manager for recommendations. These two channels, consistent documentation and project manager expertise, allowed the quality department to gain confidence

"The functionality of the Ennov platform is simple and understandable."

Axelle Dufour
Project Manager, IRE

The Committed Attitude of the IRE, A Key Factor in Autonomy

The adoption of a tool was highly anticipated by the quality department. The result was an open attitude to change, paired with motivation that facilitated a standardization of practices during the deployment of the new DMS. This enthusiasm was mobilized by efficient and engaged internal stakeholders, which played a decisive role in ensuring the link between company concerns and project expectations.

THE RESULT: The quality department feels ready to extend Ennov's DMS to other document collections.

Conclusion

- **Stability from the Get-Go:** IRE was pleasantly surprised by the level of serenity as soon as Ennov Doc went live, without the need for an adjustment period to stabilize the solution.
- **Expansion to Other Applications:** The success of Ennov Doc deployment has set a positive precedent. IRE plans to open up beyond the quality perimeter by managing its "contract library" (supplier contracts) with the Ennov platform already in place.
- **Gradual Deployment via Modular Approach:** The IRE adopted a gradual deployment by module, as a result: the ease acquired on the DMS perimeter has enabled the teams to set up the training management module themselves, thus saving additional resources.

"I was impressed by the ability to adopt and take control of Ennov Doc in complete autonomy from the software provider."

Julien Thonnart
Head of QA, QC, & Regulatory Affairs
IRE

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About Ennov

Ennov offers a unified compliance platform to power solutions that span all regulated business areas (Regulatory, Quality, PV, Clinical, Commercial). From leading pharmaceutical companies to start-up biotechs, we proudly serve over 450 companies and 500,000 users worldwide.

For more than 25 years, we have been developing innovative, powerful and easy-to-use software for regulated content, data and process management. Our solutions are designed and built to support the entire Life Sciences R&D continuum. Ennov is ISO 9001 and 27001 certified for all software products and processes, and we boast a 100% success rate in customer audits.

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