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CASE STUDY

Racing Against the Clock: Unifying Quality Across 15+ Radiopharmaceutical Sites

How a radiopharmaceutical leader harmonized quality management across 15+ manufacturing sites in five countries, while meeting both nuclear and pharmaceutical requirements

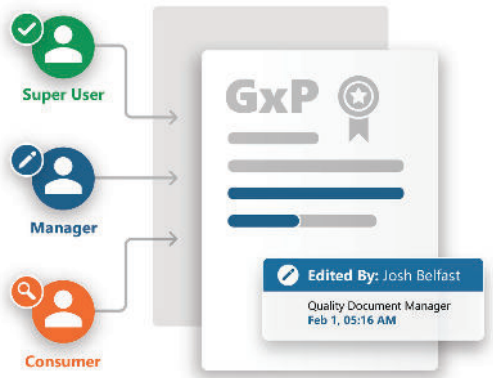
In radiopharmaceuticals, time is part of the product. Radioactive medicines used in molecular imaging lose half of their active ingredient every hour. To deliver them on time and on spec, one of the world's leading molecular imaging companies operates a manufacturing network close to patients across Europe. Keeping that network aligned across five countries, under both nuclear and pharmaceutical regulations is a major quality challenge.

Since 2012, this radiopharmaceutical specialist has partnered with Ennov to build the quality infrastructure that makes it possible. From document management to full quality process digitalization, and through two major corporate transitions, the partnership has grown alongside the organization, and the Ennov platform has proven its ability to adapt as fast as the business itself.

14+ Years of Ennov Partnership
Supporting quality transformation

15+ Manufacturing Sites Unified
On shared compliance standards

5 Countries Aligned
On shared compliance standards



Industry	Nuclear Medicine
Company Type	Molecular Imaging, Radiopharmaceutical Manufacturer
Employees	1,000+ across more than 15 European manufacturing sites
Strategic Context	Post-acquisition harmonization, multi-site scale, digital QMS transformation
Regulatory Scope	EU pharmaceutical GxP, nuclear safety regulations, 21 CFR Part 11
Models in Use	Document Management System, Business Process Management, Learning Management System, Business Intelligence and Analytics

The Challenge:
Compliance Across Nuclear and Pharmaceutical Regulations

This nuclear medicine manufacturer operates in one of the most demanding regulatory environments in life sciences. Its products are radioactive diagnostic agents, which means the business must meet both pharmaceutical GxP requirements and nuclear safety rules. Quality, traceability, and speed all matter at once.

The operating model adds another layer of complexity. The company runs 15 manufacturing sites across five European countries. Each site must follow the same documentation standards, deviation processes, and batch release controls. Before Ennov, much of this work was still paper-based.

Why the quality team decided to digitize its operations:

- **Paper-based quality management across 15 sites, limiting central visibility**
- **No standard process for deviations, CAPAs, OOS results, or complaints**
- **Dual regulatory oversight required stronger traceability**
- **New sites needed to be onboarded quickly, without disrupting operations**
- **Batch release required both rigor and speed**

The Solution: Building a Unified Quality Foundation

When a new Global QMS Manager took on the role in 2022, the organization was already building on more than a decade of document management with Ennov. The next step was to turn that foundation into a more fully digital, harmonized quality system. The rollout was phased and carefully configured to match the company's workflows.

SINCE 2012 :
DOCUMENT MANAGEMENT
Deployed across sites

2023:
PROCESS DIGITALIZATION
Change Control + Training modules go live

2024:
FULL QMS COVERAGE
Deviations, OOS, OOT, Complaints & CAPA

2025 - 2026:
SAAS TRANSITION + ANALYTICS
Cloud migration + dashboard deployment

> *"Ennov is always focused on finding the best solution for us, not the easiest one for them."*
>
> **- Global QMS Manager**

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Key Success Drivers

1

Configured to fit the business
Off-the-shelf process flows weren't enough for a business this specialized. Its workflows were more detailed, more regulated, and more connected than a typical setup. Ennov configured the platform around the company's real process logic, instead of forcing teams to adapt to generic software. This helped build trust and adoption early.

2

Continuity across phases
One of the biggest strengths of the project was continuity. The same Ennov project manager and core team stayed involved across multiple phases. A deeper knowledge of the customer's system and requirements made each new stage easier to deliver.

3

One platform for multi-site harmonization
With 15 sites across five countries, consistency was essential. Ennov made it possible to apply one shared process framework across the network. New sites could join the same model instead of creating local variations.

4

Compliance built in
Compliance with 21 CFR Part 11 was essential, particularly for batch release decisions, making audit trails and electronic signatures core requirements. Ennov provided the necessary compliance foundation, while system configuration addressed the manufacturer's more specific operational needs.

The Results: From Blind Spots to Full Visibility

COMPLETE DIGITAL TRACEABILITY

Deviations, CAPAs, change controls, and complaints are now managed in one system with automatic audit trails. Central teams and inspectors have instant visibility across sites.

HARMONIZED OPERATIONS AT SCALE

All 15+ manufacturing sites now follow the same workflows, documentation standards, and quality processes across five countries.

BUILT TO ABSORB CHANGE

The platform has supported two corporate transitions and a move from on-premises to SaaS, without disrupting operations. New sites are already being added to the same model.

Future-Ready By Design

The company's quality transformation is still moving forward. With the core modules now live, the quality organization is expanding its Ennov footprint in three directions:

- Analytics dashboards, now being deployed, to improve reporting and trend analysis
- Supplier and audit management, to extend traceability into vendor oversight
- Expansion to additional sites across the network, using the same platform foundation

The team is also exploring Ennov AI for targeted quality use cases, including accelerating audit report drafting and strengthening document change tracking through faster identification of revisions, clearer summaries of what changed, and easier access to supporting records.

Because these capabilities sit on Ennov's Unified Compliance Platform, expansion does not require new vendors, duplicate validation cycles, or retraining from scratch. The same environment can extend across more modules, more sites, and more teams.

For this nuclear medicine leader, Ennov delivered more than a digital QMS. It created a unified quality foundation that could keep pace with a time-critical business, strict regulation, and continued growth.

Start with Quality, grow your platform at your speed.

Built on a single data model and shared repository, Ennov is the only Unified Compliance Platform designed for Life Sciences.

No integration patches. No duplicate records. Just one secure system that spans the entire product lifecycle.

- **Eliminate complexity**
- **Reduce risk**
- **Scale with confidence**

More than 450 Life Sciences companies around the world are powered by **Ennov**

eNNOV
Software for Life