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CASE STUDY

From Paper-Based to Market-Ready

How a Pre-Commercial Biotech Built ISO 13485-Ready Infrastructure Before First Product Launch

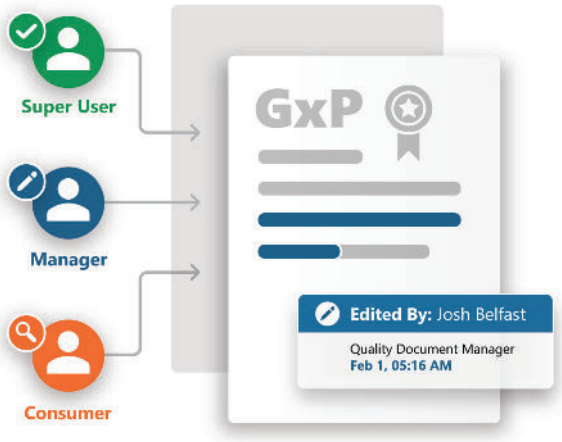
When paper-based documentation threatened to delay their first product launch and ISO 13485 certification, a European biotech startup partnered with Ennov to build enterprise-grade quality infrastructure.

The result: A lean QA team transitioned from binders to a fully validated digital QMS, enabling audit-ready compliance, electronic workflows, and a scalable foundation for post-market surveillance before their first unit shipped.

21 CFR PART 11 COMPLIANT
Electronic signatures and audit trails support regulatory inspections

ISO 13485 AUDIT-READY
Document control and traceability aligned with certification needs

SCALABLE ARCHITECTURE
Supports CAPA and complaints, with flexibility to add PMS



Industry	Biotech / Medical Device
Employees	Less than 100
Stage	Pre-commercial
Headquarters	Switzerland
Milestones:	GxP-aligned, ISO 13485 certification, 21 CFR Part 11 Compliance

The Challenge

As a pre-commercial life sciences startup prepared to bring their first product to market and pursue ISO 13485 certification, the team recognized the need to transition from paper-based documentation to a digital quality management system.

Key requirements:

- Centralized document control with automated version management
- Electronic workflows to streamline approvals across departments
- Audit-ready documentation with complete traceability
- Foundation for future post-market surveillance capabilities

The organization required a validated system that not only met immediate operational needs but could also scale to support future commercial requirements, striking the right balance between regulatory compliance and practical implementation for their stage of growth.

Why Ennov?

Ennov was selected based on several critical factors for companies at their stage: a validated platform designed specifically for life sciences, the ability to start with core capabilities and expand over time, and a support model suited to lean operations.

New team members have successfully adopted the platform and now use it confidently across core quality workflows—reinforcing the decision to select Ennov.

"With Ennov, the workflows are simple and it's easy to track the status of each document."

- QA Administrator

The Solution:

Building the Foundation for Compliant Operations

Ennov's core quality management capabilities were implemented to create a digital backbone for their operations:

DOCUMENT CONTROL & MANAGEMENT

- SOPs and quality records centralized in a digital system with automated version control
- Electronic signatures meeting 21 CFR Part 11 requirements
- Audit trail automatically generated for all quality events
- Real-time visibility into document status across departments

OPERATIONAL WORKFLOWS

- Deviation management integrated with document lifecycle
- Training record tracking for manufacturing staff qualification
- Document approval processes streamlined with electronic routing
- Traceability linking quality events to relevant documentation

AUDIT & REGULATORY READINESS

- Version tracking and change history readily available for inspectors
- Centralized repository eliminates document gathering before audits
- System designed to support ISO 13485 requirements
- Foundation for 21 CFR Part 11 compliance

The Impact

Operational Transformation

BEFORE ENNOV

- Paper SOPs stored in binders with spreadsheet version tracking
- Manual signature collection causing approval delays
- No centralized visibility into documentation status
- Audit preparation requiring extensive manual document gathering

AFTER ENNOV

- Digital repository with automated version control and approval routing
- Electronic signatures streamlining approval timelines
- Real-time tracking of document status for entire team
- Audit-ready documentation available instantly

Enabling Quality at Scale

Standardized Processes - The transition from paper created immediate operational improvements:

- All SOPs and forms now managed through centralized digital lifecycle control
- Document editing and approval flows through structured workflows
- Improved oversight and traceability ahead of ISO certification audits
- Foundation for consistent quality practices as the company scales

User Adoption Success - Despite inheriting the system mid-implementation, the new QA team achieved full operational use:

- Both QA team members trained and using Ennov regularly for deviations and quality documentation
- Document tracking and approval processes now visible and streamlined across the team
- System usability improving with experience as team builds internal expertise
- Initial training has begun in manufacturing, with plans to expand use to additional departments over time

Audit Readiness - The digital foundation dramatically improved the company's regulatory posture:

- Complete audit trails and version histories readily available for inspectors
- Document retrieval transformed from days of manual searching to instant access
- Traceability between quality events and documentation established
- Compliance risk reduced through systematic controls

Lessons for Early-Stage Life Sciences Companies

1. **Digital Quality is Achieveable for Small Teams**
   Even lean QA departments can run compliant operations confidently when they start with a right-sized, unified platform.

2. **Start Small, Scale Smart**
   Focus on core document control and essential workflows first, then expand into areas like CAPA, complaints, and post-market surveillance as your operations grow. This avoids overwhelming small teams.

3. **Build Post-Market Readiness in Early**
   Design your quality system with post-market obligations in mind to avoid costly migrations later. A single repository ensures one source of truth and no duplicate validation cycles when adding new processes or departments.

4. **A Platform Signals Maturity**
   Moving from paper to a validated digital QMS reassures investors, partners, and regulators that you understand compliance expectations and have built scalable infrastructure for commercial growth.

5. **Ease of Adoption Matters**
   If new team members can successfully use and expand a system they didn't select or implement, that's a strong sign of usability, support quality, and long-term sustainability.

What's Next

With their first product heading to market and ISO 13485 certification underway — expanding platform use to additional departments and laying the groundwork for post-market surveillance.

With quality workflows unified in a single platform, the team has moved past fragmented tools, duplicate records, and multiple validation cycles — building the connected ecosystem they need as they scale commercially.

Their journey proves that migrating from paper to digital — and preparing for the full lifecycle of quality management — is not only possible for startups, but practical with the right partner.

Ready to Build Your Quality Foundation?

For companies preparing for their first product launch: this success story demonstrates that you don't need to choose between speed, compliance, and cost. The right QMS platform can deliver all three.

See how Ennov supports early-stage life sciences companies as they transition from development to commercial operations—with systems that scale as you grow.

Contact our life sciences specialists to discuss your path to market readiness

Connect with Ennov's experts today. **ennov.com**

Ennov is a leading provider of quality management and regulatory solutions for life sciences companies worldwide, supporting organizations from startup through commercial scale with validated, integrated platforms designed for how quality teams actually work.

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