

#### CASE STUDY Q

# How HTL Biotechnology Saved 3,500+ Hours Annually by Digitalizing Quality

When manual approval processes threatened to limit growth, HTL Biotechnology partnered with Ennov to transform quality management.

**The result:** HTL Biotechnology eliminated signature bottlenecks, saved nearly two Full-Time Employees in manual effort, and positioned itself for continued global expansion, thanks to Ennov's Quality Suite.

90 weeks of work saved annually

Full-Time Employees freed up for strategic initiatives

50 x faster audit prep

(from days to instant access)



Industry	Biotechnology Manufacturing
Employees	300
Global Reach	100+ clients across 30 countries
Export Focus:	75% of production
Strategic Priority:	Industrial expansion, international growth



"We saved enormous amounts of time on tedious activities like copying from paper to Excel. Now that time goes to real Quality work that adds value."

- Tifenn Cavelier, *Quality Assurance Manager*, HTL Biotechnology

### The Challenge: Manual Processes Couldn't Scale

HTL Biotechnoloy's growth from R&D laboratory to large-scale manufacturing brought new operational requirements. As production capacity expanded, paper-based workflows became unsustainable:

- > 40-signature SOP approvals created operational bottlenecks
- Manual audit preparation consumed entire teams for days
- > Paper-based deviation tracking made trending and analysis cumbersome
- > Sequential workflows prevented parallel processing and collaboration

Supplying the pharmaceutical industry means HTL Biotechnology is held to its highest quality standards. They recognized that their manual processes were inhibiting growth while increasing compliance risk.

## Why Ennov?

#### HTL Biotechnology selected Ennov based on three critical capabilities: :

- **Complete Functionality:** All regulatory requirements are met through configuration rather than custom development, reducing implementation risk and time-to-value.
- **User Adoption Focus:** Training and support are specifically designed for life sciences teams, ensuring smooth adoption across technical and quality functions.
- Infrastructure Flexibility: On-premises deployment options aligned with HTL Biotechnology's IT security policies and data governance requirements.

## The Solution: Ennov Quality Suite

HTL Biotechnology and Ennov structured the deployment across three core areas—document control, quality processes, and validation—implemented through seven phased rollouts.

#### **Implementation Approach:**

- Incremental Go-Lives: Each phase delivered immediate value while preventing change management overload
- > Role-Based Training: Sequential skill-building allowed users to gain confidence progressively rather than overwhelming teams with all features at once
- Controlled Governance: Focused scope and timeline management ensured on-budget, on-schedule delivery

# The Impact

# 1 EFFICIENCY EQUIVALENT TO NEARLY 2 FULL-TIME EMPLOYEES

- 0.65 Full-time employees in operational QA
- 1.15 Full-time employees in systems quality
- Time redirected to high-value analysis and improvement activities

# 2 AUDIT TRANSFORMATION

- Before: Teams spent days manually gathering paper documentation
- After: Instant digital access to all quality records and metrics

# **PROCESS**ACCELERATION

- SOP acknowledgments: 40 signatures → parallel digital workflows
- Document access: from minutes of manual searching to instant access
- Change control: Sequential approvals → simultaneous reviews

# 4 USER ADOPTION SUCCESS

- 370 active users in document management and 350 in quality processes, with many staff working across both systems.
- Adoption rates remained high thanks to incremental go-lives that reduced change fatigue

# Future-Ready By Design

With a unified platform anchoring its quality operations, HTL Biotechnology can expand without disruption.

New capabilities—training, analytics, or Ennov's Al-powered quality features—can be added within the same validated system, without new vendors, duplicate training, or extra validation cycles.

The platform positions HTL Biotechnology to capitalize on growing global demand for specialized biochemicals while maintaining the regulatory compliance and operational efficiency that established their reputation among pharmaceutical and biotechnology customers worldwide.

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

## **Key Success Factors**

HTL Biotechnology's transformation demonstrates that fast-growing life sciences manufacturers can digitalize quality operations without operational disruption:

**Focused Scope:** Incremental go-lives prevent team overload while delivering value at each milestone.

**Partnership Approach:** Stable, collaborative project relationships drive superior outcomes compared to transactional vendor engagements.

**Measurable ROI:** Time and resource savings compound into long-term competitive advantages that support sustained growth.

With Ennov as their quality backbone, HTL Biotechnology maintains compliance confidence while scaling production to meet growing global demand.



"Ennov freed us from wasting days preparing audits. Now everything is instant and traceable, which makes our GxP compliance so much easier. It means our quality teams can focus on real improvement work instead of paperwork."

Tifenn Cavelier Quality Assurance Manager HTL Biotechnology

Find more Case Studies at www.ennov.com/insider

#### Want to Replicate HTL's Success?

HTL Biotechnology's digital transformation established a proven framework for life sciences companies seeking compliance-ready growth. Their strategic approach to quality management digitalization now serves as a model for other specialized manufacturers looking to scale operations while maintaining regulatory excellence and customer satisfaction.

Start with the platform designed to scale with life sciences growth.

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

