From Siloes to Synergy Aligning Quality and Regulatory Ops in Life Sciences

Executive Summary: Amidst the evolving challenges of the life sciences industry, this document provides insights on efficiently managing variation submissions, emphasizing the integration of Quality and Regulatory Information Management to navigate risks and seize opportunities. Learn how unified platforms eliminate traditional system boundaries to accelerate compliance, reduce costs, and create competitive advantage.



www.ennov.com | contact-us@ennov.com | +1 (833) 366-6887

Achieving Regulatory Operational Excellence

UNIFIED QUALITY AND REGULATORY INFORMATION MANAGEMENT

> Introduction

The life sciences landscape today presents unprecedented challenges: pricing pressures, reduced R&D returns, regulatory complexity, and global supply chain disruptions. These pressures demand a rethinking of how regulatory processes are managed across Quality and Regulatory functions.

Leading companies no longer view operational excellence as optional – it's the difference between thriving and merely surviving in today's competitive environment. This evolution requires not just streamlined processes, but intelligent technology that bridges traditional organizational boundaries.

One process that exemplifies this challenge is variation management: the critical intersection of quality and regulatory operations where manufacturing changes meet compliance requirements. This whitepaper examines how modern, unified systems transform variation submissions from a compliance risk into a competitive advantage.

The Variation Management Challenge

Managing variation submissions effectively remains an elusive goal for many organizations. These submissions, essential for keeping products market-compliant, often suffer from disconnected processes and systems that introduce unnecessary risk.

Consider a typical scenario: A manufacturing change originates in operations, triggers quality assessments, impacts supply chain planning, and ultimately requires regulatory submissions across multiple markets. Each step involves different teams with limited visibility into the others' work. When outsourced CMOs or CROs enter the mix, complexity multiplies.

The traditional approach to solving this problem has been process harmonization initiatives that produce detailed process maps, RACI matrices, and SOPs. While these efforts build consensus and identify bottlenecks, they often address only the "what" without solving the "how." More than 450
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Let's examine a typical variation change control process:

The process clearly assigns responsibilities across teams, but critical questions remain:

- > How do teams communicate when the Regulatory team needs additional information from Manufacturing?
- > How are submission documents shared and reviewed?
- > How do stakeholders track approval status and implementation progress?
- > How are cross-border regulatory requirements harmonized and managed?

The answers increasingly lie in how effectively organizations connect their core information systems.



System Landscape

Five key enterprise systems typically manage the variation process lifecycle:

- Enterprise Resource Planning (ERP): Manages materials, production planning, and finished product inventory
- 2. Quality Management System (QMS): Handles deviations, non-conformances, CAPAs, complaints, and change controls
- Electronic Document Management System (eDMS): Controls document lifecycles, versions, and approvals
- **4.** Regulatory Information Management (RIM): Tracks product registrations, submission planning, and health authority interactions
- **5.** Electronic Publishing System (EPS): Builds and validates submission packages (eCTD, NeeS, etc.)

The Integration Dilemna

When these systems operate independently, organizations face several critical challenges:

Data Redundancy: Consider an API manufacturing site change. This single change affects:

> Product SKUs in the ERP

> Regulatory submissions in the EPS

> Change control records in the QMS

- > Registration status in the RIM
- > Manufacturing documentation in the eDMS

Without system integration, manual coordination of these updates introduces significant compliance risk.

Cross-Border Complexity: Generic and biosimilar manufacturers face additional challenges managing the same change across multiple regulatory jurisdictions with different requirements and timelines.

Structured Data Requirements: Modern regulatory initiatives like IDMP (Identification of Medicinal Products), SPOR (Substances, Products, Organizations, Referentials), and PLM (Product Lifecycle Management) demand structured, standardized data that flows across traditional system boundaries.

Organizations typically address these challenges through three approaches:

- 1. Manual Coordination: Using spreadsheets, email, and meetings to manage handoffs (high risk, labor-intensive)
- 2. Point-to-Point Interfaces: Sharing limited data between systems (moderate risk, limited scope)
- **3.** Custom Integrations: Building complex connections between systems (expensive to build and maintain, challenging to validate)

Each approach comes with significant drawbacks. Let's consider a very basic process map to illustrate the organizational and technological interdependencies associated with a variation change control and submission.



DATA AND PROCESS DEPENDENCIES



Even well-designed integrations face fundamental limitations:

- System architecture differences limit integration depth
- > System updates can break existing integrations
- > Validation costs mount with each change
- > Data consistency becomes increasingly difficult to maintain

This creates what we call "system paralysis" – where organizations resort to maintaining manual processes because they can't rely on their disconnected systems.

"Our previous environment had 7 different systems trying to manage regulatory information. Each time regulations changed, we had to reconfigure each system separately. The validation costs alone were unsustainable."

- Head of Regulatory Operations, Top 20 Pharma Company



The Unified Platform Advantage

Imagine a fundamentally different approach: a unified platform where quality and regulatory operations share not just data, but an integrated process ecosystem.

This isn't theoretical. Leading life sciences organizations already use unified platforms to:

- > Access all variation-related information from one authoritative source
- Move seamlessly between regulatory data, documents, and workflows
- > Use consistent terminology and data structures across departments
- Case Study Spotlight

Vetoquinol: From Fragmentation to Global Alignment

Vetoquinol, a global veterinary pharmaceutical company operating in 25 countries, faced rising compliance risk and mounting system complexity. With separate tools managing quality, regulatory, and pharmacovigilance processes across multiple sites, the company was spending more time maintaining systems than improving them.

The turning point: leadership recognized that disconnected systems were not just inefficient, they were unsustainable.

Instead of layering more integrations, Vetoquinol replaced six siloed systems with one unified platform, consolidating operations across quality, regulatory, and safety functions.

The impact was enterprise-wide:

- > 400,000+ documents centralized
- > 18 new processes built by internal teams without vendor involvement
- > 25 countries live on a single system
- > 2,200+ users collaborating across departments

By using a unified platform, Vetoquinol eliminated duplicate licensing, streamlined validation, and empowered business users to scale operations independently, turning regulatory and quality operations into a driver of global efficiency.

This transformation illustrates what's possible when quality and regulatory teams operate from a shared foundation, not just shared goals.





- Automate post-approval updates across systems and teams
- > Leverage cross-functional data for operational insights

What Makes a Platform Truly Unified?

The unified platform represents a fundamental architectural shift—not just a collection of pre-integrated modules. Its key advantages include:

Single Source of Truth: A unified data model ensures consistency across all applications. When an API manufacturing site changes, all related records update automatically without manual intervention. This architecture eliminates the redundancy and potential errors that plague disconnected systems.

Unified User Experience: Teams work within a consistent interface regardless of function. Navigation, search, and task management operate identically across the platform, dramatically reducing training needs and improving adoption.

Process Connectivity: Workflows span traditional system boundaries, allowing seamless transitions between quality, document management, and regulatory processes. Change controls automatically trigger regulatory assessments and submission planning.

Reduced Validation Burden: Single-platform architecture simplifies validation significantly.

Organizations validate once rather than multiple times across separate systems, reducing compliance costs.

Future-Ready Architecture: Today's platforms accommodate emerging regulatory requirements and technological advances:

- > Built for structured data standards like IDMP
- > Al-ready data architecture enables automation and predictive analytics
- Cross-functional data insights improve strategic decision-making

Cultural Convergence: Beyond technical benefits, unified platforms foster organizational alignment between quality and regulatory teams. Shared systems promote shared understanding and collaborative problem-solving.

THE ENNOV PLATFORM

Ennov solutions are elegantly designed to work individually or to be combined together seamlessly for even more efficiency. Built on our Unified Compliance Platform and made specifically for the management of regulated content and processes, each solution is highly configurable, powerful, and easy-to-use. The Ennov platform is the foundation for:

- Regulatory
- Clinical
- Quality
- Pharmacovigilance
- Commercial





Unified Platform vs. Pre-Integrated Suites

It's important to distinguish between truly unified platforms and pre-integrated application suites:

Pre-integrated suites connect separate applications through pre-built interfaces. While better than custom integrations, they still maintain separate data models, user experiences, and application architectures. Each upgrade introduces risk, turning every integration point into a potential compliance vulnerability. Unified platforms are built on a common architecture that inherently supports cross-functional processes. The fundamental differences become clear when comparing key attributes:

- > Data Architecture: Unified platforms maintain a single data model, eliminating duplication and reconciliation needs. Pre-integrated suites require constant synchronization between separate databases.
- > User Experience: Unified platforms provide consistent navigation, workflows, and search functionality across all modules. Pre-integrated suites often reveal their disjointed nature through inconsistent interfaces and terminology.
- System Access: Unified platforms offer one login with seamless movement between functions. Pre-integrated suites typically require context switching between applications, even if accessed through a portal.
- Validation Approach: Unified platforms allow a holistic validation strategy. Pre-integrated suites require validating both the individual applications and their connections.

The difference becomes particularly evident when implementing new regulatory requirements:

- In pre-integrated suites, new requirements often mean extensive reconfiguration across multiple applications, with each component requiring separate testing and validation
- In unified platforms, changes are implemented once and automatically propagate across functions, dramatically reducing compliance timelines and validation costs

This architectural distinction delivers strategic advantages that extend beyond IT considerations:

> Lower total cost of ownership

- > Enhanced data confidence and integrity
- > Accelerated compliance with emerging regulations
- Improved global collaboration and process standardization

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MARKET REALITY CHECK: Many vendors claim platform unification while actually offering pre-integrated modules connected by APIs. Understanding this distinction is crucial for long-term success.

Conclusion

Life sciences companies face unprecedented pressure to enhance operational efficiency while maintaining impeccable compliance. The variation management process highlights how disconnected systems create unnecessary risk and inefficiency.

The unified quality and regulatory information management platform offers a transformative solution to these challenges. By eliminating system boundaries, organizations can:

- > Reduce compliance risk through consistent, automated processes
- > Accelerate change implementation timeframes
- > Prepare for emerging regulatory data standards
- > Foster quality-regulatory team alignment
- > Lower total cost of ownership and validation burden

Forward-thinking organizations recognize that true regulatory operational excellence isn't achieved through process mapping alone; it requires technology that fundamentally connects people, processes, and information. The unified platform delivers this connection, turning regulatory compliance from a cost center into a competitive advantage.

Is your current tech stack a source of operational excellence, or operational overhead? **Connect with Ennov** to see how a single, integrated solution can transform your operations.

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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 300 companies and 300,000 users worldwide.

For more than 20 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 9001:2015 certified for all software products and processes and we boast a 100% success rate in customer audits.

