

# Unifying Clinical Data and Submission Strategy for the Global Life Sciences Industry

Breakthrough Outsourcing

World-Class Consulting

Game-Changing Software

## Q u a n t u m

**Choose Your Future. Don't Compromise.**

**Submission Management** is a complex business challenge with global implications. It involves data and document processes that merge into the submission lifecycle, including content planning, tracking, publishing, compilation and distribution. Tools currently available to industry were designed to address a paper process and individual tasks rather than process problems. These options do not provide a path toward process improvement.

The Quantum platform is founded on an enterprise process management engine that provides comprehensive process management controls across various business applications.

It connects processes, automates tasks and provides the underpinning of cross-functional, cross-organizational efficiency. The Quantum platform may be integrated with existing data and document repositories.

Specific business applications are layered on top of the Quantum process management platform and leverage its power to provide targeted functionality that is essential to submission management. The business applications are not disparate tool sets. Rather, they are tightly integrated functions that enable users to plan and manage the process as it moves through the organization.

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### **Quantum's secure and collaborative environment is critical to submission management. The Quantum platform provides:**

- Strong process management
- Robust rules engine
- Automated metadata management
- Powerful document and data integration
- Flexible search and reporting
- Solid compliance

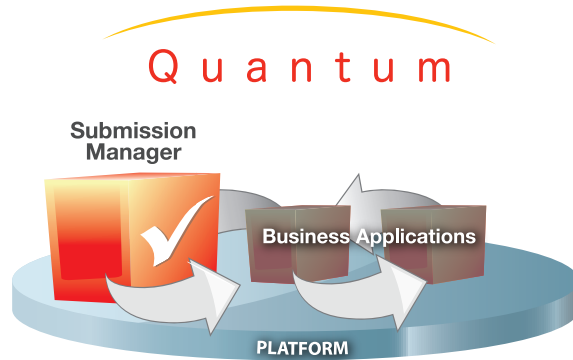
Desktop tools are not scalable, do not utilize existing business intelligence to speed processes and are not connected to upstream processes. First generation technologies in the regulatory information management arena only address points within the global process rather than the entire process. These tools often rely on complex dialog boxes rather than providing business-friendly and business-relevant terminology. They lack flexibility and often require significant manual data entry to provide any insights into complex processes.

Quantum is changing the enterprise technology landscape. It offers a comprehensive solution where authors, publishers and anyone contributing to a process can interact in one secure and collaborative environment. The process management platform provides the power and control for the process but does not dictate a specific process. Business applications offer job-specific functionality and automation of tedious manual tasks. The power behind the scenes is transparent to the user, as the user interface offers a clean, simple and familiar view into the Quantum environment. The user interface may be tailored for any consumer/user.

## QUANTUM SUBMISSION MANAGER BUSINESS APPLICATION

The Submission Manager Business Application leverages the Quantum platform to support planning and management of global projects. Submission Manager offers submission teams unprecedented visibility and flexibility to analyze the impact and react quickly when regional or country-specific strategies shift.

By utilizing the Submission Manager, Regulatory organizations can begin to centralize their understanding of regional health authority requirements and apply that global understanding from one common source. Health authority requirements, planned content, document and submission metadata, registration data and process metrics are easily accessed and utilized across the global organization.



### Quantum's Submission Manager Business Application is designed for competitive international organizations who wish to:

- Plan, develop, and manage submission plans in a global collaborative environment
- Leverage re-usable content plans for any submission type
- Access intuitively presented content plans, including content and business relevant metadata
- Leverage the configurable rules engine to define and enforce rules for health authority compliance (regional and country requirements) as well as use built-in rules
- View integrated planning, regulatory, and document information in one place
- Manage both submission-required metadata as well as internal business metadata
- Track delivery dates, supplier names, cycle times, and content requirements for submission components
- Manage planning dates, resource assignments, and cycle times more easily and quickly
- Use issue management to drive unplanned events to resolution, capture key decisions, and gather process improvement metrics
- Define custom reports through an integrated report designer and reporting engine that can be run on demand, scheduled, and automatically distributed
- Balance compliance controls and process flexibility
- Easily gather process metrics



Global companies can now begin to glean valuable insights from the complex regulatory submission process at any point in time. This information can be used to analyze the impact of new strategies, implement updated plans and rapidly react to shifting timelines around the globe.

True regulatory information management meets unprecedented process transparency with Quantum's Submission Manager.



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