



THE CLINICAL DATA AND REGULATORY EXPERTS

QUANTUM™ CONTENT MANAGER MODULE
Software as a Service (SaaS) Model



“Our project came in on time, and the quality of the project was very high. We consider ourselves fortunate to have chosen Octagon as our partner.”

*Director,
Regulatory Affairs,
Emerging pharmaceutical
company*

Traditional document management systems (DMS) require significant IT infrastructure, support and ongoing maintenance which are often cost-prohibitive for smaller and emerging biotech and pharmaceutical (pharma) organizations. Another challenge for growing organizations is that document management systems require validation programs and must be 21 CFR Part 11 compliant – often requiring substantial business resources and time. When considering the complex components, resources and tasks required to effectively manage submissions, document management systems can seem out of reach.

Growing biotech and pharma companies no longer need to compromise their expectations of document management systems. Octagon's Quantum™ Content Manager Module in a SaaS model (Software as a Service), provides these organizations with the robust DMS capabilities of large organizations without the burden of maintaining a complex IT infrastructure.

Quantum Content Manager is an easily scalable solution that provides growing organizations big-company DMS

features and functions at a fraction of the cost. Since the Quantum Content Manager is offered in a SaaS model it reduces the burden on the IT organization. In addition, it is integrated with a CTD template suite, submission publishing capabilities, and submission management tools. It also offers optional built-in rendering capabilities to efficiently create an e-Submission- ready final document. Quantum was also developed to integrate with Octagon's StartingPoint® eCTD document authoring template suite.

(see table next page)

Quantum's Content Manager Module puts big DMS capabilities in reach for smaller organizations.

Quantum Content Manager Business Capabilities	Advantage to Sponsors/Users
Out-of-the-box configuration	Pharma- biotech-focused and based on Octagon's submission and document management best practices
User-driven, flexible workflows match to any organization's business processes	Workflows can accommodate document review in Microsoft Word as well as PDF format. Workflows account for quick batch approvals as well as eApproval and eSignature tasks
Robust search capabilities	Secure searching with sophisticated parsing, results clustering and ability to save searches for future reference
Ready to use folder structures, document types, and attributes	A complete taxonomy is provided. Easily create, find, and re-use your submission-bound content.
21 CFR Part 11 compliant	Ensures all documents, records and approvals are submission compliant
SaaS model	No dedicated IT staff required for support and maintenance Low cost alternative as upgrades are included and there are no upgrade fees Quick ramp up, rapid implementation and easy deployment to global teams
24x7 support desk	Provides the support needed to maintain system at peak efficiency in any time zone, 24x7
Online tutorials	Minimizes effort and time required to train new staff or update existing staff
Validation included	Reduces burden of extra time and resources and ensures submission compliance

OCTAGON EXPERTISE EXTENDS YOUR TEAM'S CAPABILITIES

- **Lifecycle Focused:** Octagon's approach concentrates on the drug development lifecycle — from document to submission processes — to produce compliant deliverables
- **Expertise to Partner with Sponsors:** Octagon's innovative outsourcing model combines leading industry expertise and technology so Octagon serves as a true partner and extends the capabilities of sponsor companies
- **Business Process Focus:** Octagon's business process experts complement its technology and service capabilities with knowledge transfer at the core of all project engagements

THE QUANTUM PLATFORM AND ITS BUSINESS MODULES

The Quantum platform is founded on an enterprise process management engine that provides comprehensive process management controls across various business modules (Content Manager, Document Publisher, Submission Manager and Reviewer). The Quantum platform connects processes, automates tasks and provides the underpinning of cross-functional, cross-organizational efficiency and may be integrated with existing data and document repositories.

Octagon partners with its customers and extends their internal expertise and capabilities. In addition to the Quantum Content Manager Module, Octagon's software solutions include:

- Quantum™ SaaS Model
- Quantum™ Installed On-Premises
- Quantum™ Submission Manager
- Quantum™ Document Publisher
- Quantum™ Reviewer
- FUSE™ EDC
- Metadata Registry
- StartingPoint®

HERE'S WHAT OCTAGON'S VALUED CUSTOMERS SAY:

Octagon consistently receives very high customer satisfaction ratings through annual client surveys. In Octagon's recent customer satisfaction survey:

- 97% of Octagon customers are extremely satisfied, very satisfied or satisfied with our products and services
- 97% of Octagon customers are highly likely or likely to recommend Octagon to colleagues
- 98% of Octagon customers say that Octagon cares about their business

GLOBAL REACH AND EXPERTISE

Octagon offers industry expertise and a true dedication to help life science companies leverage its technology and functional expertise to significantly improve clinical R&D processes.

Octagon is a global organization with its headquarters in Wayne, Pennsylvania, USA; and with European operations in London, United Kingdom; and Asia-Pacific operations in Bangalore, India. Octagon is well positioned to provide its clients with follow-the-sun capabilities and efficiencies.

For more information please visit the Octagon website at www.octagonresearch.com or allow us to address your company's needs by emailing us at info@octagonresearch.com.



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