

TRUSTED COMPLIANCE AT WORK

The Proven Document
Management and
Collaboration
Solution on
Documentum

first | Doc.®

CSC



EMC's Preferred Regulatory Compliance Solution for Life Sciences

THE FIRSTDOC DOCUMENT AND COLLABORATION MANAGEMENT SUITE

The FirstDoc Document and Collaboration Management Suite includes a complete set of out-of-the-box preconfigured solutions that incorporate the latest in best business practices for life sciences organizations. Each business module is fully integrated with the FirstDoc Compliance platform, which provides all the functionality required to meet global regulatory requirements. FirstDoc's business modules include Research & Development, Clinical/eTMF, Quality & Manufacturing and Sales & Marketing.

With deep domain expertise and years of experience, CSC designed FirstDoc to meet global regulatory compliance requirements and to improve an organization's overall business productivity. FirstDoc works with market leading publishing solutions including ISI, Lquent and Extedo.

FirstDoc leverages the robust functionality of Documentum and adds those features necessary for highly regulated auditing, electronic signatures and document collaboration.

- Users enjoy the automation of cumbersome business processes and ease of collaboration.
- IT professionals trust the Documentum platform for storing secure information and the ease of integration with SharePoint.
- And the business realizes the benefits of increased productivity along with reduced risk of non-compliance.



FIRSTDOC IS ALSO AVAILABLE WITH A SHAREPOINT USER EXPERIENCE (SPX)

CSC offers FirstDoc SPX, a full featured SharePoint user interface to extend the use of FirstDoc to secure collaboration portals. FirstDoc enables familiar user interfaces of SharePoint and Microsoft Office tools to enable controlled, real-time co-authoring and edit capabilities while maintaining the rich functionality and security of Documentum.

COMPLIANCE AND COLLABORATION ON DOCUMENTUM'S SOLID CONTENT MANAGEMENT FOUNDATION.

EDM & COLLABORATION	SECURE COLLABORATION VIA SHAREPOINT	Regulatory Affiliates	CROs Investigators	CMOs Supply Chain	Business Partners
	BUSINESS MODULES	Research & Development	Clinical/eTMF	Quality & Manufacturing	Sales & Marketing
	FIRSTDOC COMPLIANCE PLATFORM	21 CFR Part 11 Compliance Document Templates Electronic Signature Notifications Advanced Workflow Document Lifecycle Management Search	Automation Reporting Watermarking Configuration Utility Personalization Advanced Workflow Engine	Audit Trail PDF Management and Publishing Controlled Printing Virtual Documents Web Services Validation Document Naming/Numbering	
	CONTENT MANAGEMENT	EMC Documentum			

FLEXIBILITY TO MEET YOUR BUSINESS NEEDS

FirstDoc provides the flexibility to deploy through Documentum's web based user interface or in a business portal such as SharePoint providing document views and functionality via Web Parts. These web parts can be personalized to allow access only to the information critical to each application user.

Through our more than 15 years of experience in document management, FirstDoc is designed to bring value in extending Documentum to ensure compliance with 21 CFR Part 11 standards along with other unique features and functions that meet specific industry needs.

- **21 CFR Part 11 Compliance**
 - FirstDoc provides electronic signature capability, document level audit trail reporting, and enhanced security capabilities all seamlessly integrated into Documentum.
- **Document Templates**
 - Based on property values selected, FirstDoc automatically presents the correct template to the author.
- **Document Lifecycle Management**
 - Predefined lifecycles that automatically guide documents from creation through review, approval and retirement.
- **Advanced Workflow**
 - Highly flexible workflow engine can be configured to support a multitude of business processes. Workflows can be manually launched or automatically launched based on metadata conditions or calculated dates.
- **Secure Collaboration**
 - Secure document authoring, review and approval across functions and with external partners via SharePoint.

DESIGNED FOR EMC

The FirstDoc suite has met the highest level of certification standards set by EMC Documentum, validating the design, performance and scalability of the solution — earning FirstDoc the Designed for EMC designation. FirstDoc is also developed, implemented and supported through processes that exceed the rigorous requirements of its ISO 9000:2008 certification.



- **Event Notifications and Audit Trail**
 - Configurable notifications to inform users of document related events including status changes, workflow activities, and events associated with related documents.
 - Capture and reporting of all critical events in the document lifecycle.
- **Dynamic Security**
 - Access control automatically applied based on a document's lifecycle state and document specific parameters.
- **Master Data Maintenance**
 - Tools to manage master data and the hierarchy of relationships between data values.



BUSINESS MODULES AT A GLANCE

- **Research & Development**

- Provides support for Submission documents across non-clinical, clinical, quality and regulatory functions.
- Robust, predefined inventory with a highly granular design that promotes document reuse based on the latest ICH/eCTD Guidance.
- PDF Rendition support for direct integration with electronic publishing tools.
- Automatically populates detailed metadata for eCTD consumption.

- **Clinical/eTMF**

- Provides support for Clinical documentation at the product, study and site levels.
- Predefined TMF inventory based on ICH Guideline For Good Clinical Practice (E6).
- Out-of-the-box lifecycles to support both internally authored and imported documents.
- Flexible, advanced security model to support study level security as well as the management of security for collaboration with external parties.

- **Quality & Manufacturing**

- Fully manages all controlled documentation and records such as policies, SOPs, methods, specifications, and batch records with predefined inventories.
- Out-of-the-box Change Request management
- Advanced Periodic Review capability which fully automates recurring review cycles.



NEED FIRSTDOC AS A MANAGED SERVICE?

With years of experience as a leading supplier of managed application services, CSC has a track record of reducing infrastructure and operating costs while providing exceptional service levels in highly secure and reliable data centers. With our Managed Applications Services, we relieve the management burden of daily operations, allowing you to focus on achieving your strategic objectives.

A TRUSTED SOLUTION FOR LIFE SCIENCES

- **Sales & Marketing**

- Predefined inventory to fully manage promotional material and advertisements.
- Easily collaborate and share information with co-marketing partners.
- Ensure approved content is used in all marketing materials.

Trust CSC with all of your compliance and collaboration needs. Our experience across multiple industries enables us to harness the best ideas, practices and solutions from both the public and private sectors for the benefit of every client. CSC and EMC are long standing partners committed to delivering solutions around large-scale information infrastructures and next-generation data center operations. FirstDoc is EMC's preferred regulatory compliance solution used by industry leading pharmaceutical companies worldwide.

To learn more about FirstDoc, e-mail lifesciencesinfo@csc.com or call +1.610.989.7000

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About CSC's Healthcare Group

We help our customers realize superior performance by enhancing the quality of care delivery and clinical outcomes through interoperable, standards-based information systems and optimized management processes.

About CSC

The mission of CSC is to be a global leader in providing technology-enabled business solutions and services.

With the broadest range of capabilities, CSC offers clients the solutions they need to manage complexity, focus on core businesses, collaborate with partners and clients, and improve operations.

CSC makes a special point of understanding its clients and provides experts with real-world experience to work with them. CSC is vendor-independent, delivering solutions that best meet each client's unique requirements.

For 50 years, clients in industries and governments worldwide have trusted CSC with their business process and information systems outsourcing, systems integration and consulting needs.

The company trades on the New York Stock Exchange under the symbol "CSC."

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