



*first* | Point.®

# TRUSTED COMPLIANCE AT WORK

Document Management  
and Collaboration  
for Life Sciences on  
Microsoft SharePoint



# A Complete Document Management and Collaboration Solution for Life Sciences in a SharePoint Environment

TRUST THE FIRSTPOINT COMPLIANCE PLATFORM FOR ALL OF YOUR DOCUMENT MANAGEMENT AND COLLABORATION NEEDS.

The FirstPoint Compliance platform extends SharePoint in order for organizations to fully comply with CFR Part 11 and other global regulations while ensuring secure collaboration with a myriad of external business partners.

FirstPoint's Document and Collaboration Management Suite includes a complete set of out-of-the-box preconfigured solutions that incorporate the latest in best practices for life sciences

organizations. Each business module is fully integrated with the FirstPoint Compliance platform, which provides all the functionality required to meet global regulatory requirements. FirstPoint's business modules include Research & Development, Clinical/eTMF, Quality & Manufacturing and Sales & Marketing.

FirstPoint is browser based and integrates seamlessly with Microsoft Office applications.

Whether your organization is new to SharePoint or you have an existing SharePoint infrastructure, FirstPoint requires fewer configurations, less deployment time and ultimately reduces total cost of ownership when compared to custom or legacy document management systems.



# THE FIRSTPOINT COMPLIANCE PLATFORM

EDM & COLLABORATION	<b>SECURE COLLABORATION</b>	Regulatory Affiliates	CROs Investigators	CMOs Supply Chain	Go-to-Market Partners
	<b>BUSINESS MODULES</b>	Research & Development	Clinical/eTMF	Quality & Manufacturing	Sales & Marketing
	<b>FIRSTPOINT COMPLIANCE PLATFORM</b>	Metadata Automation Authoring Templates Document Auto Numbering Document Auto Naming Change Requests	Advanced Workflow Engine Intuitive Workflow UI Auto Periodic Review Electronic Forms Audit Trail Advanced Security	Advanced Document Lifecycle PDF Renditions Metrics & Reporting Configurable E-mail Notices Administrative Utilities	
	<b>CONTENT MANAGEMENT</b>	Microsoft SharePoint			

## EXPERIENCE YOU CAN TRUST. BENEFITS YOU CAN USE.

CSC's FirstPoint Document and Collaboration Management Solution leverages all of the benefits of the SharePoint platform including a familiar and intuitive user interface, seamless integration into Microsoft Office, and ease of collaboration. Through our more than 15 years of experience in document management, FirstPoint is designed to bring value in extending SharePoint to ensure compliance with 21 CFR Part 11 and bring other features and functions that meet specific industry needs.

Key features and functions that have been developed specifically within FirstPoint include:

- **Metadata Automation:**
  - For content authors, FirstPoint filters values and auto populates values where possible to allow users to quickly create and accurately index documents.
- **Authoring Templates**
  - Based on property values selected, FirstPoint automatically presents the correct template to the author.
- **Advanced Workflow Engine**
  - 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.
- **Intuitive Workflow Initiation Interface**
  - Now available, a workflow initiation wizard to translate the robust workflow functionality into easy-to-execute steps for all levels of users.
- **Electronic Forms**
  - Based on Microsoft's advanced Silverlight™ technology, FirstPoint's eForms provide the ability to capture data to drive and automate business processes such as Change Requests and CAPA. FirstPoint also supports Microsoft InfoPath Forms. Data is stored in a Microsoft SQL database for reporting and analysis.
- **PDF Renditions**
  - FirstPoint automatically creates PDF Renditions as required as part

## BENEFITS AT A GLANCE:

- Easy Document Creation
- Feature-Rich Workflow Engine
- 21 CFR Part 11 Compliance
- User Friendly Interface
- Complete Microsoft Office Integration



of a workflow process or upon manual request. PDF Renditions are stored separately for scalability benefits, but are automatically linked to the source document. Configurable header and footer overlays and document watermarks are also supported.

- **Bulk Import Utility Tool**

- Users can quickly and easily load and index high volumes of documents from external sources.

- **21 CFR Part 11 Compliance**

- FirstPoint provides electronic signature capability, document level audit trail reporting, and enhanced security capabilities all seamlessly integrated into SharePoint.

- **Metrics and Reporting**

- FirstPoint provides predefined data models and reports for document level reporting as well as workflow processing metrics. Based on SharePoint's highly configurable Reporting Services, clients can easily create their own data models and reports.

- **Auto Document Naming/Numbering**

- FirstPoint automatically names and numbers documents based on any metadata as configured by the administrator.

- **Configurable E-mail Notifications**

- E-mails are generated to look like user-generated e-mails with a choice of formatting tools to customize messages.

- Several categories of e-mail templates available to cover all business scenarios including workflow alerts, out-of-office notifications, and more.

- **Validation Package**

- FirstPoint is delivered with the essential qualification scripts and other documentation based on industry standards to support validation in your organization's unique environment.



## BUSINESS MODULES AT A GLANCE

- **Research & Development**
  - Provides support for submission documents across nonclinical, 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 electronic forms which drive, execute and manage the change control workflow process.
  - Advanced Periodic Review capability which fully automates recurring review cycles.
- **Sales & Marketing**
  - Predefined inventory to fully manage promotional material and advertisements.
  - Easy collaboration and information sharing with co-marketing partners.
  - Ensure approved content is used in all marketing materials.



## COMPLIANCE IN THE CLOUD

CSC is a Microsoft Gold Certified partner, and one of only a handful of authorized resellers of Microsoft's Business Productivity Online Suite (BPOS). Backed by more than 2,000 .Net developers worldwide, CSC can deliver FirstPoint on-premise, through our Trusted Cloud Services or on the Microsoft Azure platform. Our experience across all industries enables us to harness the best ideas, practices and solutions from both the public and private sectors, for the benefit of every client.

## THE FIRSTPOINT ADVANTAGE

Our FirstPoint Document Management and Collaboration solution is the result of years of experience developing regulatory solutions used by industry leading pharmaceutical companies worldwide.

FirstPoint leverages the built-in functionality in Microsoft SharePoint and adds those features necessary for highly regulated environments, including process, workflow, auditing, electronic signatures and document collaboration.

- Users enjoy the familiar interface and working in the Microsoft Office applications they use every day.
- IT professionals benefit from the ease of implementation with SharePoint.
- And with higher user adoption rates, business productivity increases along with a lower cost of ownership and reduced risk of non-compliance.

To learn more about CSC's FirstPoint Document Management and Collaboration solution, e-mail [lifesciencesinfo@csc.com](mailto:lifesciencesinfo@csc.com) or call +1.610.989.7000

[www.csc.com/firstpoint](http://www.csc.com/firstpoint)



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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."*

[www.csc.com](http://www.csc.com)