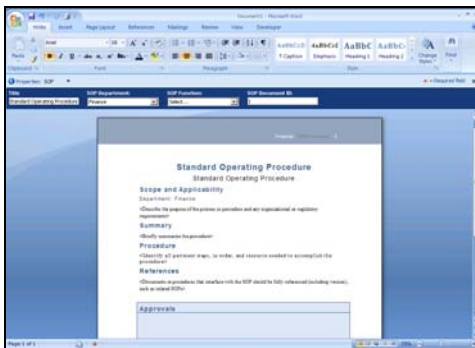


■ **Product Overview**

Open Text Regulated Documents for Microsoft SharePoint

Enable your organization to manage and control key documents throughout their entire lifecycle

The pharmaceutical and life sciences industries are subject to strict regulations that dictate how, when, and under what circumstances electronic documents can be authored, updated, approved, published, and archived. In the race to market, regulated companies need to make compliance with regulations an integrated part of their document management and control processes to reduce risk and gain competitive advantage by bringing new products to market faster.



Manage and control key documents throughout their lifecycles

Designed to meet the strict requirements of the pharmaceutical industry, Open Text Regulated Documents for Microsoft® SharePoint® is a complete solution that enables your organization to manage and control key documents throughout their entire lifecycle.

By providing a consistent process for creating, managing, updating, and storing content, Open Text Regulated Documents for Microsoft SharePoint ensures compliance with various regulations, including the U.S. Food and Drug Administration's (FDA's) 21 CFR Part 11. The solution is designed to carefully manage critical documents through a controlled lifecycle that includes document authoring, reviews, approvals, and dissemination.

Based on Microsoft® Office SharePoint® Server 2007, Regulated Documents for SharePoint provides an extensible platform that organizations can enhance with their own custom content types and workflows. Sample business content, including forms and workflows, are provided to help customers quickly establish common business processes.

Standardize processes and documents

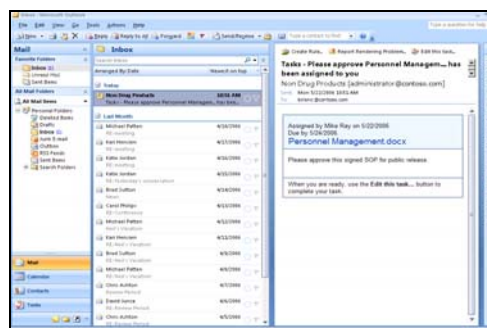
Regulated Documents for SharePoint leverages the underlying document management features of the SharePoint platform and adds features across a fully automated workflow process, including:

- Enforceable document templates to simplify and control the document creation process
- Automated document numbering based on content type
- Enforceable metadata entry and capture
- Version control with check-in and check-out
- Auditing, classification, retention and disposition, holds, and long-term archiving

Manage Standard Operating Procedures and other documents

Standard Operating Procedures (SOPs) are a key part of many business processes. With Regulated Documents for SharePoint, you can carefully manage and control business-critical documents, such as SOPs, from creation through to final destruction. SOPs pass through a series of stages where multiple users or groups must review and approve the document before it is distributed.

Users continue to work in the familiar Microsoft Office environment, and tasks are fully automated across the document lifecycle. For example, when a user is required to approve a new or revised document, an automated email provides notification that the document is pending review.



“Open Text’s new solution takes full advantage of the new features in the 2007 Office system, including Microsoft Office SharePoint Server 2007, to increase the effectiveness of users in highly regulated environments. Because this solution taps Open Text’s extensive pharmaceutical and life sciences expertise, it will offer companies using SharePoint Server 2007 immediate productivity benefits by working in a system that is already FDA-compliant, while also stepping up to meet enterprise-wide scalability.”

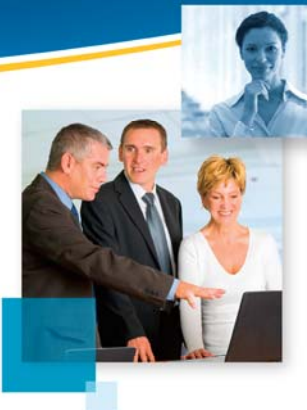
Steve Shihadeh,
General Manager of Healthcare and Life Sciences,
Microsoft Corporation

Product Overview

Regulated Documents for SharePoint is tightly integrated with Microsoft Office and Microsoft SharePoint, enabling mandatory metadata fields for new documents to be exposed in the Microsoft Office Word interface. When users complete these fields, the information is automatically associated with the document in SharePoint, and the content inherits the appropriate retention schedule from the records management engine.

Ensure compliance, reduce time-to-market

Pharmaceutical and life sciences companies operate in a highly regulated environment with long product lifecycles. Their operations are both data and document-intensive. Pharmaceutical product development can take up to 15 years and \$1 billion or more per product. By making the management and control of key documents in heavily regulated industries more efficient and compliant with relevant regulations, Regulated Documents for SharePoint reduces the risk associated with non-compliance, helps improve corporate accountability, and accelerates time-to-market.



Open Text Regulated Documents for Microsoft SharePoint Features

Author documents	Document authoring is performed entirely in the familiar Microsoft Office Word 2007 environment. Document templates and workflows guide users throughout the process; automatic document numbering ensures that documents are identified in accordance with regulatory requirements. Document authors can connect directly from Microsoft Office Word to the SharePoint repository to save new documents or to check-out existing documents for which there has been a change request.
Review documents	Using workflows and tasks, Regulated Documents for SharePoint helps you effectively manage the review and modification of documents. The solution supports major and minor document versions—meaning that revisions can be assigned minor version numbers and that once a document is formally approved, a major version is created. Typically, the system is configured to automatically archive major versions and associated audit trails, ensuring retention of official content.
Approve documents	Using workflows and electronic signatures, Regulated Documents for SharePoint ensures that only documents that meet organizational guidelines, policies and procedures are approved. Electronic signatures are added to a non-modifiable rendition of the document. Regulated Documents for SharePoint fully manages signing authority administration in compliance with 21 CFR 11, ensuring that users can sign only the appropriate documents, and that only authorized users can assign and revoke the signing rights of other users.
Archive documents	Integrated archiving capabilities enable companies to ensure that regulated documents are retained and stored in accordance with internal policy and regulatory requirements. Both active and archived documents are accessible from the SharePoint interface with a single click, and can be retrieved with a single search.
Transparent metadata management	The Microsoft Office 2007 system enables metadata to be embedded directly into documents and surfaced through a document template, making this information accessible and usable within applications like Microsoft Word. An InfoPath form allows users to provide information about each regulated document as an integrated step of the document creation process.
Shared infrastructure	A unified architecture provides a common set of services such as unified administration, integrated search, integrated user management and user rights, workflow, a web part framework and a common usage pattern for document access regardless of the underlying repository. This ensures integration and consistency across SharePoint and other ECM components. Customers can reuse applications, code, and site content, enabling a common development and deployment experience for developers and IT professionals respectively.



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