



## Streamlining Regulated Document Management Using the Microsoft Office System

**To comply with an ever-increasing number of regulations governing electronic data, the life sciences industry must maintain strict controls over the way this data is managed and tracked. But these same controls can also impede workflow speed and efficiency. The Microsoft Office System provides the tools and flexibility needed for efficient documents management—without compromising the security needed for compliance.**



*By extending the collaboration and indexing capabilities of SharePoint® Portal Server to a company's secure document repository, the Microsoft Office System can make it easier to locate, edit and publish data in a highly regulated environment*

### The Challenge of Managing Regulated Documents

In order to ensure the accuracy and security of data in the life sciences industry, the FDA introduced a regulation known as 21 CFR Part 11. This regulation places strict guidelines on how electronic files are managed.

Specific requirements of 21 CFR Part 11 include: secure storage and controlled access of electronic records; computer-generated audit trails and time stamps; and electronic digital signatures for authentication.

There are a number of document management systems that offer tracking and workflow features necessary to meet compliance regulations such as 21 CFR 11.

However, maintaining this compliance often comes at the expense of efficient document collaboration and editing features. In fact, working with the systems needed for regulatory compliance can impede document management in a number of ways, including:

- Inefficient editing and approval processes
- Difficulty locating files across databases and applications
- Inability to collaborate efficiently and maintain competitive speed-to-market
- Difficulties enforcing how and when to check in and out content without disrupting workflow
- Lack of integration with familiar document management applications

These challenges can be overcome with a regulated document management solution using the Microsoft Office System.

### A Regulated Document Management Solution

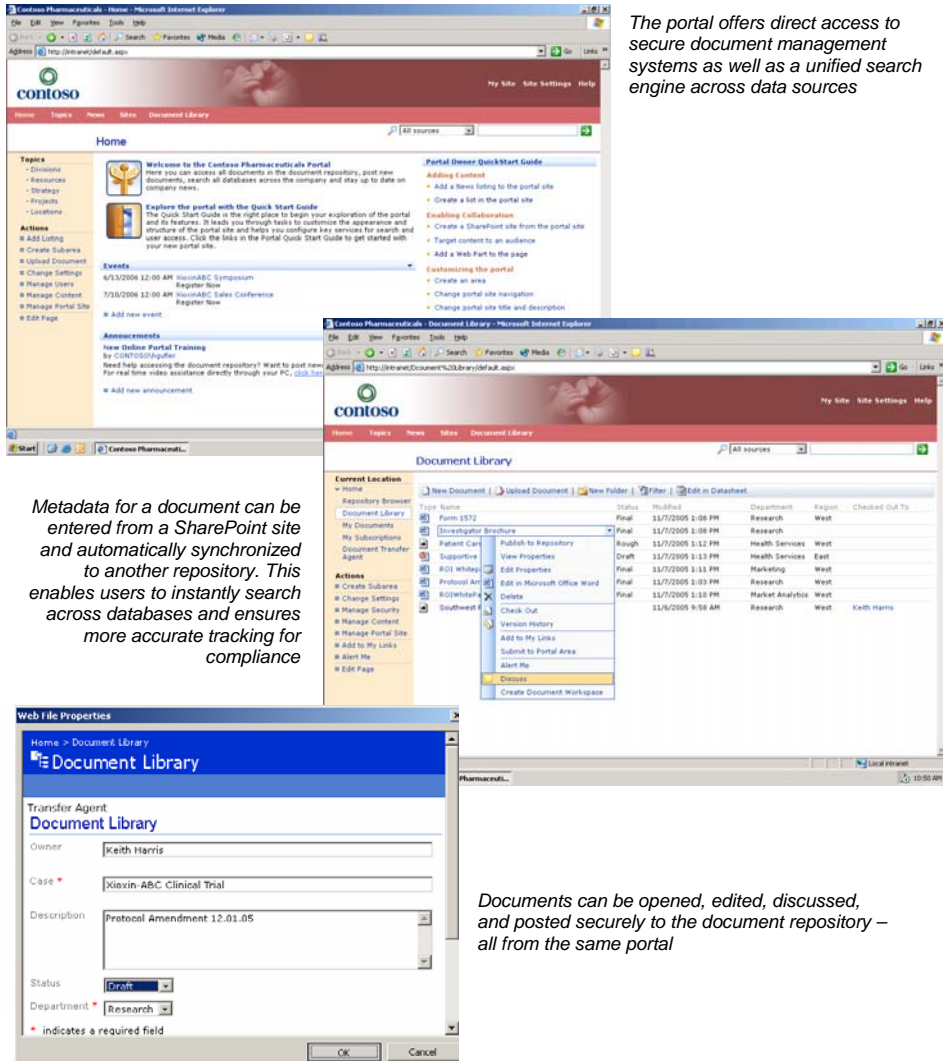
By integrating SharePoint Portal Server with compliant document repositories, companies can streamline document management processes while maintaining the tracking, auditing, and workflow controls necessary for compliance. This can dramatically streamline and simplify the document management process — and the speed-to-market of the products dependent on those processes. Specific benefits include:

#### A User-Friendly Portal Interface

- Provide even casual users with easy, personalized access to trusted content
- Support a wide range of views into data maintained in the document repository using customized Web Parts

#### Easier Access to Data Without Compromising Security

- Log on to a document repository directly through the SharePoint Portal
- Check content into document repository directly from the Portal
- Synchronize metadata automatically between data sources
- Check content out of the document repository through a SharePoint site without disrupting workflow controls or version tracking



The portal offers direct access to secure document management systems as well as a unified search engine across data sources

Metadata for a document can be entered from a SharePoint site and automatically synchronized to another repository. This enables users to instantly search across databases and ensures more accurate tracking for compliance

Documents can be opened, edited, discussed, and posted securely to the document repository – all from the same portal

- Users can find documents through an easy-to-use SharePoint search engine – even if the file is locked in another repository
- Increasing document workflow efficiency can lead to valuable gains in productivity and faster speed-to-market

**Next Steps**

To learn more about regulated document management solutions built using the Microsoft Office System visit:

[www.microsoft.com/office/showcase/rdm](http://www.microsoft.com/office/showcase/rdm)

**Solution Showcase for the Microsoft Office System**

A regulated document management solution is one of the many business scenarios available in the Solution Showcase for the Microsoft Office System.

The Solution Showcase highlights examples of how leading organizations can solve business problems using the Microsoft Office System. The Solution Showcase provides guidance so Microsoft customers can obtain more value from their investments in the Microsoft Office System, and provides a featured listing of Microsoft technology partners who can help customers design, build, and implement Microsoft Office-based solutions.

For more information about the Solution Showcase, please visit:

[www.microsoft.com/office/showcase](http://www.microsoft.com/office/showcase)

**More Efficient Collaboration**

- Microsoft SharePoint Portal Server supports workgroup collaboration, subscriptions, notifications, message boards, and other collaboration tools

**Powerful Unified Search Capabilities**

- Extend the SharePoint Products and Technologies search infrastructure to the document repository
- Provide users with a single global search interface to a variety of other information sources, including the Web, databases, and enterprise applications

- Search for materials directly from Microsoft Office Word 2003
- View content ranked for relevance as it relates to your enterprise content
- Set the system to periodically search for new and/or modified content

**Business Benefits**

- Users can collaborate on the initial stages of a document without being restricted by the workflow controls of the repository
- Documents can then be checked into the repository where they can be tracked and secured for compliance