

# 21 CFR PART 11 BASED DOCUMENT CONTROL SYSTEM

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## Introduction

In today's complex business environment every company faces regulatory and business mandates of increasing magnitude and frequency that come at an increasingly higher cost. As a result, enterprises need to adapt - moving from a compliance-only, departmental, or ad hoc approach to a more enterprise-wide approach. How companies face compliance, such as 21 CFR Parts 11/58, affects not only the risk of non-compliance - it affects their bottom lines.

Working with industry experts, Innovative Automation has developed a series of solutions to drive down the operational costs of compliance and reduce the risk of non-compliance. Innovative Automation's enterprise compliance solutions provide unprecedented visibility and control while enabling companies to more efficiently and effectively manage their requirements through controlled repositories, process automation, collaboration, communications, and archival and business integration capabilities.

Innovative Automation's DocMan™ Portal Server extends the capabilities of a traditional LIMS (Laboratory Information Management System) by offering scientists and knowledge workers a powerful new way to organize, find, and share regulated and controlled information. For QA (Quality Assurance) and RCV (Regulatory

Compliance and Validation) managers, DocMan Portal Server is a solution that delivers dramatic new value by combining the ability to easily create corporate or departmental web portals with document management, and enterprise content indexing features.

As pharmaceutical and biotechnology companies create and acquire product development and research information, scientists spend increasing amounts of time searching, organizing, and managing that information. DocMan Portal Server combines the ability to quickly create corporate or departmental Web portals with search functions, document management features, and collaboration options. DocMan Portal Server is tightly integrated with the tools that you use every day—Windows Explorer, Office applications such as MS-Word, MS-Excel, and MS Internet Explorer browser—to help you create, manage, and share content throughout your organization.

DocMan lets user transform their current non-compliant document repositories (SOP, Study/Protocol contracts, HR training records, MS Excel® spreadsheets, MS Word® documents and other business contents) into an automated, secure and audited environment, resulting in better compliance with government (21 CFR Part 11, GLP, GMP-compliance) and industry regulations (ISO standards) and good business practices. By automating the process of document creation, review, revision, approval, distribution and controlled access/sharing, DocMan helps companies bring products and services to market faster and with greater confidence.

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## Document Management, Control and Publishing

QA and RCV managers have long recognized that with increasing workloads, rapidly changing regulatory requirements, tighter timelines and fewer resources require an efficient document creation, distribution and control system. While it has never been easier to create, duplicate and post documents, it has also never been more difficult to control them. There is a significant difference between the terms "Document Management" and "Document Control" and understanding the clear distinction is critical when implementing a system to meet ISO 9000 and 21 CFR Part 11 requirements.



**Document Management:** In general, the steps of creating, editing, viewing, storing, distributing and archiving constitutes the process of document management. Recently, it has become a generic term to describe the process of converting a paper-based document by scanning to electronic formats.

**Document Control:** The term specifically refers to a set of guidelines required based on company and regulatory requirements that control the creation, modification and access of electronic documents, including maintaining the document's creation history, its distribution list and usage.

**Document Publishing:** The process of document posting and distribution to a controlled work group in a secure and an auditable environment is the key to accomplishing a successful deployment of a document management and control system.

DocMan Portal Server offers a number of features to help streamline document management, control and publishing needs such as:

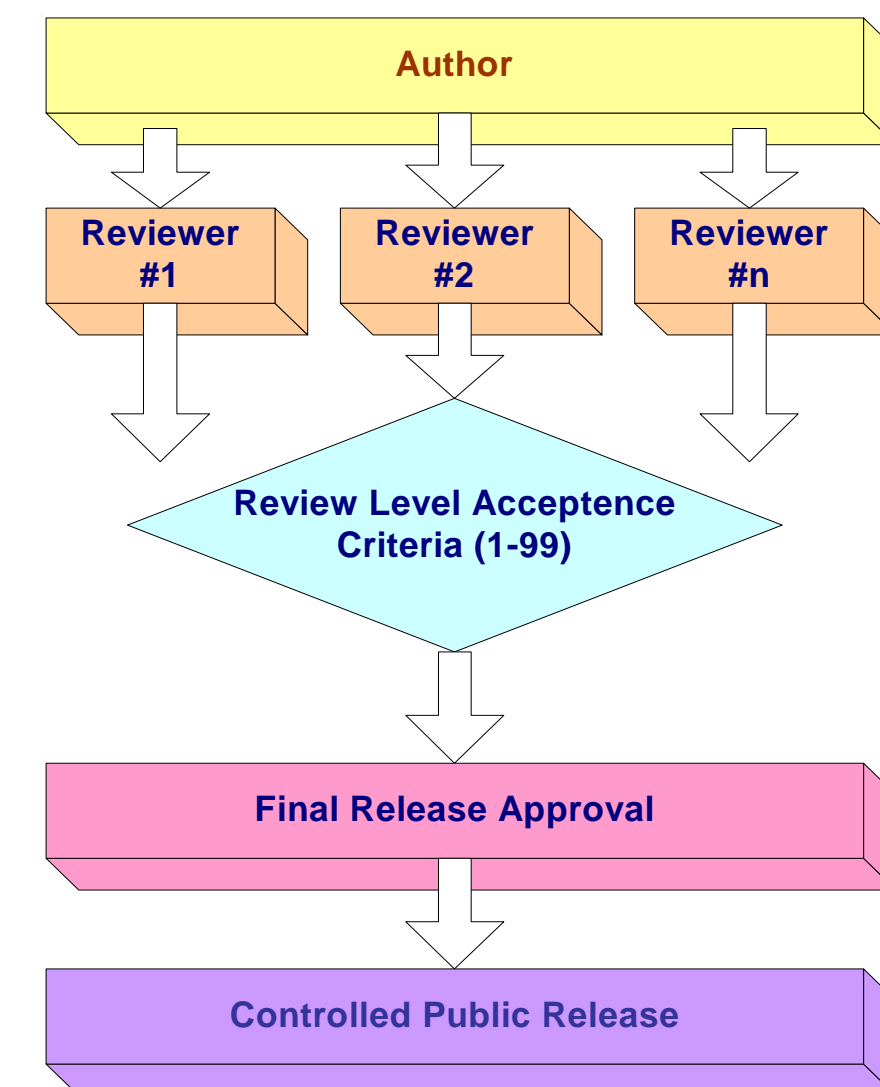
- Version tracking to record the history of documents.
- Application of descriptive, searchable information (metadata) to identify a document.
- Document publishing control.
- Automated approval routes for documents to be sent to reviewers.
- Web discussions for online comments by multiple document reviewers.
- Control of document access based on user roles.

**Version Control:** DocMan Portal Server records a document's history to help track changes and eliminate the possibility of someone overwriting another user's modifications. To edit a document, you must check it out first. This prevents others from changing it until you check it in. Every time you check in a document, DocMan assigns a new version number to the document and the previous version is archived. When you check out a document, you retrieve the most recent version unless you specifically select an earlier version.

**Document Profiles:** The document's profile provide a way to add searchable information pertaining to a document. This information, known as metadata, can help describe or identify the document. By default, a document profile includes basic properties such as Author and Title. You can easily add custom data to capture additional information that makes it easier to organize and find documents.

**Document Publishing:** DocMan Portal Server can store all versions of a document as it passes through the "document life cycle" – "Under Review", "Approved", "Released", "Archived", and "Checked Out". You can automatically release and publish a document each time you check it in or you can choose to check in private drafts and release and publish the document when it is complete. You can generate as many drafts as you want before publishing a version of a document. Only released and published documents are available for users to search or view on the DocBoard site.

**Document Approval:** All documents created and modified within DocMan system requires "Document Approval" prior to its final public release and publication. When an author is assigned to create a new or modify an existing document, a user definable number of reviewers can be assigned for review before publishing it. Each of these reviewers's has the option of approving or rejecting the document, upon receiving the minimum number of reviewer's input the document can be released by the final "approver".



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## DocBoard Site – A "Point & Click Portal in a Box"

DocMan creates a Web portal—known as the *DocBoard site*—automatically during document release and distribution. The DocBoard site offers a centralized access point for finding and managing information. By using a browser to view the DocMan site, users can perform document management tasks and find information. The DocBoard site allows users to:

- Browse through documents (information) by categories.
- Search for information.

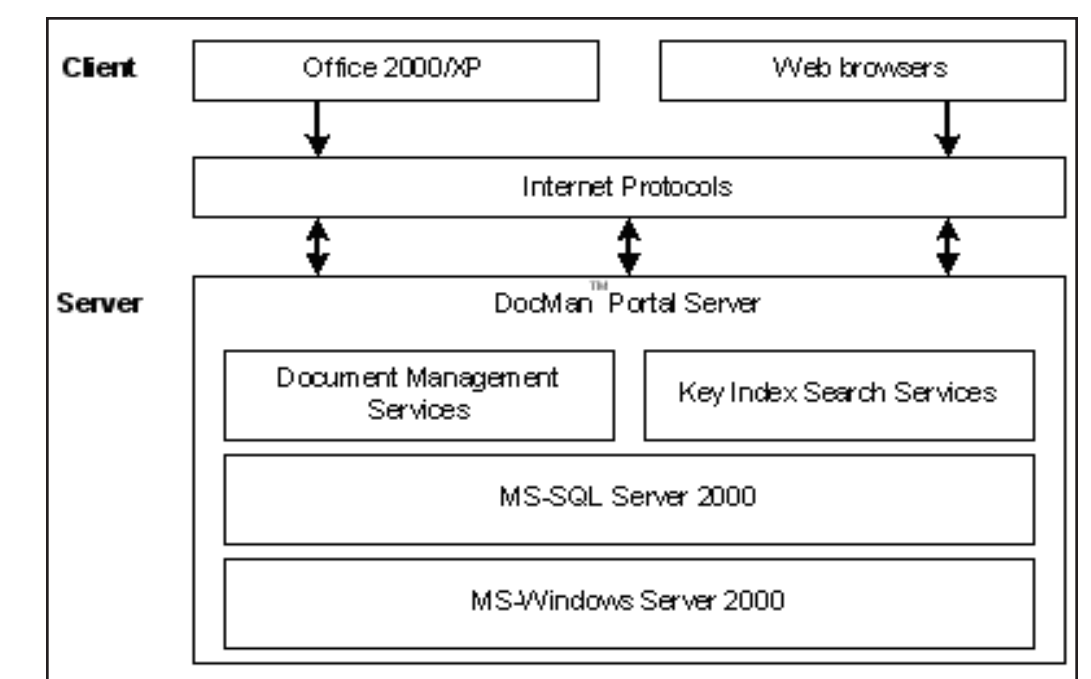
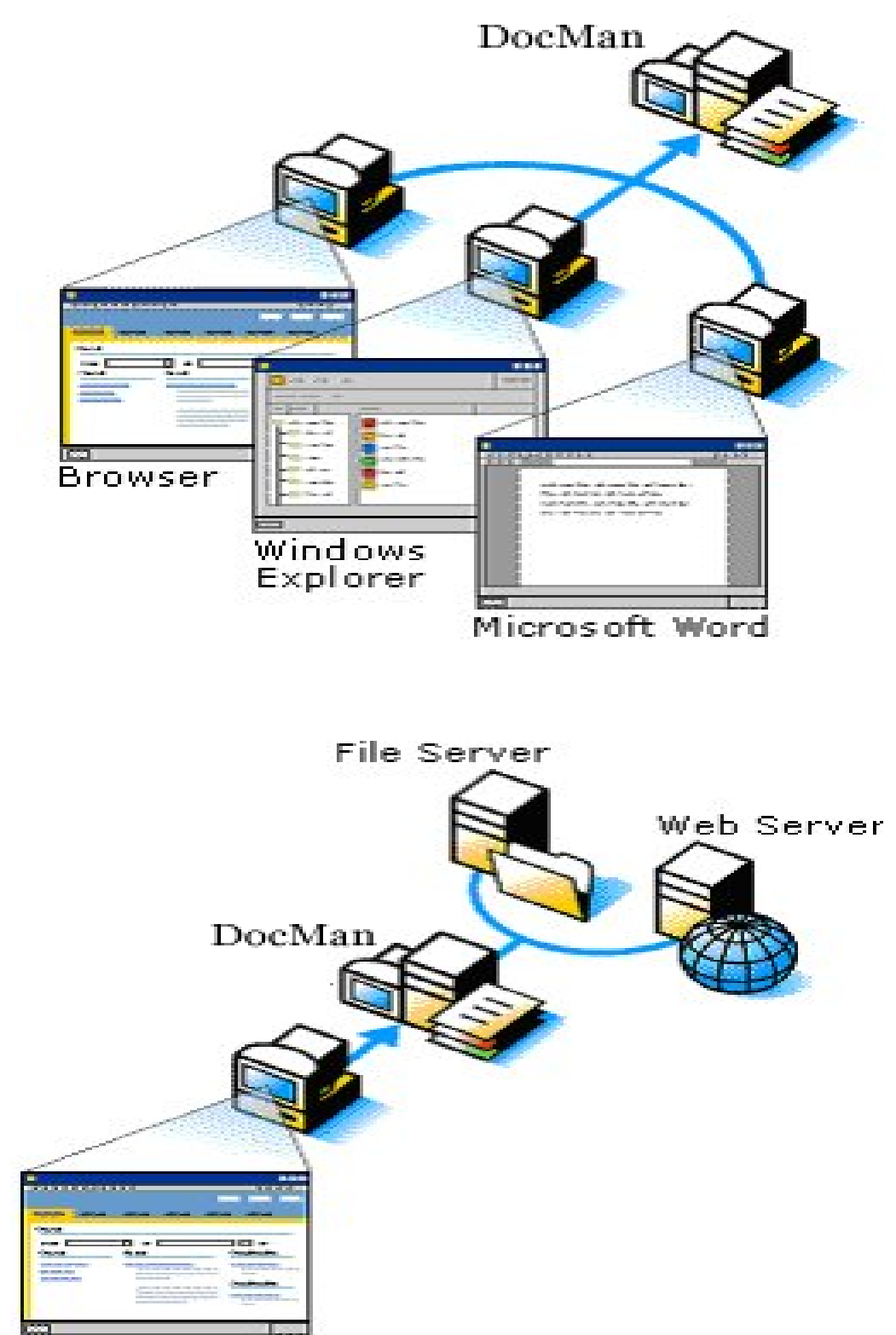
The DocBoard site can provide access to information stored both inside and outside your organization, allowing users to find and share documents regardless of location or format. In addition, you can customize the home page of the DocBoard site to display organizational news and other important information. The DocBoard site uses a familiar "tree" interface thereby allowing users to organize and display information by a simple point and click. A DocBoard site consists of reusable, customizable Java Bean that can present information from a wide variety of sources, such as Adobe's PDF documents, MS-Office documents Word, Excel, Visio, etc. and Web sites. You can add or remove DocBoard components to customize the DocBoard site for your company. In addition to providing a default, company-wide DocBoard site, you can easily customize "departmental" DocBoards to organize and present information that is especially relevant to each department, such as project- or workgroup-specific information – patient sample collection, clinical trial sample distribution to CRO, instrument analysis group, sample extraction, study and protocol based report compilation, etc.

**DocBoard Discussions:** Web discussions allow you to conduct online discussions about a document without modifying the document. Instead of using e-mail to discuss a document or trying to capture conversations about a document, authors, reviewers and approver can now communicate with each other through Web discussions. Simultaneous discussions about a document can occur even if one person has the document checked out. Comments are stored as threaded conversations, grouping comments and replies together. With all comments grouped into a single place, document authors no longer need to compile hand-written comments from reviewers or comments sent through individual e-mail messages.

**Role-based Security:** DocMan Portal Server uses *roles* to control access to content. You can assign the *coordinator*, *author*, *reviewer*, *releaser*, and *reader* roles to users based on the tasks they perform. Each role identifies a specific set of permissions: coordinators handle management tasks such as web discussions, authors add modify and update files, releasers have management responsibilities and release documents for public viewing and readers have read-only access to published documents. DocMan Portal Server also offers the option of denying a user access to specific documents.

**Product Architecture:** DocMan and DocSite Portal Server runs on Windows 2000/XP/2003 and integrates with and makes use of key Microsoft technologies, Office 2000/XP/2003, Microsoft Internet Explorer, the Microsoft SQL Server 2000 Web Storage System and Microsoft Search Service. The following figure represents an overview of the DocMan Portal Server product architecture.

The client components consist of extensions to MS Office applications and Windows Explorer. These components allow users to perform document management and search tasks within those applications. The DocBoard site, viewed through a browser, provides a Web-based view on the document management and search services the product provides.



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## Conclusion

DocMan Portal Server helps pharmaceutical and biotechnology companies achieve regulatory compliance and improve productivity at the same time. DocMan Server Portal and its web-based Docsite, using the DocBoard communication forum empower QA (Quality Assurance) and RCV (Regulatory Compliance and Validation) managers to meet the rapidly changing regulatory requirements with fewer resources and effectively share regulated information in a controlled environment.

For Windows and Office users, DocMan Portal Server is a rich server for knowledge workers to easily find, share, and publish information. DocMan Portal Server delivers dramatic new value as a single solution for corporate DocBoard sites, document management, content searching, and team collaboration.