






nextdocs



Regulatory Documents Module

The NextDocs Regulatory Documents Module includes:

-  **Ready-to-Use...**
 for managing all types of regulatory content including labeling documents, correspondence and forms
-  **Seamless Integration...**
 with the leading submission management systems
-  **Automated Workflows...**
 with lifecycle management from creation through review, effectivity and retirement
-  **Compliant...**
 Compliance with all GxP and 21 CFR Part 11 requirements
-  **Digital Signatures...**
 for role-based electronic sign-off

Manage the Complete Lifecycle of Regulatory and Submission Documents

The NextDocs Regulatory Documents Module provides a SharePoint-based, out-of-the-box solution to the challenge of collecting and managing the wide array of documents that comprise a regulatory submission.

The NextDocs Regulatory Documents Module is part of the NextDocs Document Management System, which includes a comprehensive set of features that addresses all GxP and 21 CFR Part 11 requirements.

Like all NextDocs solutions, it is "Built in SharePoint" and ready-to-deploy, which means faster deployment, higher adoption rates and dramatically lower costs than proprietary systems built on legacy platforms.

By providing template-based folder structures, the NextDocs Regulatory Documents Module enforces consistent folder structures and naming conventions. And with our optional Microsoft Word-based submission document templates, authors automatically create documents with consistent formatting and structure so that they are ready to integrate with your submission publishing solution.

The NextDocs Regulatory Documents Module provides a single, organized and compliant system for managing the entire range of regulatory and submission documents



ISV/Software Solutions



The NextDocs Difference: Compliance without Complexity

The **NextDocs Document Management Systems** are off-the-shelf applications that address all FDA 21 CFR Part 11 requirements. Built on the **NextDocs Compliance Platform**, they are 100% browser-based and completely integrated into the SharePoint framework.

SharePoint's familiar user interface and seamless integration with Microsoft Office applications provide a familiar environment for users. IT professionals enjoy the fact that NextDocs modular solutions install directly into their SharePoint environment, extending rather than replacing familiar system administration processes. The result is faster deployment, higher adoption rates and far lower costs than alternatives based on legacy platforms.

The NextDocs Compliance Platform

The NextDocs Document and Quality Management systems are built on the NextDocs Compliance Platform which addresses the entire range of 21 CFR Part 11 requirements.

- 🔗 **Lifecycle management** allows management of the document from inception to obsolescence
- 🔗 **Version tracking** with major and minor versioning, version history and previous version restoration
- 🔗 **Audit trails** provide a detailed log including every activity performed in the system
- 🔗 **Check In/Check Out** controls to prevent documents from being overwritten
- 🔗 Configurable **document numbering** allows flexible numbering schemes
- 🔗 Real time **Adobe PDF conversion** triggered by document state or workflow step
- 🔗 **Electronic/Digital signatures** that address all regulatory requirements
- 🔗 **Metadata tagging** that can drive folder placement and/or lifecycle decisions automatically
- 🔗 **Folder templates** that allow all or part of a folder structure to be saved as a template
- 🔗 Controlled document management including configurable application of **watermarks & overlays**

