

## The NextDocs Document Management System

SOP  
Management  
Module

Clinical  
Documents  
Module

Regulatory  
Documents  
Module



# The NextDocs Document Management System

## The NextDocs Document Management System includes three modules:

### Regulatory Documents Module:

- Template-based folder structures for consistent management of submission documents
- Optional Microsoft Word-based templates for a wide variety of submission documents
- Integration with leading Submission Publishing systems such as those from ISI, Lipient, Datafarm, Lorenz and Extedo

### SOP Management Module:

- Creating, approving and tracking Standard Operating Procedures (SOPs)
- Template-based authoring
- Pre-defined approval workflows
- Controlled printing with watermarks and overlays

### Clinical Documents Module:

- Management of essential Study Documents including Investigator Brochures, Study Protocols, Investigator CVs and Case Report Forms
- Collaboration between the sponsor and external parties in a clinical trial including investigators, monitors, IRBs, etc.

## Comprehensive Document Management Capabilities in a SharePoint-based Environment

The NextDocs Document Management System delivers everything you expect in a regulatory compliant enterprise content management solution, all in a SharePoint environment.

The NextDocs Document Management System is built on the NextDocs Compliance Platform, which provides an integrated and extended set of features to address 21 CFR Part 11 and similar regulatory requirements. And since it leverages Microsoft SharePoint's familiar user interface and seamless integration with Microsoft Office applications, user adoption is far easier and faster than with traditional proprietary document management systems.

With modules for Regulatory Documents, Clinical Documents and SOPs, the system provides out-of-the-box solutions to the most typical requirements of life sciences companies. In addition, the NextDocs solution fits readily into an existing SharePoint infrastructure. The result is less configuration effort, faster deployment and reduced IT infrastructure costs.

**The NextDocs Document Management System includes everything required for compliant document management ... all in a SharePoint-based environment**



## The NextDocs Difference: Compliance without Complexity

The **NextDocs Document and Quality 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.

### NextDocs Document Management System

- ⤵ **Regulatory and R&D Module**
  - Submission Content Management
  - Folder and Document Templates
  - eCTD Integration
- ⤵ **SOP Management Module**
  - SOP Creation, Review and Approval
  - Employee Training Records
  - SOP Change Control
- ⤵ **Clinical Documents Module**
  - Trial Master File
  - Site Visit Reports
  - Vendor Collaboration

### NextDocs Quality Management System

- Out-of-the-Box applications for...**
- Quality Process Management
  - Corrective & Preventative Actions (CAPA)
  - Deviation Control
  - Audit Preparation and Management
  - Equipment Schedule and Documentation
  - Complaint Resolution Tracking
  - Pharmacovigilance and Drug Safety
  - And More

### nextdocs Compliance Platform

- Digital/Electronic Signatures
- Visual Workflows
- Advanced Versioning
- Audit Trails
- Controlled Printing
- Document Numbering
- Watermarks and Overlays
- PDF Renditions
- Document Lifecycle

Content Management & Collaboration (Microsoft Office SharePoint Server 2007)

## 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 restoral
- ⤵ **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**

