

# Regulatory Document Management



# Complete Life cycle Management of Regulatory and Submission Documents in a Single, Organized, and Compliant System

Creating and managing regulatory submissions becomes more challenging every year. The size of US NDAs continues to expand, with some containing in excess of 500,000 pages of documents and data. Then there is the sheer volume of submissions – managing all of the amendments, supplements and variations needed to maintain and expand the product portfolio across regions and countries. Ever-tightening submission time frames amplify the cost of mistakes and rework. On the back end, documents intended for electronic submissions must be authored to a higher standard.

According to a 2010 FDA CTD/eCTD Quality reviewer survey, only about half of sponsors do a good or excellent job in organizing documents according to CTD.

## The NextDocs Solution

NextDocs' pre configured solution for managing submission documentation addresses these key challenges to deliver a compliant, user-friendly solution while minimizing the demands on your already overtaxed business and IT users.

### A FAMILIAR INTERFACE

Because NextDocs is built within SharePoint, a technology that many business users already use, training and ramp-up time are reduced. Most companies already have the ability to support and administer SharePoint – unlike highly specialized document management technologies where several administrators must sometimes be hired just to support a single application.

### BUILT FOR SUBMISSIONS

ICH and regional authorities have published many specifications and guidance documents specifying the contents of various regulatory submissions. You could study all the documents and define your own document classifications and metadata – or you could take advantage of the EDM Reference Model already configured into NextDocs. The EDM Reference Model is a taxonomy/metadata reference model developed by an industry working group that incorporates best practices and lessons learned across the industry, and maps extensively to regulatory requirements.

### AUTOMATED PRODUCTION OF SUBMISSION READY DOCUMENTS

NextDocs guides users through the production of submission ready documents by enforcing the use of CTD/eCTD required granularity, requiring templates, producing PDF renditions that meet the myriad of agency requirements, and collecting 21 CFR Part 11 compliant electronic signatures.

### SCALABLE FOR THE REGULATORY ENTERPRISE

SharePoint has the proven ability to manage millions of documents over local and wide area networks, providing users with the performance they expect. By using SharePoint, you eliminate the need to implement complicated IT solutions if you expand to a new region or office.

## Key Features and Benefits

### All the benefits of traditional document management system plus more:

- » Support for and enforcement of your business processes
- » Organization of documentation to facilitate creation of CTDs, eCTDs, and other submission types
- » Decreased time to review and approve documents
- » Significantly decreased handling of paper
- » 21 CFR Part 11 compliance
- » Streamlined validation, assisted by our validation toolkit
- » Streamlined deployment and increased user acceptance due to our familiar user interface
- » Decreased cost of ownership and accelerated return on investment

## CONFIGURED TO YOUR NEEDS

In recent years, the life sciences industry has learned through experience about the high cost of ownership associated with custom solutions. Although NextDocs starts with an industry proven configuration, we understand that you may have sound business reasons to expand the inventory of documents managed, implement variants on our standard review and approval processes, or track special properties that provide valuable information to system users. In short, the software should support your business processes, not the other way around. Almost all user requests can be accommodated by simple system configurations, without requiring custom software development.

### Sample View: NextDocs Regulatory Document Management System

Type	Name	Submission Name	Lifecycle Status	Modified
<b>Drug Product : NC289 (2)</b>				
	Submission Document Checklist for NC289 - CMC Supplement	NC289 - CMC Supplement Oct2010	Draft	11/3/2010
	Submission Document Checklist for NC289 - Annual Report	NC289 - IND Annual Report	Draft	7/30/2010

## Regulatory Solution Components

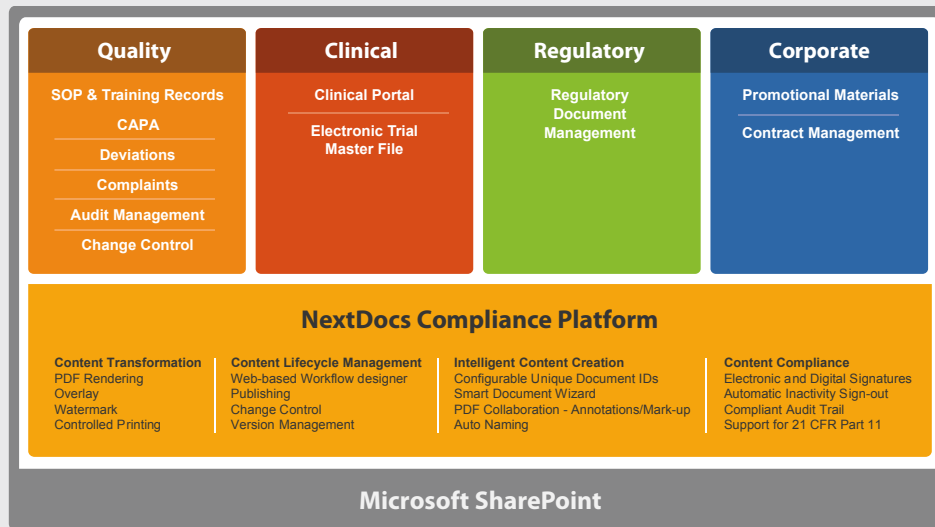
When you purchase the NextDocs Regulatory Document Management solution, you start with a product that is fully configured for use in managing submission documents, and which could be validated and deployed by doing nothing more than adding specific information about your products, studies, etc. to pre-existing lists, importing your templates, and adding your users to appropriate roles.

### STANDARD SOLUTION COMPONENTS

- » Complete inventory of Non clinical, Clinical, Quality and Regulatory/Administrative documents, built on EDM Reference Model specifications.
- » Predefined lists that limit valid values for document properties to values that you supply
- » Creating of documents from your templates or by import from the file system
- » Best practice life cycle for review, approval, finalization, and revision
- » Smart Document Wizard that minimizes user metadata entry by auto-populating document properties and filing in a standard folder structure
- » Comprehensive life cycle including review and approval work flows
- » Role-based security
- » Optional digital signature
- » Audit trail
- » Ability to archive a published eCTD
- » 21 CFR Part 11 Compliance

# NEXTDOCS COMPLIANCE PLATFORM

The NextDocs Compliance Platform includes a comprehensive set of features that addresses all ICH, FDA, EMEA, and MHLW regulatory requirements. It is built in and fully integrated with the Microsoft SharePoint Server framework.



- Real-time Adobe PDF conversion triggered by document state change or workflow step
- Controlled document management including configurable application of watermarks & overlays
- Full life cycle management of the document from inception to obsolescence
- Flexible and powerful process automation tools for change requests, document review, and approval
- Check in/Check out controls to prevent documents from being overwritten
- Version tracking with major and minor versioning, version history and previous version restoration
- Configurable document numbering
- Auto population of document properties
- Electronic/digital signatures that address all regulatory requirements
- Audit trails that provide a detailed log of every activity performed in the system



NextDocs is the global leader in providing Microsoft SharePoint-based compliance solutions to life sciences organizations. It enables businesses in regulated industries to achieve compliance with FDA and other agencies while automating processes, improving efficiency and dramatically reducing costs. NextDocs provides solutions for managing regulatory documents, SOPs, clinical documents as well as a full set of quality processes from CAPA to complaints. NextDocs customers include pharmaceutical companies, biotech firms, device manufacturers and contract research organizations.

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