

SOP and Employee Training



Simple, Effective and Compliant SOP and Employee Training Management through the Entire Lifecycle

“Failure to follow established SOPs is one of the most frequently cited violations in FDA 483s and warning letters. The frequency of SOP-related violations points to the need for all regulated companies to review their SOPs, their methods for distributing compliant SOP training curricula, their methods of validating receipt and testing for comprehension of the materials, and their documentation of SOP training activities. Additionally, enterprise-wide training programs must include automated methods for new employee on boarding, and for annual refresher training. “

BioPharm International

Global Quality Assurance and Regulatory Compliance
by Denise Queffelec and David Peterson

The NextDocs Solution

Our pre configured solution for managing procedural 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 upon 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-IN COMPLIANCE

For SOPs and related documents, the ability to comply with 21 CFR Part 11 is necessary in order to use electronic documents in place of paper documents. Part 11 also applies to electronic systems that generate, track and recall official paper copies.

NextDocs supports both GxP and Part 11 compliance through the use of built-in and configurable business processes providing compliant procedures for review, approval, signature, effectivity, period review, change requests, and user training and training records.

SCALABLE FOR THE 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

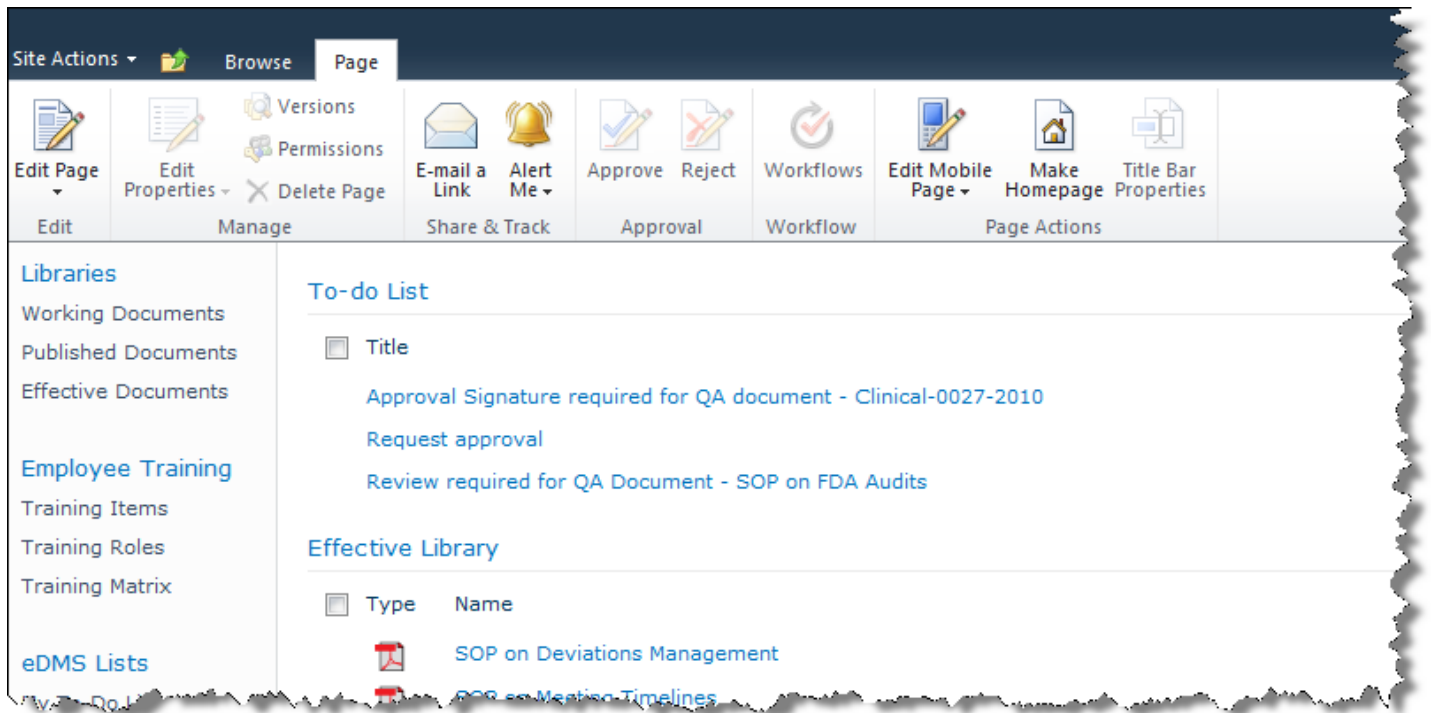
All the benefits of traditional document management system plus more:

- » Support for and enforcement of your business processes
- » 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
- » Ability to provide user interface in the local language
- » 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 SOP and Employee Training Management System



SOP Solution Components

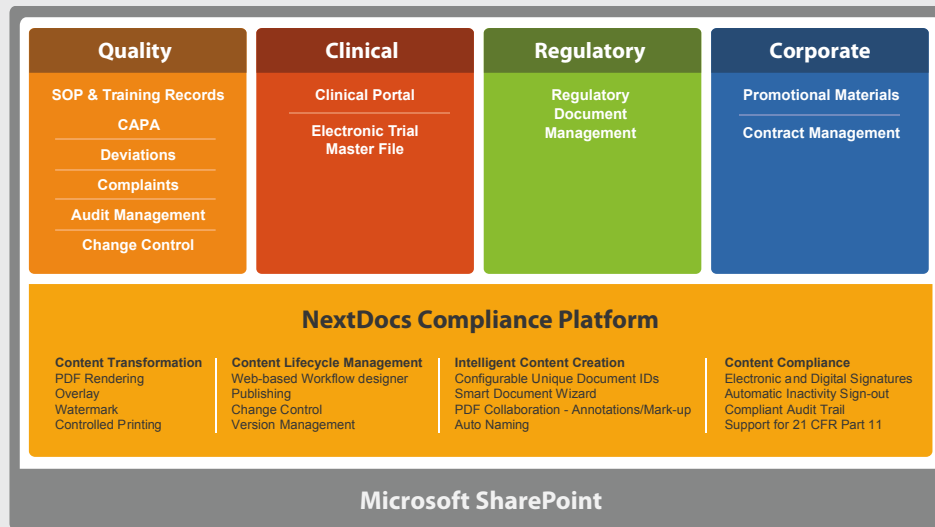
When you purchase the NextDocs Procedural Document Management solution, you start with a product that is fully configured for use in managing SOPs, and which could be validated and deployed by doing nothing more than adding specific information about your products, departments, etc. to pre-existing lists,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

STANDARD SOLUTION COMPONENTS

- » Preconfigured SOPs, Policies, Forms, Work Instructions, Attachments, and Change Requests
- » 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 lifecycle for review, approval, finalization, and revision with appropriate change requests
- » Review and approval workflows
- » Automatic or manual release for training and effectivity
- » Change Request forms and processes designed to your requirements
- » Role-based security
- » Periodic review process
- » Watermarks and overlays
- » Controlled, uncontrolled and clean copy printing

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 lifecycle 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.

Main Headquarters
 500 N. Gulph Road
 Suite 240
 King of Prussia, PA 19406
 Tel: 610.265.9474

EU Headquarters
 Elisabethstrasse 91,
 80797 Munich
 Germany
 Tel: +49.89.5908.1435

For more information visit www.nextdocs.com

