

Quality Management System



A Collaborative Quality Management Platform that Provides Transparency and Insight Across the Enterprise

In recent years, the ICH, FDA and other regulatory authorities have re-established their positions on quality management systems to stress the importance of product quality monitoring, corrective and preventative action (CAPA), change control, and management review of quality performance.

Many companies are poorly equipped to meet these challenges due to a lack of truly closed-loop process models and an inability to collaborate and pass information between and among the full set of stakeholders including corporate management, quality assurance, and employees responsible for any quality-related job function.

A Recent FDA presentation on Inspections and Findings states that 29% of 483s and 84% of Warning Letters contain references to CAPA Deficiencies

The NextDocs Solution

Our pre configured solutions for managing deviations, complains, audit findings, change control and CAPA addresses these key challenges to deliver a compliant, user-friendly solution while minimizing the demands on your already overtaxed business and IT Users.

- **SOPs:** An integrated solution that connects the entire SOP lifecycle from creation through distribution and beyond.
- **CAPA:** A comprehensive solution for managing Corrective and Preventative Actions used in continuous improvement in quality and processes.
- **Deviations:** A fully configurable and automated solution to manage Deviations and OOS from occurrence to investigation and closure.
- **Complaints:** A full featured solution to manage recording, routing, and resolution of all customer complaints.
- **Audit:** Provides complete tracking of observations, findings, and recommendations.
- **Change Control:** A solution for controlling changes or modifications to products and processes together with the management of associated tasks.

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.

Key Features and Benefits

All the benefits of a traditional document management system and 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

A CLOSED LOOP SYSTEM

Many audit and inspection findings are related to deviations, complaints and CAPAs not being tracked to closure. NextDocs offers form-based workflows that respond dynamically to decision factors such as the need for specific investigations, escalations, or approvals. Processes are automatically tracked to closure.

Tight integration with email ensures that users are alerted to assigned, due and overdue tasks in the system they use all day – email.

In addition, NextDocs views provide transparency and insight by highlighting incomplete or overdue processes and exposing overall trends.

A COLLABORATIVE PROCESS

Quality issue investigation and resolution normally rely upon collaboration. Because NextDocs is built on SharePoint, the industry-leading collaboration platform, all of the tools needed for true collaboration are available out of the box.

BUILT-IN COMPLIANCE

NextDocs supports GxP and Part 11 compliance through the use of built-in and configurable business processes for electronic review, approval and closure. Electronic signatures are required at any stages of the process that you specify.

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.

The NextDocs Quality Management System is one of our four platforms that provide Life Science companies with best-of-breed solutions in document and quality management

Quality

SOP & Training Records

CAPA

Deviations

Complaints

Audit management

Change Control

NextDocs Solutions

Quality

Clinical

Regulatory

Corporate

NextDocs Compliance Platform

Microsoft SharePoint

Quality Management Solution Components

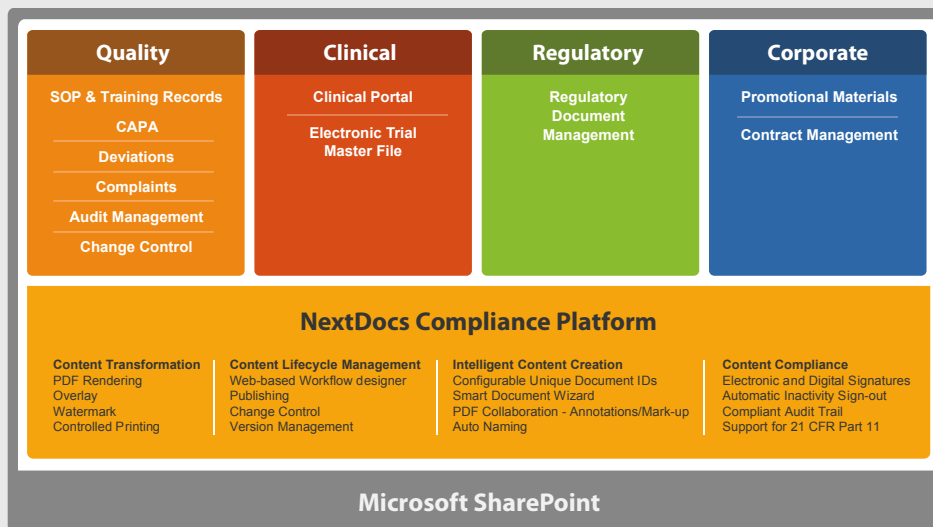
When you purchase a NextDocs Quality Management System solution, you start with a product that is fully configured for use in managing QMS processes, and which could be validated and deployed by doing nothing more than adding specific information about your products, departments, etc. to pre-existing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

STANDARD SOLUTION COMPONENTS

- » Preconfigured QMS Processes for one or more of the following:
- » Predefined lists that limit valid values for document properties to values that you supply
- » Forms to gather the data required in your QMS processes
- » Dynamic review and approval workflows that dynamically adjust processes as content is added to forms
- » Views for tracking overall process status
- » Role-based security
- » Electronic signature
- » Audit trail
- » 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 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.

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