

The Next Generation of Quality Management Software

NextDocs **Quality Management software** is the leading enterprise solution based on Microsoft SharePoint 2007. Our products are purpose-built for businesses in highly regulated environments.

NextDocs Quality Management software extends the Microsoft SharePoint platform. Our software products are cost effective, intuitive, flexible and scalable.

CORE QUALITY MANAGEMENT COMPONENTS

- 🔗 **Audit Management (AM)** • Designed for external and internal audits AM includes four content types: Audit Plan, Audit Checklist, Audit Notebook and Audit Report. AM feeds into Deviation Processing and thereby offers a self-healing solution for nonconformance and observations.
- 🔗 **Deviation Processing** • Designed for Nonconformance and for Observation registration. Once registered, the deviations feed the CAPA process.
- 🔗 **Full CAPA Capabilities** • Built for Corrective and Preventive Actions starting with deviation registration through root cause analysis and proposed corrective and preventive actions, to effectiveness measurement and ensured root cause elimination.
- 🔗 **Trending Report Capabilities** • Trending Reports, one of the most successful means of deviation detection, allow escalation as the trends develop, which facilitates timely correction.
- 🔗 **Customer Complaint (CC)/Severe Adverse Event Management (SAE)** • Includes MedWatch-reporting details and trending reports. CC and SAE fully integrate with Deviation Processing, CAPA and Change Control.
- 🔗 **Equipment Management (EM)** • Includes calibration, maintenance and verification tracking; certificate and contract monitoring. EM tracks the due date for all maintenance activities and reduces the risk of deviations by assuring equipment is maintained and is integrated with Deviation Processing, CAPA and Change Control.
- 🔗 **Change Control** • Designed to manage change for any feature or component and provides a formal, structured process to ensure stability, safety and continuity of quality.

The NextDocs Advantage

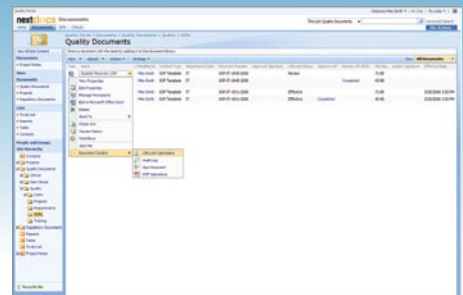
NextDocs enables businesses in regulated industries to comply with FDA and ISO regulations and ever-evolving standards—while at the same time automating processes, improving efficiency and dramatically reducing costs.

NextDocs was first to market and has the most SharePoint installs in regulated environments. Our hands-on expertise gives you the peace of mind that an experienced team is helping you manage your mission-critical document management applications.

NextDocs solutions are off-the-shelf applications built on our revolutionary document and quality management products.

NextDocs Life Sciences Solutions

- 🔗 Regulatory Document Management
- 🔗 Marketing Management
- 🔗 Clinical Trials Document Management
- 🔗 Project Document Management



NextDocs Document Management software is powered by Microsoft SharePoint and seamlessly integrates with MS Office applications. That means **NextDocs** is easy to learn, easy to use—and is significantly less expensive than outdated legacy document management systems.

NextDocs Core Product Features

Lifecycle Processes simplify document creation and allow you to manage the document from inception to obsolescence. Lifecycle Template Wizard provides an easy point-and-click method of lifecycle design.

Workflow Designer features drag-and-drop workflow creation to streamline processes such as review and approval.

Document Versioning automates tracking document changes. It provides major and minor versioning, version history and previous version restoration.

Document Audit provides a detailed log of data that is saved for every activity performed in the system. Auditing is available at all levels and provides full document, system or user history.

Check In/Check Out protects documents from being overwritten.

Intelligent Document Numbering applies a unique number to the document. The number is defined in a template and associated to the category of documents that it defines. Intelligent Document Numbers can contain metadata values, dates and/or predefined static values.

Real-Time Adobe PDF Conversion converts documents to Adobe PDF with just two clicks.

Electronic/Digital Signatures are applied directly onto the document, are as unique as fingerprints, ensure authenticity, save time, protect documents and satisfy regulatory requirements. NextDocs offers direct document signing as well as signature workflow processing. Workflows allow a group of users to review and sign documents quickly and efficiently.

Metadata Tagging tags documents within a folder or within a folder structure. The user determines the metadata and assigns a value. Tagging metadata will drive document and/or lifecycle decisions automatically.

Save Folder Template allows the user to save all or part of a folder structure as a template and determine which folder characteristics to save. Once it is saved, the template can be deployed to create new structures with the chosen characteristics.

Watermark & Overlay add layers to your document through the lifecycle template. They can be used to classify or provide security.

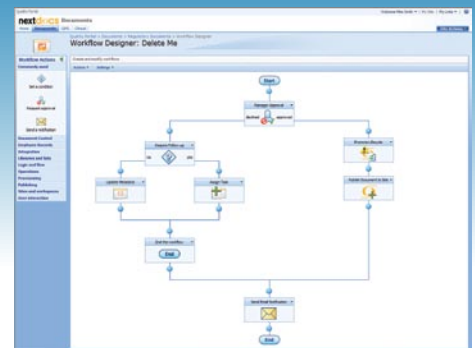
PDF Permissions provides security to Adobe PDF documents by allowing the assignment of passwords for document access or for document printing. It also provides the option to apply an "Uncontrolled Document" watermark to printed documents.



The winning combination of NextDocs and SharePoint allows full electronic document lifecycle management, from creation and approval to publishing and archiving, at less than 50 percent of the cost of proprietary systems.

NextDocs Product Suite

- Document Management Software
- NextDocs Quality Management Software
- NextDocs SOP & Employee Records Software



NextDocs Quality Management software processes are a combination of workflows and lifecycles that are easily tailored to suit any business needs.

The **Workflow Designer** enables users to drag-and-drop workflows to streamline important processes (such as reviews and approvals), providing a flexible, configurable solution without the need for expensive custom programming.