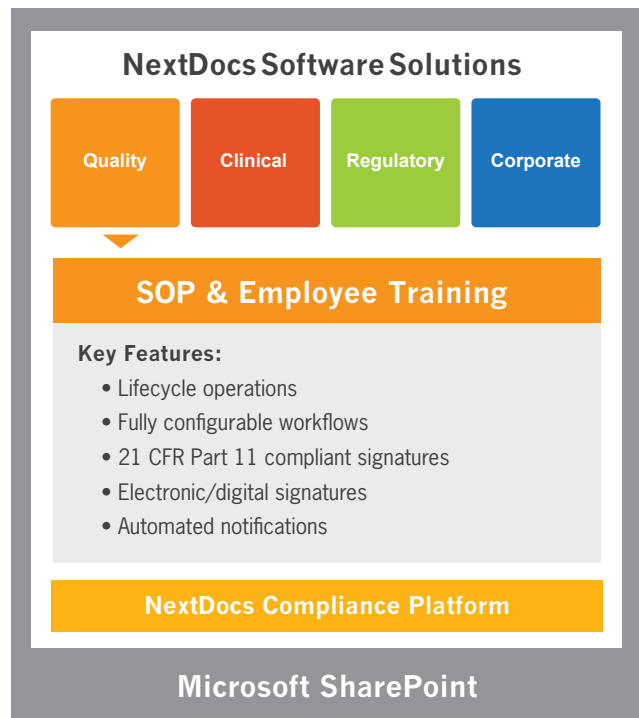# NextDocs
SOP and Employee Training Management

Integrated Solution that Logically Connects the Entire SOP Lifecycle from Creation through Distribution and Beyond

The NextDocs SOP Management solution provides a complete solution for managing Standard Operating Procedures and related processes in a SharePoint-based system. With the ability to track related change control documents and maintain associated employee training records, it is a complete, out-of-the-box SOP management system.

The NextDocs SOP Management solution is part of the NextDocs Document Management System, which includes a comprehensive set of features that addresses all ICH, FDA, EMEA, and MHLW regulatory requirements.

The Employee Training solution allows the ability to create quizzes or questions and to then link them to any SOP stored in SharePoint for evaluation. Scoring thresholds as well as pass/fail standards can be set up to measure employee progress. Test results can then automatically update an employee's training record.

NextDocs Software Solutions

Quality	Clinical	Regulatory	Corporate

SOP & Employee Training

Key Features:
- Lifecycle operations
- Fully configurable workflows
- 21 CFR Part 11 compliant signatures
- Electronic/digital signatures
- Automated notifications

NextDocs Compliance Platform

Microsoft SharePoint

Key Benefits

✓ Decrease cycle time and the associated costs by increasing efficiencies

✓ Track and identify document stage in life cycle and route it to

✓ Version history recognizes changes between versions and ensures that the latest version is in use

✓ Automate the drafting, reviewing, approving, assigning to training, and promotion to an effective SOP

✓ Automate creating PDF annotations, watermarking, and print control features

✓ Support for Electronic and Digital Signatures and for role-based electronic sign-off

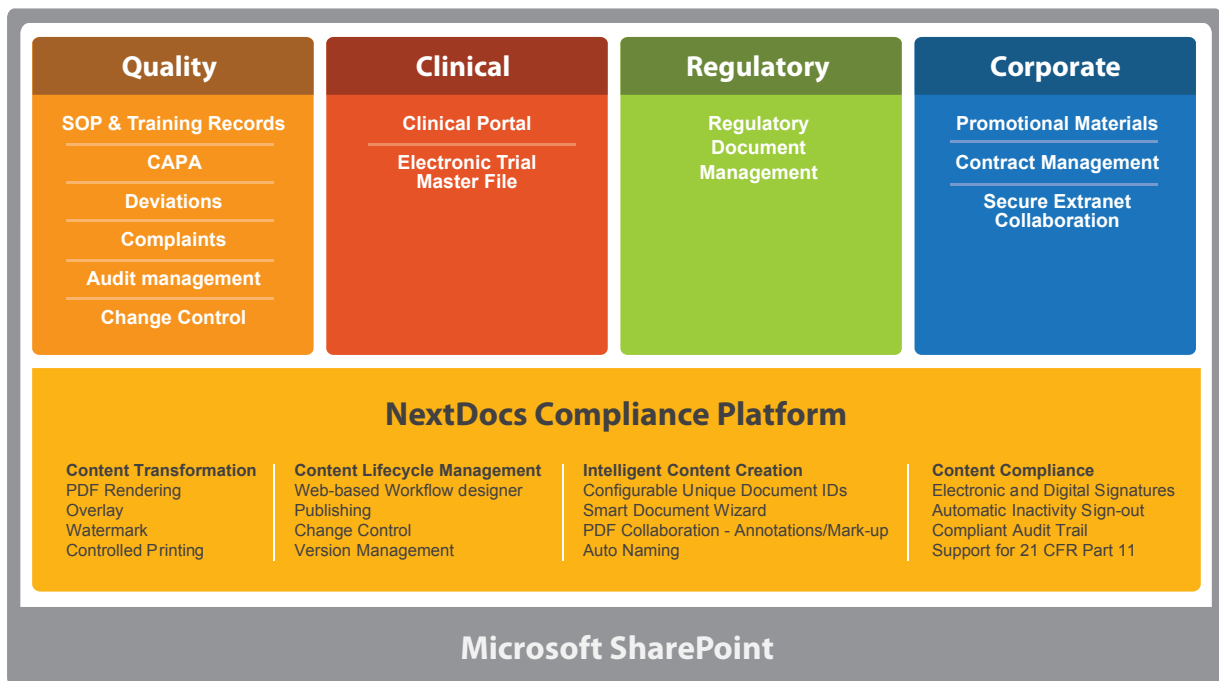Microsoft® Office SharePoint® Server 2007

Microsoft® SharePoint® 2010

Microsoft GOLD CERTIFIED *Partner* | ISV/Software Solutions

Microsoft® LifeSciences **Partner of the Year**

ISO9001:2008 KEMA CERTIFIED

nextdocs

Compliance without Complexity

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.

SharePoint's familiar user interface and seamless integration with Microsoft Office applications provide an easy-to-use environment for users. NextDocs software solutions install directly into the Microsoft SharePoint environment, extending rather than replacing familiar document management processes. The result is faster deployment, higher adoption rates and far lower costs than alternatives based on legacy platforms.

Quality

SOP & Training Records

CAPA

Deviations

Complaints

Audit management

Change Control

Clinical

Clinical Portal

Electronic Trial Master File

Regulatory

Regulatory Document Management

Corporate

Promotional Materials

Contract Management

Secure Extranet Collaboration

NextDocs Compliance Platform

Content Transformation
PDF Rendering
Overlay
Watermark
Controlled Printing

Content Lifecycle Management
Web-based Workflow designer
Publishing
Change Control
Version Management

Intelligent Content Creation
Configurable Unique Document IDs
Smart Document Wizard
PDF Collaboration - Annotations/Mark-up
Auto Naming

Content Compliance
Electronic and Digital Signatures
Automatic Inactivity Sign-out
Compliant Audit Trail
Support for 21 CFR Part 11

Microsoft SharePoint

- 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 management, 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
- Metadata tagging automatically sets document properties
- Folder templates that allow all or part of a folder structure to be replaced
- Electronic/digital signatures that address all regulatory requirements
- Audit trails that provide a detailed log of every activity performed in the system

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