

NextDocs

Corrective and Preventative Actions Management

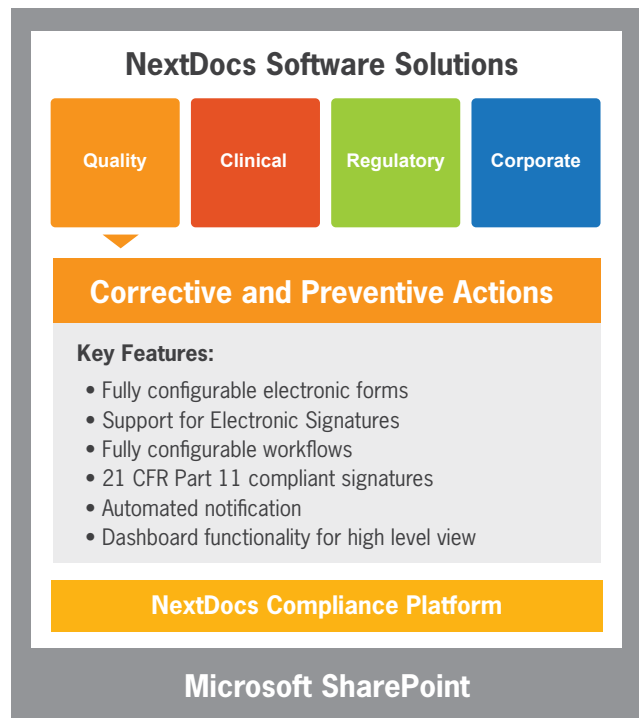
Comprehensive Solution for Deviations and Nonconformance for Continuous Improvement in Quality and Processes

The NextDocs Corrective and Preventative Actions (CAPA) solution is a comprehensive, Microsoft SharePoint-based solution that connects issues, investigators, and resolutions in a closed-loop module.

Any incident can be quickly and easily captured, assigned to an investigator, and tracked through resolution. The result is faster resolutions, better information and more effective preventative actions.

The NextDocs CAPA solution includes electronic signatures, defined workflows, a complete audit trail and a range of other features to address regulatory requirements. It can be seamlessly integrated with other NextDocs quality solutions, allowing all types of incidents to automatically trigger a CAPA.

It can also be implemented in a pre-configured manner or can be fully configured to achieve compatibility with current processes.



Key Benefits

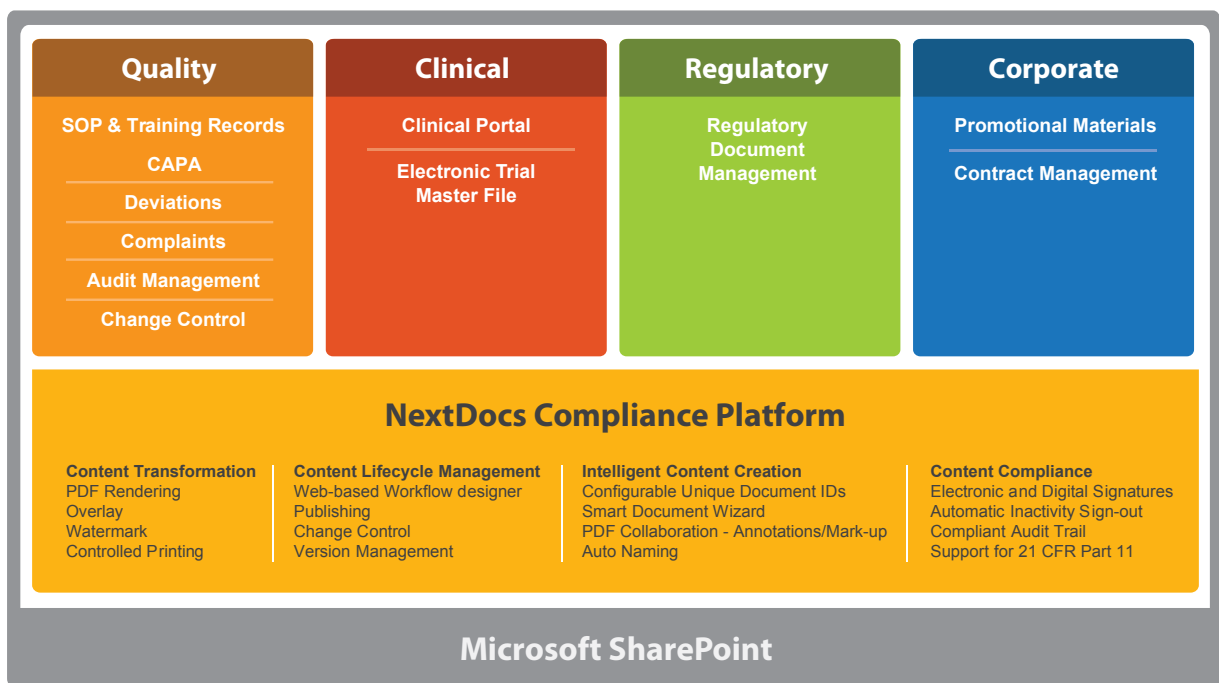
- ✓ Track incidents and causes of Corrective and Preventative Actions
- ✓ Decrease cycle time and the associated costs by increasing efficiencies
- ✓ Utilize previous data entered into an incident form into your CAPA forms thus minimizing transcription errors and wasteful manual tasks
- ✓ Fully configurable allowing for compatibility with current processes
- ✓ Lowers risk of compliance issues and lost data
- ✓ Automates the management of the entire CAPA lifecycle, from draft to closure

The NextDocs Difference

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.



- 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

