

NextDocs Implementation Services

NextDocs is a SharePoint-Based Compliance Platform

The NextDocs Product Suite provides a SharePoint-based document management platform for life sciences companies operating in regulated environments. It is an easy to use, web-based enterprise software solution that enables organizations to comply with FDA 21 CFR 11, GMP, GLP, GCP, and other regulations and industry standards. The NextDocs Product Suite includes the following applications:

- Document Management
- Quality Management
- Compliance Management
- Marketing Management

Built on the industry-leading Microsoft Office SharePoint Server 2007 platform, NextDocs delivers unmatched ease of use and product functionality.

NextDocs products require zero desktop installation, enabling rapid corporate deployment and providing organizations with immediate ROI.

Glemser has built an out-of-the-box set of implementation services to accelerate NextDocs deployments

Glemser Implementation Services for NextDocs

Glemser Technologies, a Microsoft and NextDocs partner, has over twenty years of proven experience providing document management implementation, migration and validation services to leading life sciences community.

Glemser's NextDocs implementations include execution of a complete, seven-phase systems development lifecycle from requirements through deployment, resulting in a validated, ready-to-use system.

Our implementation services are tailored to address the specific validation requirements for systems in FDA-regulated environments.

Specific Glemser services for NextDocs include:

- NextDocs and SharePoint "Fit and Readiness" Analysis
- Proof Of Concept (POC) Projects
- Comprehensive NextDocs Implementation and Validation



NextDocs Document Management

- Document life cycle management provides consistency and control over document creation and management
- Versioning provides support for major and minor versions with associated metadata
- Flexible security to easily manage access to documents and all associated functions
- Templates allow easy access to common document types eliminating errors and redundant effort
- Automated workflows provide the ability to control document life cycle from creation to archival
- Universal digital signatures provide visible embedded signatures that protect the authenticity of documents and signatures. Word, PDF, Excel and other common file formats are supported
- Support for FDA 21 CFR Part 11

NextDocs Compliance Management

- Ability to track data in tabular format including Microsoft Excel with complete version history and detailed audit trails at the cell level
- Ability to automate processing and approval of data using built-in workflows through tasks and email reminders
- Approvals and signatures supported through the use of universal PKI based digital signatures
- Extensive file compare capabilities providing detailed change tracking down to the cell and formula level in Microsoft Excel
- Easy to use browser based application and zero desktop install
- Support for FDA 21 CFR Part 11

NextDocs Quality Management

- Enterprise wide process and SOP management
- Employee training, certifications and records management
- Audits and investigations
- Exceptions and deviations
- Correction Action / Preventive Action (CAPA)
- Project control and documentation
- Built in workflows
- Detailed audit logs and reports

NextDocs Marketing Management

- Online annotation and markup
- Ability to automate processing and approval of data using built-in workflows through tasks and email reminders
- Approvals and signatures supported through the use of universal PKI based digital signatures

About Glemser

Founded in 1987, Glemser designs and implements XML and content management solutions for life sciences companies. Glemser's solutions help our pharmaceutical, consumer healthcare, medical device, and biotechnology clients effectively address the information management needs of their research and development, regulatory affairs, manufacturing, quality assurance and sales and marketing organizations.

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