nextdocs

The NextDocs Document Management System Hosted by Distributed Compliance Solutions

The NextDocs Document Management System includes

Regulatory Documents Module:

- Template-based folder structures for consistent management of submission documents
- Optional Microsoft Wordbased templates for a wide variety of submission documents
- Integration with leading Submission Publishing systems such as those from ISI, Liquent, Lorenz, Extedo and hosting partner Datafarm

SOP Management Module:

- Creating, approving and tracking Standard Operating Procedures (SOPs)
- Template-based authoring
- Pre-defined approval workflows
- Controlled printing with watermarks and overlays

Clinical Documents Module:

- Management of essential Study Documents for Site and Trial Master Files
- Scheduling and tracking of site monitoring visits
- Clinical Trials Collaboration between sponsor and external parties, including investigators, monitors, IRBs, etc.

Comprehensive Document Management Capabilities in a SharePoint-based Environment

NextDocs Document Management System delivers everything you expect in a regulatory compliant enterprise content management solution, all in a SharePoint environment.

NextDocs Document Management System is built on the NextDocs Compliance Platform, which provides an integrated and extended set of features to address 21 CFR Part 11 and similar regulatory requirements.

Since NextDocs leverages Microsoft SharePoint's familiar user interface and seamless integration with Microsoft Office applications, user adoption and training is far easier and faster than with traditional proprietary document management systems.

With modules for Regulatory Documents, Clinical Documents and SOPs, the system provides out-of-the-box solutions to the most typical requirements of life sciences companies. With Distributed Compliance Solutions hosting there is little configuration effort, faster deployment and no IT infrastructure costs.

Distributed Compliance Solutions host servers and software already configured with NextDocs best practices business process. After a Configuration Workshop you can start placing your content under control with-in the week.

DCS Hosting

Why DCS?

In the initial stages of drug development, life science and biotechnology companies need to focus their talents, time and financial resources on research and development. And yet, there is an obvious need for collaboration with outside vendors and partners while controlling content and protecting IP.

DCS provides the solution with a price structure that reduces IT costs dramatically over purchasing and maintaining the necessary IT structure.

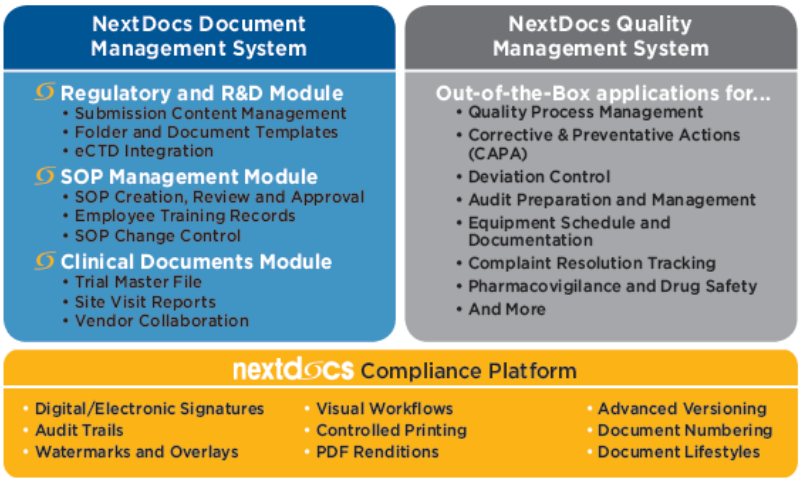
DCS Hosting

The NextDocs Difference:

Compliance without Complexity

NextDocs Document and Quality Management Systems are off-the-shelf applications that address all FDA 21 CFR Part 11 requirements. Built on the NextDocs Compliance Platform, they are 100% browser-based and completely integrated into the SharePoint framework.

NextDocs Complete Architecture
Hosted DM Offering and Complementary Modules



DCS and our Hosting Site

Our hosting partners provide 'state of the art' facilities. Each, provides highly skilled technical personnel, on site, 24x7x365 and are engineered with multiple levels of security, uninterruptible power, redundant HVAC systems and fire suppression. Data backup solutions are included and disaster recovery services are available, including auto hot-site failover. All this, means around-the-clock monitoring and management of your critical content.

Regulatory Compliance

The sites are SAS70 Type II compliant. SAS 70, is an auditing statement issued by the Auditing Standards Board of the American Institute of Certified Public Accountants (AICPA). SAS 70 defines the professional standards used by a service auditor to assess the internal controls of a service organization and issue a service auditor's report. A Type II service auditor's report includes the service auditor's opinion on the fairness of the presentation of the service organization's description of controls that have been placed in operation and the suitability of the design of the controls along with the auditor's opinion on whether the specific controls were operating effectively during the period under review.

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