Office PLM

White Paper on **FDA 21 CFR Part 11**

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Benefits

We recognize that meeting & remaining compliant with **FDA 21 CFR Part 11** and international standards is important to your business. OFFICE PLM, a .net Document Management System, automates and seamlessly manages your document control process to ensure compliance with these regulations. Office PLM is specifically designed for organizations that design what they make, where **ease of installation, ease of use, regulatory compliance, and affordability** are the primary business drivers.

Office PLM is specifically designed to manage, store and integrate Parts, Documents and Business Process to ERP systems. Organizations that need seamless integration to all business systems and process visibility need Office PLM.

Office PLM manages the entire document life-cycle process and gives you the tools to securely manage a wide range of business documents, including those related to regulated environments.

Office PLM is a **fully 21 CFR Part 11 compliant** document management solution based on Microsoft Windows .net technology. Office PLM is designed specifically for management of SOPs, Work Instructions, and other documents within business areas regulated by the FDA.

Why Office PLM is the right solution

- **Automated Numbering**: Document Number Manager keeps track of the numbers you assign to SOPs and validation documents.
- **Revision / Version Control**: Automatic document revision / version control to ensure the most up-to-date information is available
- **Complete Audit Trail**: Secure, time-stamped audit trail meeting **21 CFR Part 11** Requirements
- **Electronic Signature:** Electronically signoff and approve documents
- **Custom Standardized Templates**: Document Template Manager helps standardize document formats and jump-start the process of creating new documents.
- **Automated Workflow**
- **Task Management**

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- **Audit Logs**: An extensive Auditing feature automatically logs critical activities and presents audit records for on-line analysis.
- **Workflow Logs**: An extensive Auditing feature automatically logs all workflow activities and presents audit records for on-line analysis.
- **Loss Recovery**: Automatic back-up and recovery for all database attributes.
- **Fully Integrated**: Office PLM fully integrates with MS-Office, MS-Outlook.
- **Audit Log Viewer**: Activities related to documents and users are fully audited. An on-line Audit Log Viewer provides authorized personnel a way to see the entire history of activity for a specific document, or everything a specific User has done on the system.
- **User Management**: User Management is a key component of any controlled system. Office PLM implements secure user accounts with logon and password credentials. Users have access to functions and documents based on access rights assigned to Groups and Workflow Roles.
- **Implementation Services**: Part 11 compliance and validation is dependent on how a system is implemented. Office PLM professional services are a key component in the sale of Office PLM.

Training Records Management System

21 CRF Part 211 *Current Good Manufacturing Practice for Finished Pharmaceuticals* states that training in standard operations for each employee must be provided to ensure all employees are properly qualified to complete their assigned work tasks. The management of technical training and maintenance of a comprehensive and accurate file of training records for each employee is a daunting task. Office PLM can be designed to manage the entire process and give you the tools to ensure your employees training records are adequately maintained such that you can prove you are compliant.

Office PLM is designed specifically for management of Document Types and record retention of training related to SOPs, Work Instructions, and other Specifications documents within business areas regulated by the FDA. It can also be used for documenting any other employee training within your organization.

Key Office PLM features include:

- Email notifications to both Employees and Supervisors about any upcoming training that may be required.
- Can be configured for automatic notification of retraining when Specifications are updated.
- E-Signatures for updating training records when needed.

Electronic Common Technical Document

The FDA is NOW recommending that sponsors wishing to submit applications electronically use the most efficient and internationally agreed to formats recommended in their most recent guidance. The application table of contents may be designed and submitted as an **XML** file. Office PLM allows you configure the XML adaptor to submit in this new FDA recommended format.

The standards involve standardized technologies (i.e. XML, Portable Document Format) as well as definitions for file naming, hyper linking, and event font and text color specifications. Office PLM is a **fully 21 CFR Part 11** compliant solution based on Microsoft Windows .net technology.

Key Office PLM features include:

- Integrated document management and XML publishing features.
- Role-based document authoring and access management for multi-user electronic submission and authoring
- Produces XML backbone

Preparing documents for submissions requires many repetitious and time-consuming functions, all with an eye towards conformity and compliance.

Creating submissions-ready documents throughout your organization can be facilitated through the use of well formatted and easy to use templates. With specific customization, authors with limited knowledge of Microsoft Word® can easily use Office PLM and produce XML strings. Creating and storing the blueprint for text, graphics, styles and formatting of submission-ready documents, templates and procedures in Office PLM leads to increased efficiency, productivity, and consistency.

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