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Innovation You Can Use

EDM for Asset Management



Cyco AutoManager® Meridian For the Pharmaceutical, Biotech, and Medical Device Industries

FDA Module

21 CFR Part 11 and GMP Compliance

Agenda

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Background
Turnkey Solution
Validation
Features and Components
Summary

Cyco Software - Innovation You Can Use

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- ✓ The leading engineering data management provider since 1990
- ✓ A global company with customers and partners in > 45 countries
- ✓ 20,000 companies are using Cyco Software's solutions
- ✓ Offices in USA, UK, Germany, The Netherlands, Italy and Russia
- ✓ One hundred employees in R&D, Service and Sales
- ✓ 200+ highly trained channel partners
- ✓ Profitable & growing

Cyco Software - Solutions

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Autodesk®

Authorized Developer



isah



DataCore Technology, Inc.

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- In business since 1996 with four U.S. offices (GA, NJ, PA, WA)
- Providing EDM to Pharmaceutical, Energy, Manufacturing and Government markets
- 250+ customers
- Strong Quality Management System – Hosted numerous vendor audits
- 21 CFR Part 11 and Validation expertise (GAMP 4)
- Active member within multiple professional organizations



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- Companies strive for leanness and efficiency
- Currently using heavy procedural controls and difficult to manage, or non-compliant hybrid systems - 21 CFR Part 11 and GMP compliance needed
- Heavy price to pay for non-compliance with risk of product recalls, site closures, product launch delays and damaging publicity.
- A great proportion of warning letters and non-compliance observations result from documentation-related problems.

Many of these problems can be eliminated through best practice documentation processes supported by automated EDM solutions.

Recognizing The Need For A Targeted Application

- Many customers share a similar problem with similar needs
- Generic platform offering not suited to managing controlled documents in a regulatory compliant manner
- “One size fits all” approach is not well suited to an engineering environment. Required functionality and usability (for an engineering environment) is missing.
- Enterprise solutions are too “heavy”. They require too much time and money to implement and maintain in an environment where a compliant “best of breed” solution is the most pragmatic approach.

- Configurable add-on to Cyco AutoManager Meridian
- Implemented with consulting services
- Made for rapid deployment to comply with 21 CFR Part 11
- Manage GMP controlled engineering documents
 - pre-configured templates
 - workflows and life cycles
 - audit trails
 - security
 - electronic signatures
 - controlled printing

- Drastically improves compliance effectiveness and reduces residual compliance risk
- 21 CFR Part 11 technical controls
- Incorporates industry best practices
- Reduces validation effort
- Lowers total cost of ownership

The FDA Module for AM-Meridian facilitates cost-effective implementation and maximizes benefit realization!

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- Good e-Business Practice – Moving from “Cowboy” Systems to Trustworthy Reliable Systems.
- Electronic record and electronic signature systems consist of both manual procedural controls and technical controls
- Validation is Crucial and Includes:
 - Validation Documentation
 - Design and Implementation Documents
 - Software and Hardware Manuals
 - SOPs (Standard Operating Procedures)
 - Test Scripts
 - Training

As part of its deployment of AM-Meridian and the FDA Module, an organization can perform a quality assurance audit of DataCore's development processes, procedures and standards, and can review the history of its employee training.

Representative Procedures

- Project Management
- Software Quality Control
- Software Development Life Cycle
- Development Standards
- Change Management
- Configuration Management
- Documentation Review and Approval
- Incident Reporting
- Corrective and Preventive Action
- Personnel Qualifications and Training
- Backup and Restore/Disaster Recovery
- Security
- Internal Audit

Project Delivery Methodology

DataCore's proven methodology, adapted to your corporate standards, dramatically improves project team productivity, accelerates implementation and shortens time to realized benefits. Typical phases, activities and deliverables include the following:

Plan

- Project Plan
- Project Schedule
- User Requirements Specification
- Validation Plan

Define

- Traceability Matrix
- Functional Specification
- Configuration Specification

Design

- Training Plan
- System Design Specification
- Data Migration Plan

Build

- Training Material
- Implementation Plan
- Create configuration instances for development and testing
- Production of user and technical procedures
- Unit Testing
- Code Review
- System Test Plan
- Test Scripts
- System Testing
- Test Report

Deploy

- IQ/OQ/PQ Protocols
- Training
- Source Code

Close

- Validation Report
- Project Review Report

Project Streams

- Project Management
- Issues/Actions Log
- Status Reports
- Meeting Minutes

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FDA Module Components

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- Enhanced access control
- Configurable event auditing
- Audit trail compliant with 21 CFR Part 11
- Electronic signatures compliant with 21 CFR Part 11
- Signature manifestation with PDF Renditions
- Pre-configured workflows and document types
- User life cycle notifications
- Controlled printing
- Standard and ad hoc reports
- Administrative tools

We place a high importance on professional services and when we enter into a partnership with you we ensure that you receive all the support you need to make your project a success from building a business case through to roll out across your organization.

DataCore offers customers access to the experience and knowledge gained by it during the planning, implementation and roll-out of large scale electronic document management systems.

- Project Management
- Requirements Analysis
- System Design
- Custom Development
- System Configuration
- Testing
- Implementation
- Documentation
- Training
- Validation
- Support

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The FDA Module for Cyco AutoManager Meridian helps you maximize throughput (get more done) and minimize costs and risks (with less) by:

- Assisting with regulatory compliance
- Ensuring quality and process streamlining
- Ensuring process repeatability and efficiency
- Speed time to market
- Reduce implementation and validation costs
- Providing an easy to use solution your engineering department can and will want to use

For More Information

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