Prelude Computer Solutions, Inc.

DocuKnowledge Suite Presentation for the FDA
August 9, 2001
Objectives

- Introduce Prelude Computer Solutions, Inc.
- Get FDA feedback on Prelude’s DocuKnowledge Suite
- Recognition on Public Docket
Package Contents

- Presentation
- Part 11 Response
- Validation Approach
- Screen Shots
Specializing in regulated solutions for the pharmaceutical and life sciences.

Full service integrator

Concentrating on Document Management and Publishing of documents for the FDA

Founded in 1989
Agenda

- The Business Challenge - The DocuKnowledge Suite and why it came to be
  - Prelude Design Requirements
  - Business Goals
  - Testing Process
- DocuKnowledge Suite - what is it
  - Features and Benefits
- DocuKnowledge Demonstration
- Part 11 Test Results
The Business Challenge

- Results of a Business Analysis for large OTC Consumer Health organization
- Build an affordable, turn-key system for Electronic Submissions based on industry standard software, that is Part 11 compliant and follows the Guidance for Industry Documents.
Target Market

Who our product appeals to:
- Companies without large staffs
- OTC
- Small Pharma
- Medical Device
- Biotech
- Rx companies without systems or augmenting existing systems
Prelude Design Requirements

- System must meet requirements of FDA Part 11
- System must produce .pdf files formatted and organized as per FDA:
  - Guidance for Industry Documents
- Automate as much as possible to make it easier for users and reduce potential errors
Prelude Design Requirements

- Out-of-the-box, lower cost solution for electronic submissions
- Software had to be
  - Name brand software platforms
  - Web based document management
  - Scalable- entry level to enterprise
  - Secure
Prelude Design
Requirements

- IBM/Lotus Domino.Doc document management
  - Global, multi language support
  - Several million licenses sold
  - Corporate standard for mail
- CDC Solutions EZsub Team publishing
Prelude Design Requirements

- Audit Trails & Version Control
  - Computer Generated
  - Time and Date Stamped
  - Operator Identified
  - Anytime Record is Created, Modified, or Deleted
  - Modifications Can Not Obscure Previous Information

- Enforce Review and/or Approval
Prelude Design Requirements

- Integrated
  - Word templates must work with the publishing system to create TOC’s
  - Word templates need to include metadata in properties field when converted to .pdf as per Guidance Documents
Prelude Design Requirements

- Documents must be automatically extracted from EDMS into file system to create an NDA.
- Extraction program needs to create the directory structure and be flexible enough to handle diverse submission types.
- Publishing system should have initial TOC’s automatically created.
Prelude Design Requirements

- Extraction program able to be used as a Project Management tool to determine the status of a submission.
- Replaces manual tracking sheets
Prelude Business Goals

- Provide a solution that can be used by a broader group of companies
- Provide faster turnaround and easier implementation
- Reduce manual errors and enforce compliance by automating as much as possible
- Only non-Documentum based alternative that fully automates integration between document management and publishing (As of presentation date, we are the only one)
Process of Testing

- Using our Requirements Based on Part 11 and Guidance Documents
- Evaluated Domino.Doc and EZsubs Team
- Tested Domino.Doc for Part 11 suitability
  - Renowned security, global support
  - Tested specific features for audit trail, versioning, change/deletion, security
- Evaluated EZsubs for integration with Domino.Doc
  - EZsubs had already been used for submissions
Our Testing Results

- Documented our testing
- Created list of enhancements to Domino.Doc
- Created specs for Domino.Doc/EZsubs integration module
- Implemented enhancements, documented, validated
- Created validation kits for use by customers

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DocuKnowledge Suite

A Full Service Integrated Solution for Document Management and Publishing
DocuKnowledge Suite

- Consulting and Integration Services
  - DocuPartner
- Document Management Products
  - DocuLibrary, DocuSub, DocuLabel, DocuSOP, DocuPromo, DocuStyle
- DDManager
  - Extraction and Project Management
- Publishing Products
  - DocuPub
- Validation Products and Services
DocuKnowledge Suite

DocuLibrary- Document Management Architecture

- DocuSub
- DocuLabel
- DocuPromo
- DocuLab

DocuTemplates
- Create/Edit
- Check In/Out
- Version
- Audit Trail

DocuLibrary/Domino.Doc
- Web Interface
- E-Mail
- Workflow
- Security

Lotus Notes/Domino

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DocuSub Package for Electronic Submissions

IBM/Lotus Domino.Doc
Document Management

CDC EZsubs Team
Publishing
DocuSub Package for Electronic Submissions

- Completely integrated system for Electronic Submissions including:
  - Document Management
  - Publishing
  - Integration
  - Business Analysis- Requirements, Workflow, Process
  - Validation
DocuSub Package for Electronic Submissions

- Document Management
  - DocuLibrary- Domino.Doc
  - Part 11 Extensions
  - Specialized Templates for
    - DocuTemplates -Document Management
    - DocuStyle- Word
    - DocuTest- Validation

- DDManager
  - Project Management
  - Document Extraction and Directory Creation
  - PDF Rendering
DocuSub Package for Electronic Submissions

- Publishing
  - DocuPub- EZsubs Team
  - Specialized Templates
    - NDA Template
- DocuPartner
  - Business Analysis
    - Requirements Document
    - Workflow
    - Project Planning
- Validation
  - DocuTest- Boiler Plate Kits
  - Services
DocuTemplate Components

Library

File Room

Cabinets

Binders/Folders

Documents
DocuTemplates

- Additional Templates for Domino.Doc
  - Label Tracking and Approval Templates
  - Promotional Material Approval Templates
  - Lab Notebook Templates
  - SOP’s
Advantages to Domino.Doc

- Web Enabled
  - Ease of use, training, IT support
  - Web-Enabled Review*
  - Web-Enabled Approval*
- Infrastructure Friendly
  - Works with Common Mail Systems

* Both integrated into your current mail system
Advantages to Domino.Doc

- Easily Configured
- Departmental Administration
  - Leverage and train existing staff instead of hiring more people
- Attributes Migrate for Upgrades without Programming Changes
- Personalized Workspace
  - Increase Productivity
  - Increase Ease of Use
Advantages to Domino.Doc

- Personal Workspace/Home Page Contains
  - Checked Out Documents
    - Editors can see what they have checked out
  - Recently Edited
    - Editors see what they have recently been working on
  - Lifecycle View
    - Reviewers see only their own work
- Favorites
  - Authors and Editors can bookmark their favorite pages
DOMINO.DOC REPOSITORY

- Domino Doc NDA Folders
  - Controls document life cycle in NDA library

DOMINO DOC MANAGER

- Extracts documents from Domino.Doc repository
- Creates PDF's from Word docs
- Generates and maintains NDA Publishing Profiles

PUBLISHING

- EZsubs Team publishes content according to formatted DD Manager Profiles that follow the FDA guidelines.

ELECTRONIC SUBMISSION

- PostPublish - Create and append search indexes, Burn CD-Rom or other Media

PDF PAPER VOLUMES

- Send to printer
DDManager Functions

- DDManager is the interface between Domino.Doc and Publishing
- Provides extraction of all content from Domino.Doc repository to the Publishing Server
- Creates and maintains EZsubs Publishing Profiles
- Provides document progress reports
  - Management of documents
  - Audit trail of activities
  - Log reports of DDManager activities
**DDManager- Extraction Features**

- Extracts all or selected documents for publishing
- Creates the File structure required by FDA for submission media
- Updates all required document properties
  - Moves Domino.Doc Index card fields (metadata) to Word properties field
- Converts MS Word documents to PDF format
DDManager- Extraction

Features

- Audit Log - event activities and exceptions
  - Session ID, Task, User, Date, Time Stamp, successful completion
- Document Log - view log of documents extracted
- Submission specific extraction
  - NDA structure
  - PDF rendering
- Generic extraction
  - Native document format
  - User defined directories
DDManager- Project Management Features

- Status Reports
  - List of documents for the complete submission or sections of a submission with:
    - Status- Draft, Version, In Review, In Approval
    - Last person to modify
    - Date last modified
**Process Flow**

- **DOMINO.DOC REPOSITORY**
  - Domino Doc NDA Folders
  - Controls document life cycle in NDA library

- **DOMINO DOC MANAGER**
  - Extracts documents from Domino.Doc repository
  - Creates PDF's from Word docs
  - Generates and maintains NDA Publishing Profiles

- **PUBLISHING**
  - EZsubs Team publishes content according to formatted DD Manager Profiles that follow the FDA guidelines.

- **ELECTRONIC SUBMISSION**
  - PostPublish - Create and append search indexes, Burn CD-Rom or other Media

- **PDF PAPER VOLUMES**
  - Send to printer

- **Approved Documents & Content**

- **Publishing Profiles**

- **Table of Contents**
  - Templates for Master TOC, Sectional TOC's and sub-sectional TOC's
CDC Solutions- EZsubs Team
- Team uses Publishing Profiles for adjusting content
- Initial publishing Profile organization is created and maintained by DDManager according to FDA Guidance for Industry guidelines
- EZsubs Team is a full featured desktop Publishing client
- CDC PDF Fusion is the publishing engine residing on a central publishing server
Publishing using EZsubs Team

Open DDM Created NDA Profile

Adjust content order and position in sectional Table of Contents

Publish using PDF Fusion Publishing Server

Publishing Server Folders
Content Profiles

Saved Profiles

Master Table of Contents Sectional Tables of Contents

Published organized NDA submission files on Publishing Server

CD ROM Submission or other media

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Validation
Products & Services

- **DocuTest**
  - Boiler Plate Model Kits for applications that include
    - Functional Requirements
    - System Design Spec
    - IQ, OQ, PQ
    - Test Scripts

- **DocuPartner**
  - Services for Assistance in
    - User Acceptance
    - Summary Reports

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DocuKnowledge Suite

- Part 11 Compliant
- Web Enabled
- Backed By Industry Leaders
- Affordable
- Expandable and Scalable
- Easy to Use and Configure
- Departmental Administration
Demonstration

DocuKnowledge Suite
DocuSub- Electronic Submission System
Part 11 Results
Part 11 Results

11.10 (b)

The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection review and copying by the agency.

DocuKnowledge Response-

All records, audit trails, and versions can be viewed, copied, and printed in human readable form.
Part 11 Results

11.10 (c)

Protection of records to enable their accurate and ready retrieval throughout the records retention period.

DocuKnowledge Response-

The DocuKnowledge Suite provides customized templates (metadata) for retrieval of records. Industry standard search engines based upon IBM technology insure accurate retrieval.
**Part 11 Results**

11.10 (d)

Limiting systems access to authorized individuals.

DocuKnowledge Response-

Users must login using a unique login and password.
11.10 (e)

Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information.

DocuKnowledge Response-
Audit Trails, Version Control, and Security Agent
11.10 (f)

Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

DocuKnowledge Response-

The DocuKnowledge Suite only presents appropriate choices for selection.
Part 11 Results

11.10 (g)

Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation of computer system input or output device, alter a record, or perform the operation at hand.

DocuKnowledge Response-

Users must login with unique user name and password. Users can only see what they have the authority to read or edit. Currently comply to Part 11 and Guidance Documents for electronic signatures.
11.10 (i)

Determination that the persons who develop, maintain, or use electronic record/signature systems have the education, training, and experience to perform their assigned tasks.

DocuKnowledge Response-

Maintains CV’s on all persons who develop, maintain, document, validate, train, and install the DocuKnowledge Suite products.
Part 11 Results

11.10 (i) continued-

Prelude also requires all consultants to read the Part 11 and Guidance for Industry documents and complete review questions which are kept on file. Further training is done on SDLC policies and procedures. Technical training is also performed as new base product software is released, ie: document management and publishing.
11.10 (j)

The establishment of, and adherence to written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

DocuKnowledge Response-

Prelude maintains SDLC’s and SOP’ for our development. We assist pharmaceuticals in creating and maintaining SOP’s.
Part 11 Results

11.10 (k 1)
Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

DocuKnowledge Response-
Administration and user documentation is available both in paper and on-line.
Part 11 Results

11.10 (k 2)
Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

DocuKnowledge Response-
Procedures for revision and change control are maintained in Prelude’s SOPs.
Part 11 Results

11.50

Signature Manifestations & Sub Part C- Electronic Signatures

DocuKnowledge Response-

Manifestation and meaning of all signatures is displayed on the profile attached to the specific document and version.
Appendix A

Validation Approach
Validation Approach

- Validation of Standard Product – Prelude Software Development
- Validation of Customer Solution
Prelude SDLC

- System Development Methodology
  - Phased approach
  - Well-defined roles and responsibilities
  - Quality assurance
  - Specific deliverables for each phase
  - Produce documented evidence
Prelude SDLC

- Analysis
- Design
- Development - Unit Testing
- Pilot Implementation
- Integrated System Testing
- Qualification Testing & Deployment (Release)
- Change Control
Gap Analysis Results

- Domino.Doc Customization
  - Met most requirements
  - Required customizations in the areas of deletion control and authentication enhancements

- CDC EZSubs Team Customization
  - Required standard templates to meet requirements outlined in guidance documents

- DDManager Module
  - Identified need for automated integration between document management and publishing
DocuSub Product

- **Requirements:**
  - FDA Guidance for Industry
  - 21 CFR Part 11

- **Design & Development:**
  - Domino.Doc was customized by utilizing Lotus Best Practices, ensuring an upgrade path for future versions
  - CDC EZSubs configuration of templates
  - DDManager was developed in Visual Basic adhering to a full development life cycle

- **Testing:**
  - Validated within the Prelude environment
Validation of Customer Solution

- Requirements
- Functional Specs.
- Design Specs.
- Detailed Design Specs.
- Design Qualification
- System Construction
- System Testing
- Installation Qualification/Operational Qualification
- Performance Qualification
OTC Consumer Health

- Prelude validation team working with OTC QA
- Followed OTC Quality policies and standard validation templates
- Validated against NCH Part 11 interpretation
- Validation effort nearing completion
OTC Validation Deliverables

- User Requirements Specification
- Functional Specification
- Functional Risk Assessment
- Validation Protocol (Plan)
- Design Specification for Document Management
- Design Specification for DDManager
- Design Specification for Ezsubs
- Test Plan
- Traceability Matrix
OTC Validation Deliverables

- Test Script for Domino.Doc Server Installation Qualification (IQ)
- Test Script for Document Management Client Installation Qualification (IQ)
- Test Script for Document Management Operational Qualification (OQ)
- Test Script for Document Management Performance Qualification (PQ)
- Test Script for Publishing Server/Workstation Installation Qualification (IQ)
OTC Validation Deliverables

- Test Script for Publishing Client Installation Qualification (IQ)
- Test Script for DDManager Installation Qualification (IQ)
- Test Script for DDManager Operational Qualification (OQ)
- Test Script for DDManager Performance Qualification (PQ)
- Test Script for EZsubs Team Operational Qualification (OQ)
- Test Script for EZsubs Team Performance Qualification (PQ)
- Validation Summary Report