

Memo of Meeting

Date: August 9, 2001
1350 Piccard Drive, Rockville, MD 20850

Representing Prelude Computer Solutions, Inc. Parsippany, NJ 07054:

Barbara J. Brennan, President/CEO
Ryan T. Johnson, Director, Technical Resources
Sandy Drew, Sr. Business Consultant

Representing the Food and Drug Administration:

Paul J. Motise, Consumer Safety Officer, Office of Enforcement
Tom Chin, Consumer Safety Officer, Office of Enforcement

The meeting was held at the request of Prelude Computer Solutions, to discuss the firm's suite of electronic records software in the context of 21 Code of Federal Regulations, Part 11; Electronic Records, Electronic Signatures. At the start of the meeting we explained that FDA does not approve or disapprove of products and services that enable regulated firms to comply with FDA requirements and that our comments should be considered in that light.

The firm's representatives explained that the firm is a systems integrator that provides a software suite, DocuKnowledge, built upon standard applications. The software functionality is engineered for electronic submissions, with Part 11 requirements in mind. At the core of these applications is the Lotus/IBM Domino.doc application. The firm can provide add on software to companies that already have this application, or can provide a pre-defined package. The system produces PDF file formats, and a scalable, secure, web based document management system.

The firm's presentation outlined how various part 11 requirements were implemented by the DocuKnowledge suite.

During the meeting we discussed the firm's validation activities. The firm provides its customers with test scripts and system design specifications. The firm is also amenable to audits of its software development activities.

The representatives gave us a brief product demonstration, showing how the web based system authenticates users, implements audit trails, displays electronic record meta data and integrates with web browser and word processing software.

During the course of the meeting we commented that PDF file formats that did not permit the processing of record information would be problematic. We noted that for records containing only text, there should be no problem with a PDF file that permitted word searches; however, we remarked that information in the files that could not be processed, such as images of spreadsheets and tables would be problematic from a part 11 perspective. Part 11 requires that persons be able to generate electronic copies of electronic records that are suitable for FDA review.

Regarding audit trails, we commented that the system was inappropriately allowing end users to write comments to the audit trail at will. We suggested moving comments to a different file because end users should not be able to write to an audit trail at will. We expressed the same suggestion and comment regarding the audit trail entry field called "initial draft." We also noted that electronic record deletions were apparently documented in a file separate from what is called the audit trail, making it appear that the audit trail did not capture deletions.

Regarding the system's implementation of electronic signatures, we commented that the profile display did not indicate what the signature means. Part 11 requires that the meaning of the signature be part of the human readable display of a signed electronic record. We also commented that from the record approval feature, it was not clear exactly what record the approver was signing.

We discussed archiving. The firm preserves files in the native electronic format and is considering augmenting that with XML formats.

Concerning password controls, the system implements configurable password aging, length, and composition.

The meeting lasted about two hours.

Subsequent to the meeting, the firm provided the attached PDF files, an explanation of electronic signature manifestations, and slides from the firm's demonstration/presentation that could be posted to the public docket.

cc:
FDA meeting attendees
HFA-224
Part 11 Guidance Dockets

doc id: MemoOfMeetingPrelude080901.doc
P. Motise
9/4/01



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Prelude Computer Solutions, Inc.

**DocuKnowledge Suite
Presentation for the FDA
August 9, 2001**



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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

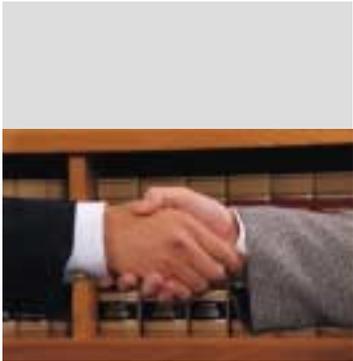




Prelude Computer Solutions, Inc.

- 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

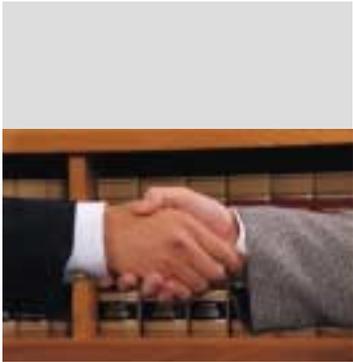




The Business Challenge

- 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 EZ*subs* 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





DocuKnowledge Suite

**A Full Service Integrated Solution
for Document Management and
Publishing**



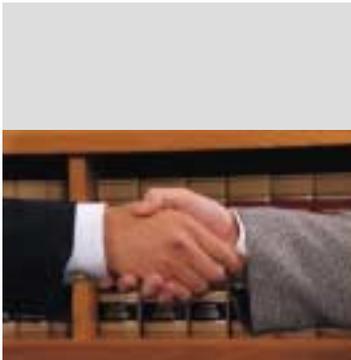
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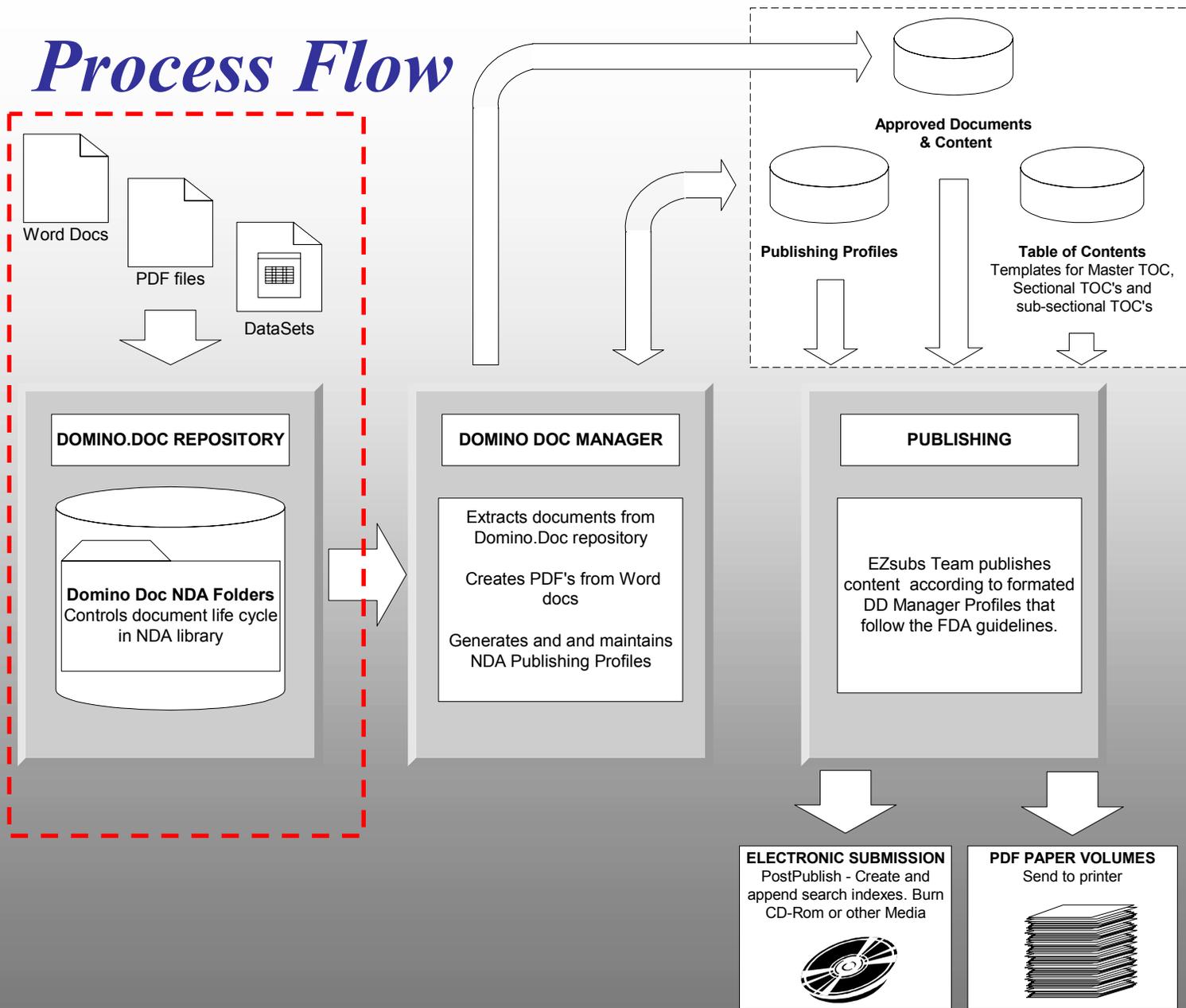
DocuKnowledge Suite

- 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





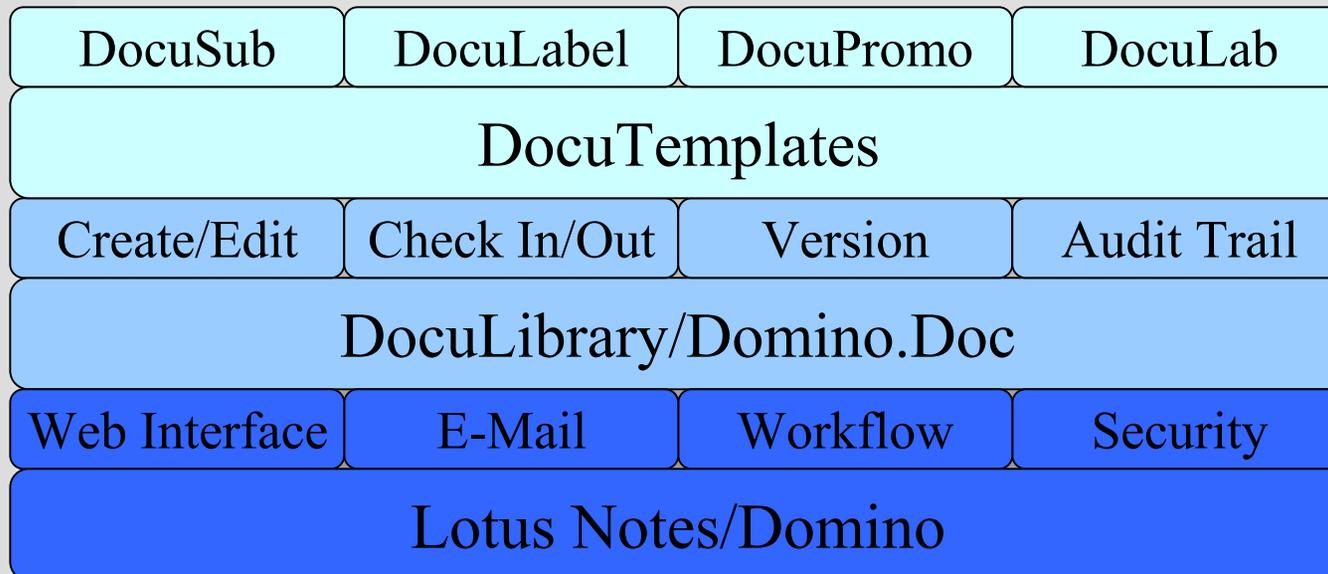
Process Flow





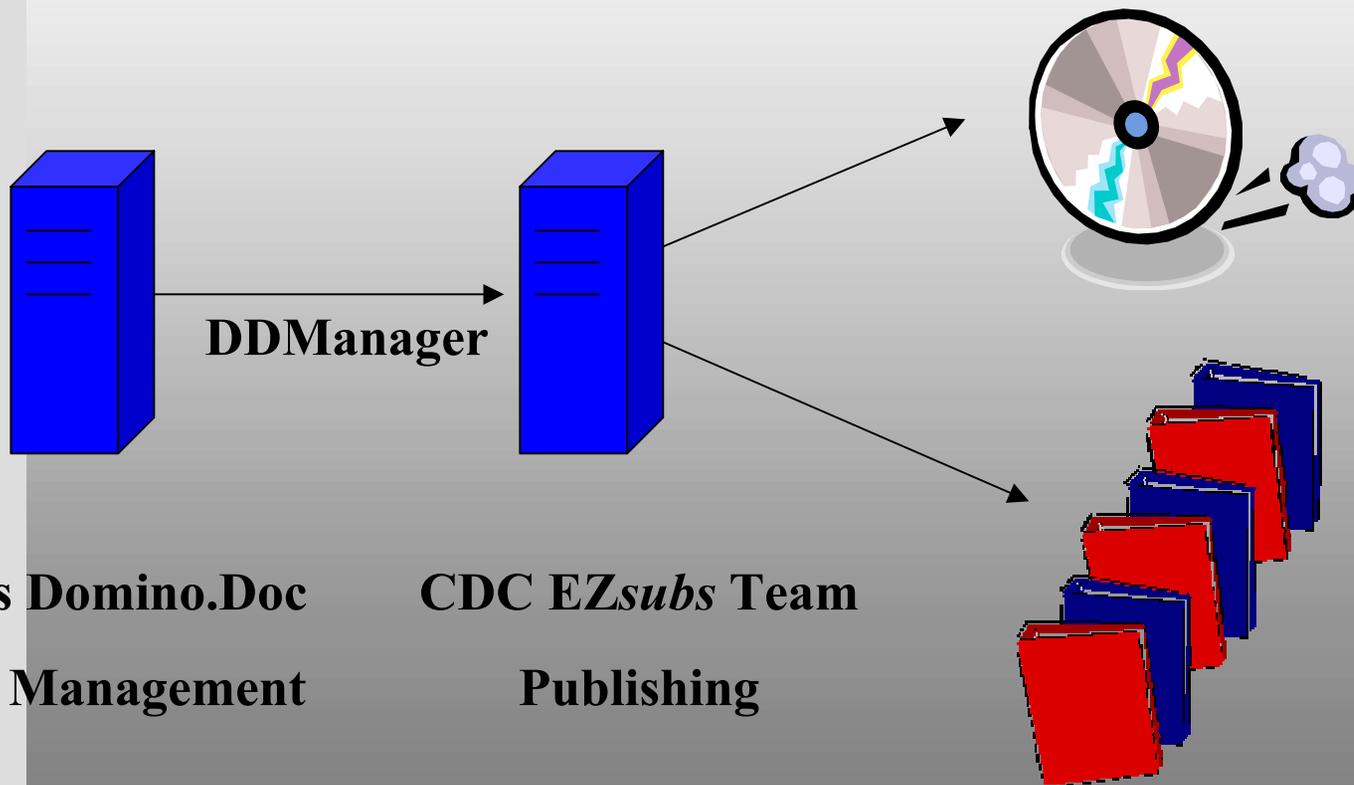
DocuKnowledge Suite

DocuLibrary- Document Management Architecture





DocuSub Package for Electronic Submissions



**IBM/Lotus Domino.Doc
Document Management**

**CDC EZsubs Team
Publishing**



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DocuSub Package for Electronic Submissions

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

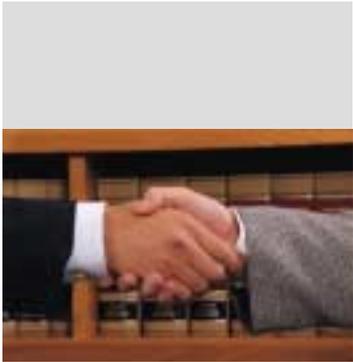




DocuSub Package for Electronic Submissions

- 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- EZ*subs* Team
 - Specialized Templates
 - NDA Template
- DocuPartner
 - Business Analysis
 - Requirements Document
 - Workflow
 - Project Planning
- Validation
 - DocuTest- Boiler Plate Kits
 - Services





DocuTemplate Components



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



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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





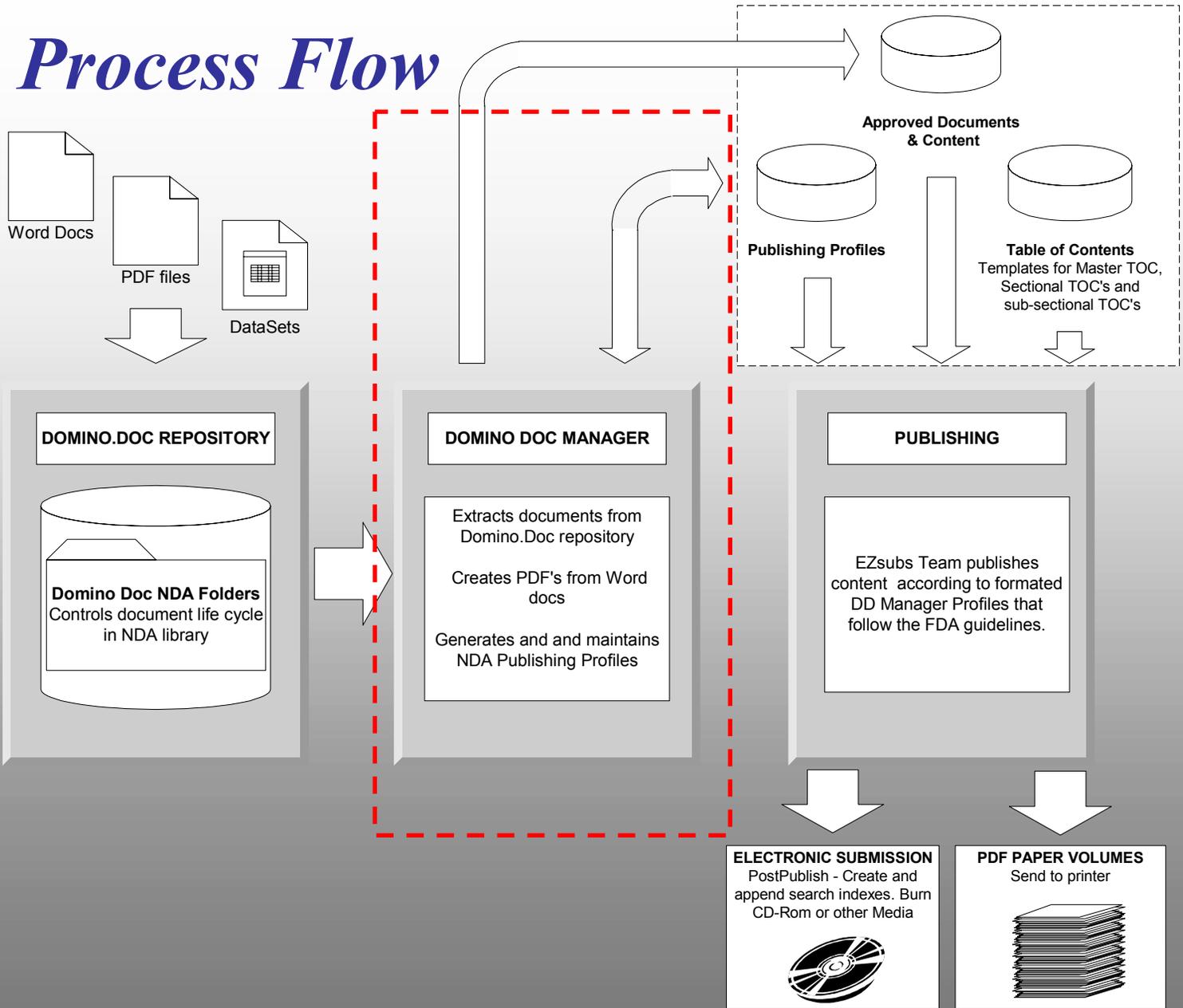
Advantages to Domino.Doc

- 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





Process Flow

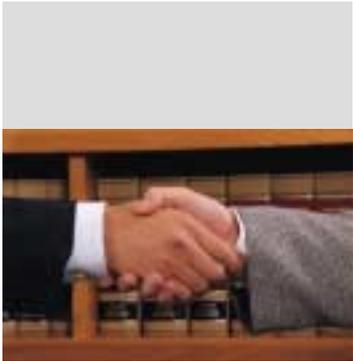




DDManager Functions

- 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

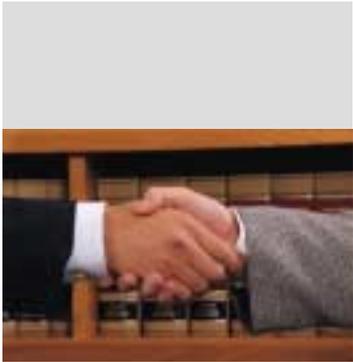




DDManager- Extraction Features

- 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





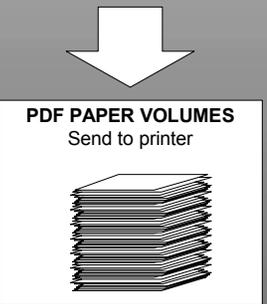
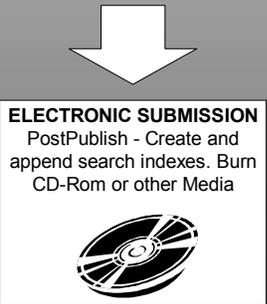
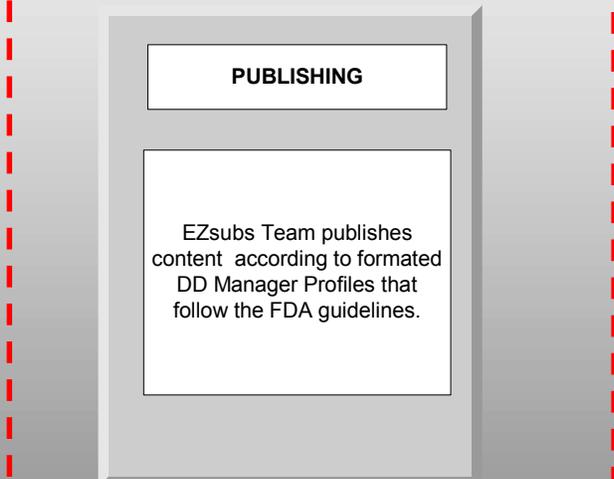
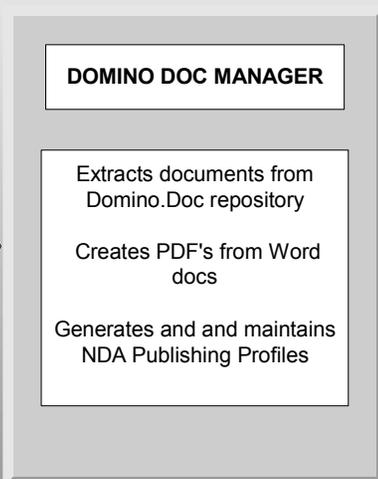
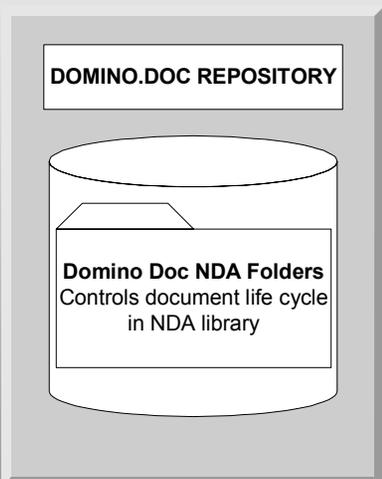
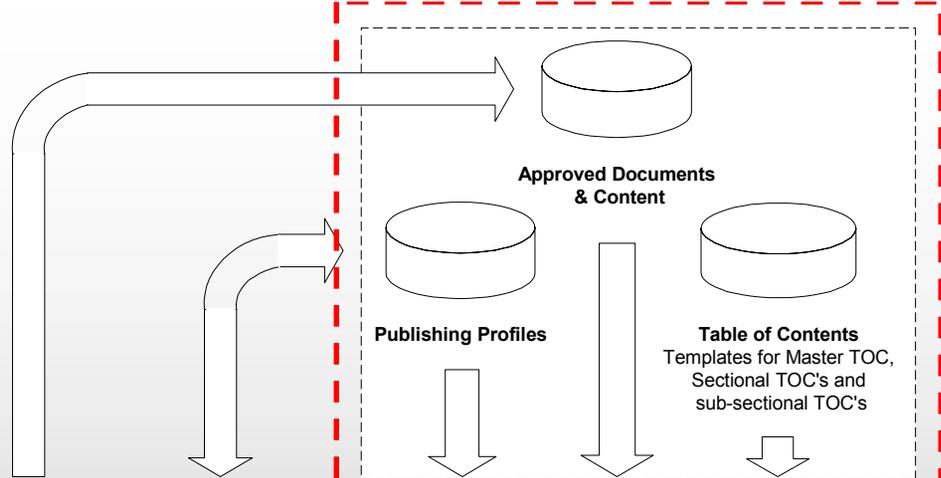
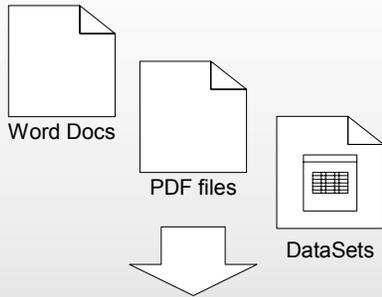
DDManager- Project Management Features

- 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





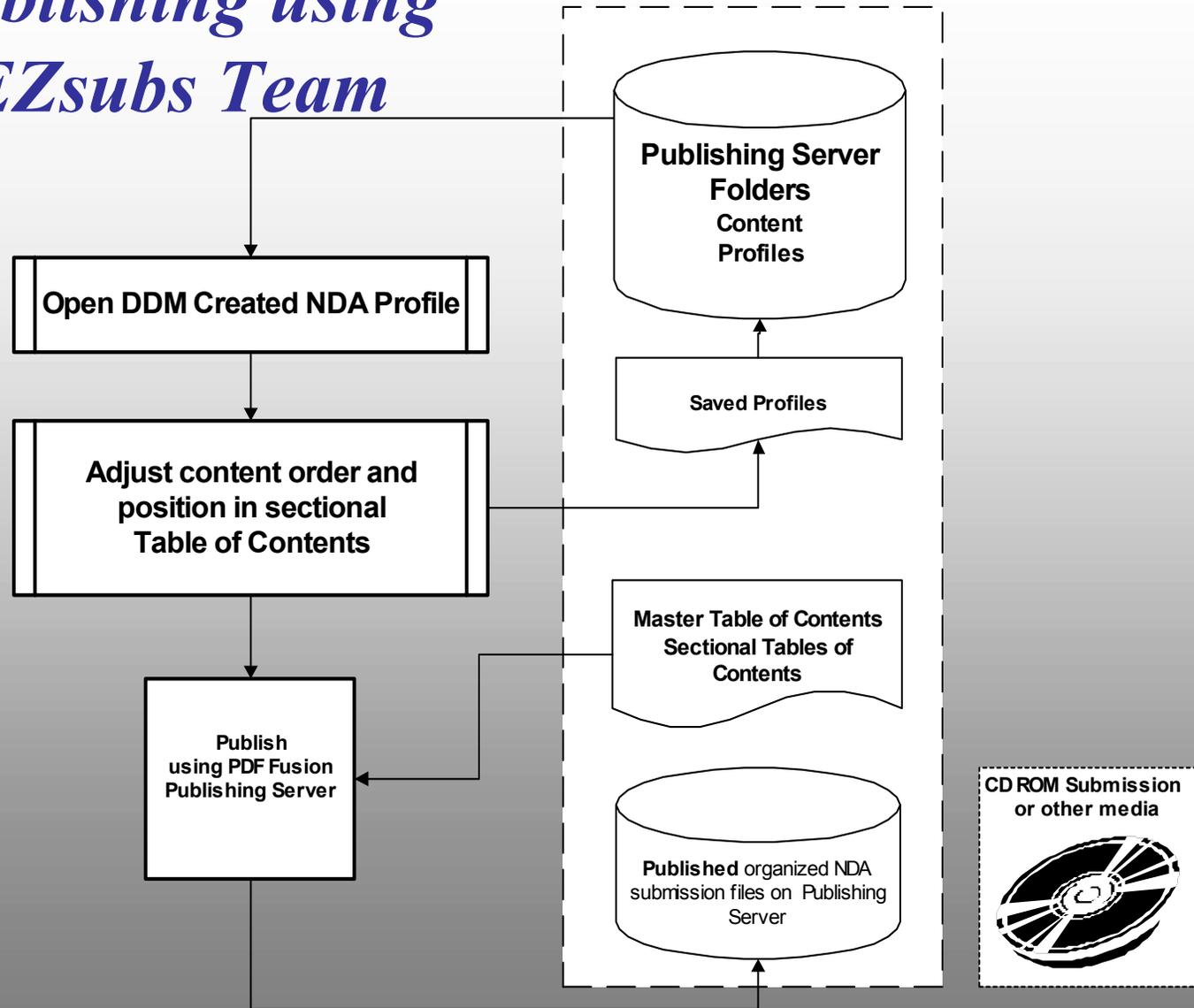
DocuPub- Publishing

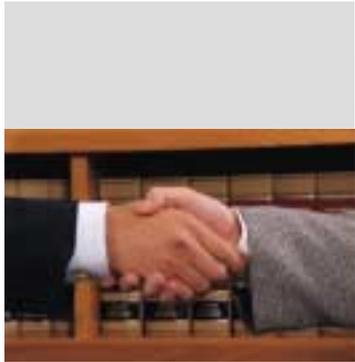
- CDC Solutions- *EZsubs* Team
- Team uses Publishing Profiles for adjusting content
- Initial publishing Profile organization is created and maintained by DDManager according to FDA Guidance for Industry guidelines
- *EZsubs* Team is a full featured desktop Publishing client
- CDC PDF Fusion is the publishing engine residing on a central publishing server





Publishing using EZsubs Team





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





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



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Part 11 Results



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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.





Part 11 Results

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





Part 11 Results

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.





Part 11 Results

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.





Part 11 Results

11.10 (j)

The establishment of, and adherence to written policies that hold individuals accountable and responsible for actions initialed 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





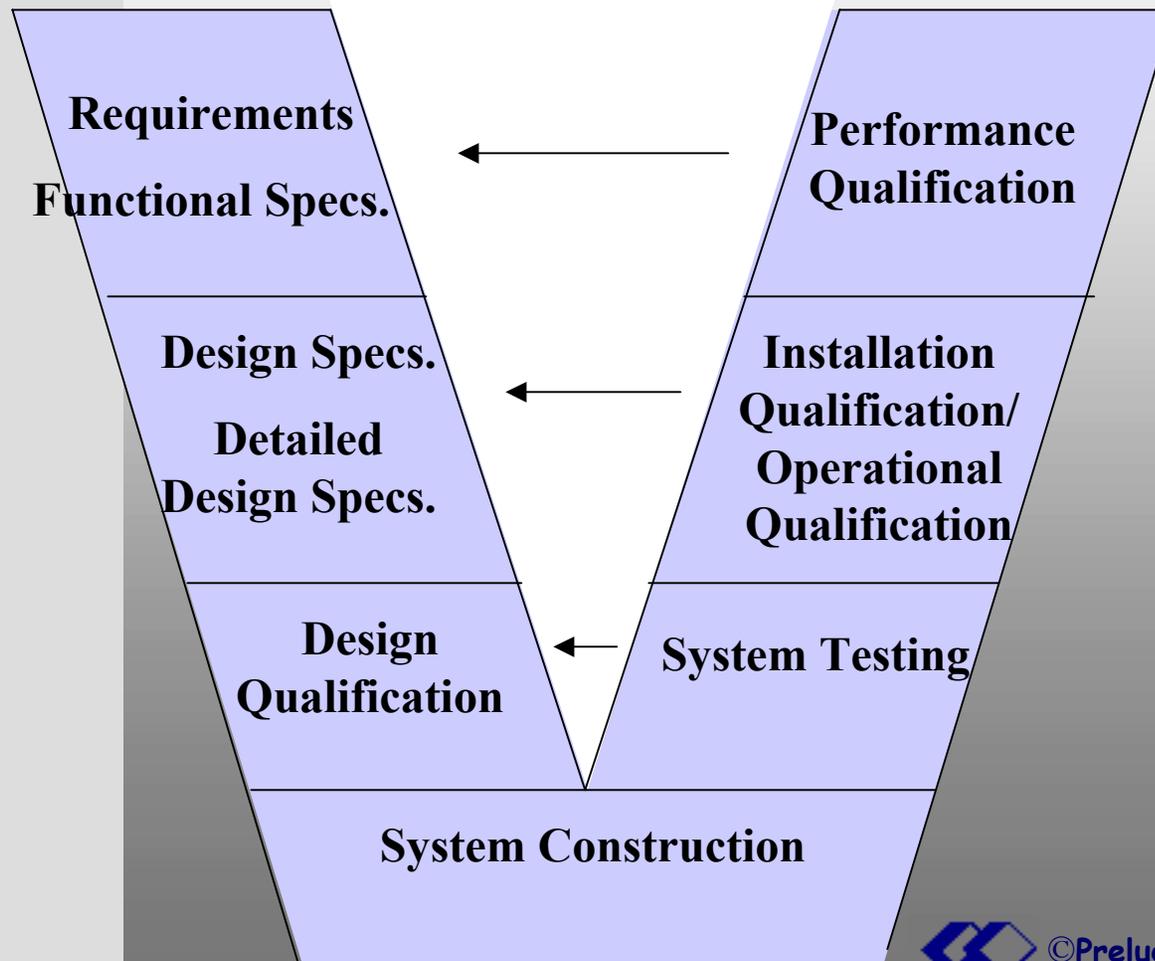
DocuSub Product

- 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





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



Domino.Doc - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Print Mail News RSS Feeds

Address http://cheeta/domdoc/d Go Links Hotbar Search... The Web Shop Free More>>

Lotus **DocuKnowledge™** Search for

Powered by **Domino.Doc** Go Advanced Search

Document Discussion

ClinStat > ISS > **Signature Test**

Document Number: 08272001-QG2X-GF96
Created By: Cheeta Admin/DD3Test
Date Created: 08/27/2001 04:43:52 PM
File name: ethelpad.pdf
Version: 2.0
Document Type: ISS
Document State: Released
Description:

ISS

Drug Name:	test1
Generic Name:	test
Formulation:	test
Indication(s):	test
Study #s	test

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Electronic Signatures
Signed as Approver by: Cheeta Admin/DD3Test - Date: 08/27/2001 05:04:28 PM EDT
© Prelude Computer Solutions, Inc.

Done Local intranet

Signature manifestation includes the meaning of the signature, the name of the signer, and the date / time stamp of the signature event. The signature manifestation is attached to the specific version of the electronic record. Earlier/later versions of the controlled document and the unique signatures for each are not obscured and are viewable through the revision history. This implementation supports multiple signatures for a single document version.