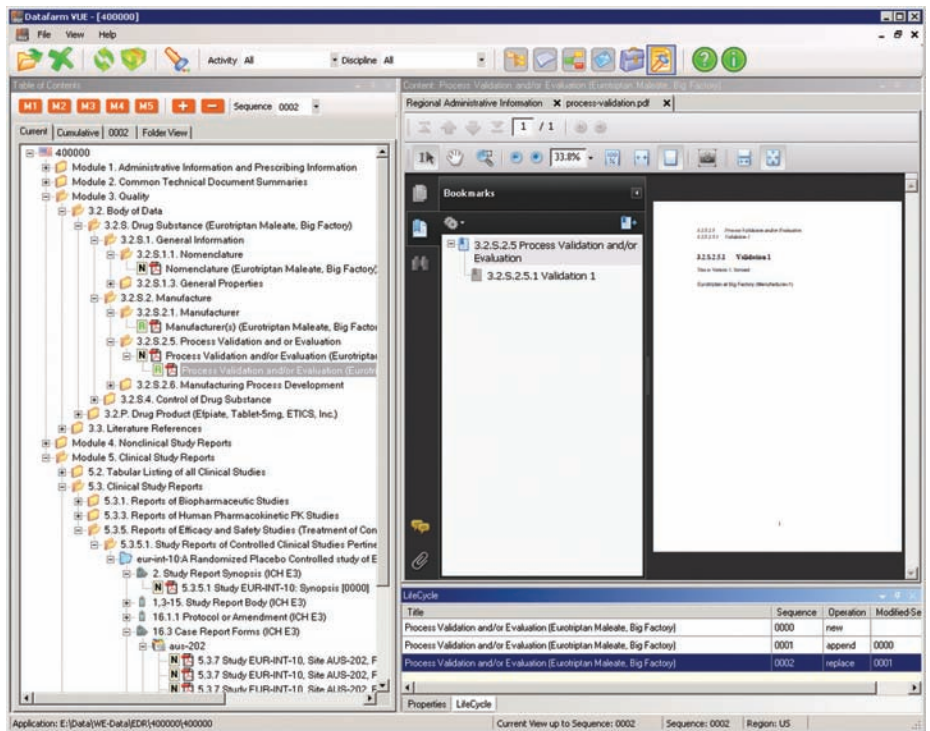


Datafarm® VUE

A Multi-Regional eCTD Viewer

Datafarm introduces the first product in its newest line of desktop tools with the debut of Datafarm® VUE, a self contained, stand-alone Windows® desktop application for viewing eCTD submissions. Datafarm® VUE users can view submitted or in-progress eCTD submissions created for the United States, Canada, Europe, Japan, Switzerland and Taiwan as long as the associated XML backbone files are compliant with ICH and regional specifications.

- VUE supports eCTD submissions created using the following specifications:
 - ICH eCTD specifications v3.2
 - ICH Study Tagging File (STF) specification, v2.6 (v2.2 and v2.0 DTD) - FDA Implementation
- Regional Specifications:
 - Canada (CA) - v0.9 and 1.0
 - Europe (EU) - v1.0, 1.1, 1.2.1, 1.3 and 1.4
 - Japan (JP) - v0.1 and 1.0
 - USA (US) - v2.01
 - Swiss (CH) - v1.0.1
 - Taiwan (TW) - v1.0



Datafarm VUE "Current" view

FEATURES

• Easy to use User interface

- Intuitive visual indicator in the Table of Contents for lifecycle operations and status
- Easy access to lifecycle history and document properties
- Simplified lifecycle operation
- Visual indicators for cross-referenced documents along with detailed report

• Performance and Portability

- Allows users to open eCTD application with 100s of sequences instantly

- Builds the Table of Contents on-the-fly based on the sequences selected
- Intelligent caching, filters and refreshing techniques reduce loading time dramatically
- Runs as a standalone desktop application as well as on Citrix or Terminal server environment

• Multi-tab Table of Contents

- Current View
- Cumulative View
- Sequence View
- Folder View



- **Customizable Display Panels**
 - Document Viewer with Multi-Documents Display option
 - Administrative/Envelope View
 - Cross Reference Details
 - Properties Panel (Leaf/Section/STF/Node Extension)
 - Lifecycle Details Panel
 - Offline Content Details Panel
- **Filters – options to subset the submission content**
 - Country (EU only)
 - Discipline
 - Module
 - Submission Activity
- **Search**
 - Leaf metadata
 - Section metadata
 - Administrative Information
 - STF and Node Extension metadata
- **Offline Viewing**
 - Downloads documents from the server to your local hard drive for offline viewing
 - Built-in offline document management capability
- **Other unique features**
 - Create a new submission sequence from the current view.
 - pTOC - Create a Word and PDF version of the TOC with links and bookmarks from any view.

The screenshot shows the 'Search' window with four main sections:

- Search - Documents (Leaves):** A table with columns 'Name' and 'Value'. The row 'Title' has the value 'Study*'. Below the table is a large empty area for search results.
- Search - CTD Sections (ICH XML):** A table with columns 'Name' and 'Value'. The row 'Indication' has the value 'X*'. Below the table is a large empty area for search results.
- Search - Regional Administrative Section:** A table with columns 'Name' and 'Value'. The row 'Submitted Date' has the value '01-01-2009'. Below the table is a large empty area for search results.
- Search Options:** A text box explaining that the search uses a cumulative view. It includes radio buttons for 'Selected Activity' and 'All Submissions' (which is selected). Below that, it asks for a search method with radio buttons for 'All ("and" condition)' and 'Any ("or" condition)' (which is selected). At the bottom are buttons for 'Clear All', 'Clear', 'Search', and 'Cancel'.

Datafarm VUE Search

Datafarm also offers enterprise-level solutions that are suitable for company-wide or global deployment. Datafarm's eCTDViewer® Web Edition provides role-based security as part of its enterprise-level capabilities for viewing submissions. This Web-based application supports both eCTD and Non-eCTD submissions (NeES).

TRUST IN A PARTNER THAT DELIVERS – eSUBMISSIONS MADE EASY

Datafarm approaches each client as a partner to create the optimum solution for each specific business challenge. With more than a decade of experience in eSubmissions software and services, Datafarm has partnered with hundreds of life science companies to help ensure compliant eSubmissions. Whether the organization needs software, services or a combination of the two, Datafarm will help design a comprehensive, cost-effective solution.

ABOUT DATAFARM

Established in 1997, Datafarm is a world leader in high performance electronic solutions for the Life Sciences industry. Datafarm's open, modular technologies and professional services experts enable Life Sciences companies to meet the strict standards of regulatory authorities across the world, helping them achieve quality, accuracy, and compliance to efficiently deliver regulatory reports and submissions. Datafarm has helped hundreds of sponsor companies compress the regulatory submissions approval process, improving speed to market, cost control and productivity in order to achieve their ultimate goal of ensuring patients' and physicians' timely access to new drugs.

As a total solutions provider, Datafarm employs some of the industry's pioneers in document-based software development as well as world renowned life sciences regulatory specialists who proactively work with customers and business partners to drive new initiatives and maintain a market lead approach to development and services.

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