

eCTDViewer® Web Edition

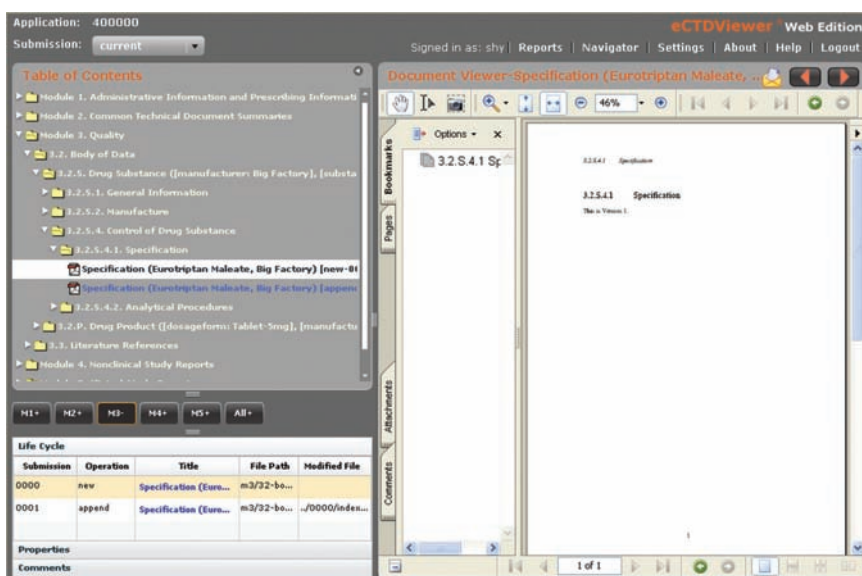
A Scalable, Cost-Efficient Solution for Global eCTD Viewing

eCTDViewer Web Edition is simple, easy to use, scalable, and appropriate for companies of all sizes. This cost effective solution uses industry standard web browser applications, such as Internet Explorer®, Firefox®, Google Chrome™ or Safari®, and can significantly reduce the cost of deployment and on-going ownership. End users can be assigned with permissions to review electronic Common Technical Document (eCTD) and Non-eCTD electronic Submissions (NeES) applications and submissions from anywhere.

eCTDViewer Web Edition provides the following features and capabilities:

PERFORMANCE & SCALABILITY

- Intelligent cache mechanism, offering instant display of the table of contents from large applications with 100s of submission sequences
- Indexed content ensures fast effective searching for content across the collection of applications
- Scalable architecture, enterprise application that scales to a large user base, achieved through application server cluster
- Database replication achieves optimal performance for global operations with user base in several countries utilizing a single repository



NAVIGATION AND VIEWS

- Table of Contents: Current, Cumulative and Sequence views
- Integrated Document display supports all types of documents*
- Document Lifecycle display
- Document Properties display
- Powerful and fast search for metadata and content
- Administrative Information display

USABILITY & EFFICIENCY

- User friendly
- Integrated commenting (annotating) capability
- Multiple reports
- Easy to deploy
- Easy to maintain
- Multi-language support

TECHNICAL

- Zero footprint client
- Browser based/HTML/Adobe® Flex® Builder™
- Windows and Java
- Adobe® Acrobat® Reader® support

* Associated application(s) are required on the client system to view those documents.



COMPLIANCE

- eCTD
 - ICH, USA, European Union, Canada, Japan, and Taiwan
 - Study Tagging Files support
 - SPL and PIM support
 - Node extension support
- Non-eCTD electronic submission (NeES)
 - Any type of electronic submission

SECURITY

- Application level security
- User groups – applications can now be restricted to individual users or groups of users
- Roles – reviewer/administrator

APPLICATION MANAGEMENT

- Flexible and easy to use application administration features
- Add/edit/delete applications
- Add/edit/delete submissions
- Enable/disable applications/submissions
- Manage content indexing
- Manage auto update and auto load of new and updated submissions
- Manage notification associated with the Commenting features

Submission Number	Details	Comments	Date	Status	Select
0000	View		12/04/2006	Active	<input type="checkbox"/>
0001	View		12/05/2006	Active	<input type="checkbox"/>
0002	View		12/06/2006	Active	<input type="checkbox"/>

Application Management

eCTDViewer Web Edition is built based upon recognized technology standards such as Adobe® Flex® Builder®, HTML, XML, and JAVA. This combination of cross-platform technologies makes the application easy to deploy on a Windows server and allows it to support, Oracle® WebLogic and Apache Tomcat. Using a standards-based approach, Datafarm makes it possible for any organization, regardless of size, to seamlessly incorporate this application into their existing environment.

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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