

S-Cubed[®] NeeS MODULE

Many agencies across the world accept or require PDF-based electronic submissions. In addition to the eCTD format, NeeS is widely accepted by many of regional, European agencies.

S-Cubed NeeS enables production of any type of PDF-based electronic submissions. These submissions include a PDF-based table of contents for navigation of the submission content. With customizable templates, users can design submission structure from scratch or modify one of the supplied templates. S-Cubed NeeS module includes templates for ACTD, vNeeS, and the ICH E3 Clinical Study Report. In addition to its versatile submission creation capabilities, S-Cubed NeeS extends user capabilities by providing the additional Report Level Publishing (RLP) feature. With the RLP feature, users can build clinical study reports in both granular as well as single document formats along with the required table of contents.

The following highlights some of the features and functionalities of S-Cubed NeeS:

PUBLISH

- PDF rendition from various source formats e.g. Microsoft[®] Word[®]
- PDF publishing, including bookmarking, hypertext linking, headers, footers, watermark and etc.

COMPILE

- Define structure of submissions using customizable templates
- Populate submission ready document into submission using submission Table of Contents (TOC)
- Create PDF TOC for submission navigation
- Perform post-compilation PDF publishing tasks
- Review content

VALIDATE

- Validate for PDF-related items such as links and bookmarks

S-Cubed[®] PUBLISHER

S-Cubed Publisher enables the production of paper dossiers from electronic dossiers that include both eCTD and NeeS formats. The creation of printer-ready paper volumes is provided through an intuitive, multi-agency compliant, web-based interface.

S-Cubed Publisher delivers significant benefits to organizations by allowing retention of the electronic submission process and the benefits associated with it while being proficient in delivering a paper dossier - all from a single source. Preparing submissions in an electronic format today offers many cost efficiencies, and when those agencies currently requiring paper are ready to accept electronic submissions, organizations can take advantage by being prepared for both requirements.

The following highlights some of the features and functionalities of S-Cubed Publisher:

- Create paper dossiers from existing eSubmissions (eCTD or NeeS)
- Automatically paginate, include tab sheets, slip sheets and organize content into volumes
- Automatically create TOCs at multiple levels (module, volume, dossier)
- Create custom paper dossier settings for future use
- View changes online as they are implemented
- View and approve virtual paper dossier before producing paper
- Produce print ready Postscript/PDF volumes with Xerox Docu Tech[®] compatible job tickets

ABOUT DATAFARM

Established in 1997, Datafarm is a world leader in high performance electronic regulatory submission 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.

GLOBAL LOCATIONS:

Corporate office:
Marlborough, MA, USA
+1 508 624 6454
info@datafarminc.com

North America:
San Diego, CA, USA
+1 858 453 5256
wc@datafarminc.com

Philadelphia, PA, USA
+1 610 914 2146
pa@datafarminc.com

Europe:
Slough, England
+44 (0) 870 774 4298
uk@datafarminc.com

Paris, France
+33 (0) 1 56 60 50 22
eu@datafarminc.com

Asia:
Bangalore, India
+91 (0) 80 3290 3619
in@datafarminc.com

Japan:
Tokyo, Japan
+81 (3) 4580 1744
jp@datafarminc.com

S-Cubed[®]



A MULTI-REGIONAL REGULATORY SUBMISSIONS SOLUTION



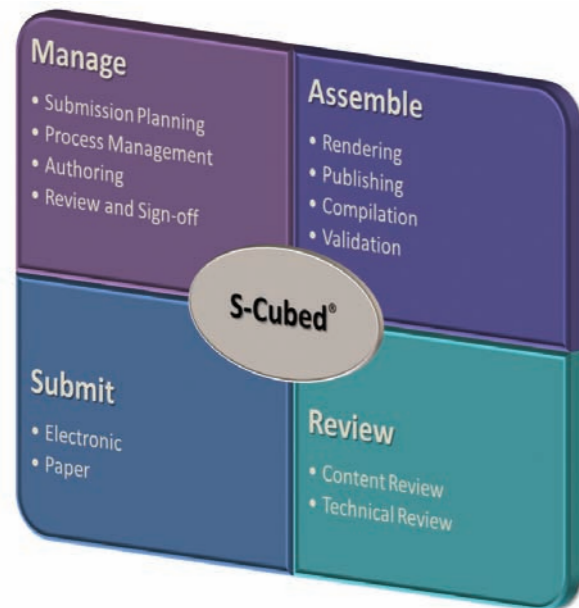
S-Cubed®

AN END-TO-END SOLUTION FOR REGULATORY SUBMISSION PRODUCTION

The challenges facing regulatory operations teams continue to evolve and become increasingly complex. Many health authorities have announced their intent to migrate to a full electronic submission process,

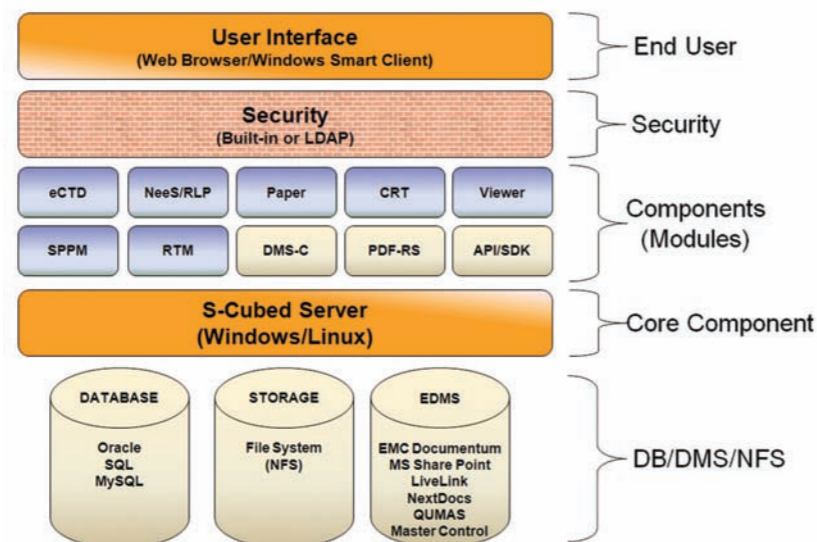
while others are still entrenched in a paper submission process. In this transition phase, pharmaceutical companies could be faced with creating different submission formats such as eCTD (Electronic Common Technical Document), NeeS (Non eCTD Electronic Submissions), ACTD (ASEAN Common Technical Document), vNeeS (Veterinary NeeS) and Paper. At times, companies may be required to submit both electronic and paper formats to meet regional requirements.

S-Cubed conforms to all current regulatory agency requirements, as stipulated in the eCTD guidelines and specifications, and supports NeeS format standards including ACTD and vNeeS. S-Cubed can produce paper-based regulatory submissions from eCTD or NeeS formats. S-cubed includes built-in capabilities to support upcoming HL7/RPS (Regulatory Product Submissions) submission standards. With role-based security, submission and process management, validation and review capabilities, S-Cubed is an end-to-end solution for the entire regulatory submissions process.



INDIVIDUAL MODULES, INTEGRATED SOLUTION

S-Cubed is a collection of individual software modules integrated to provide a complete solution offering comprehensive publishing, compilation, review, printing, submission planning, process management and registration tracking capabilities for companies of all sizes.



S-Cubed® TECHNICAL OVERVIEW

Supporting multiple standards and formats such as eCTD, NeeS, ACTD, RPS and others, and with multi-language support, including English, French and Japanese, S-Cubed requires a minimal number of specialized tools (such as a database and Web server), thus allowing organizations to leverage existing systems.

S-Cubed supports Apache Tomcat, Oracle® Web Logic and IBM® WebSphere® web servers and MySQL, Oracle and Microsoft SQL Servers for databases. The security options include role-based security at the application and submissions level and can be deployed using LDAP or built-in security models. S-Cubed also includes integration with leading Electronic Document Management systems such as EMC Documentum, OpenText ECM, Microsoft SharePoint, NextDocs, Qumas and MasterControl.

S-Cubed® eCTD

S-Cubed eCTD module conforms to the current International Conference on Harmonization (ICH) and regional requirements for delivering eCTD submissions to the US, EU, Canada, Japan, Switzerland and Taiwan regulatory agencies. S-Cubed eCTD includes extensive multi-agency specifications and validation rules to ensure that the eCTD submissions are compliant in the most effective and efficient manner.

S-Cubed eCTD is based on a simple and flexible process model that offers intuitive solutions to diverse business needs at each process level, increasing efficiency and reducing preparation time. Based on the end users specific business and functional needs, S-Cubed eCTD is designed to work as a standalone module or with other modules.

S-Cubed eCTD applies intelligent and automated business logic that help end users immediately see return on their investment, reduced time to deliver mission critical submissions and can be implemented quickly and easily.

