Increase the speed and efficiency of regulatory submissions and shorten submission cycles with Publisher — the most powerful submission tool on the market.

Product at a Glance
Publisher is the cornerstone of a suite of regulatory submission products. Publisher can help biopharmaceutical companies manage the multicountry submission process and publish, manage and validate submissions in any paper or non-eCTD electronic submission (NeeS) format.

Performance Benefits
- Build intuitive submissions in any paper to non-eCTD format.
- Gain powerful, report-level publishing capabilities through improved table of contents, figures, tables, and listings, as well as enhanced navigation.
- Maximize exclusivity windows by targeting many countries at once from one publication template.
- Realize cost savings through rapid deployment.
- Get global support for emerging markets with robust functionality to support regional requirements.
- Shorten submission cycles by automating and simplifying complex regulatory processes.

How the Solution Works
Although health authorities in regions such as Europe and Asia have announced their intent to migrate to the electronic Common Technical Document (eCTD) submission standard, the timeline is being determined country by country, and the exact format and requirements will vary. For biopharmaceutical companies launching new or existing therapies during this transitional phase, submission of investigational applications in multiple markets is a complicated process, with many countries still accepting only the non-eCTD electronic format or the paper format as the legal basis for submission.

To simplify the technology infrastructure burdens and to increase the speed and efficiency of regulatory submissions, Publisher is built on the Web-based Microsoft .NET Framework. Microsoft .NET’s widely supported, standards-based platform delivers Publisher via a Web connection in a collaborative, highly usable environment.

Publisher works seamlessly within the Regulatory Solutions Suite of submission products: eCTDXPress, Virtual Link Manager, and Submissions Manager. The modular design facilitates easy alteration and expansion of products over time, based on a company’s submission requirements. Components are added via Web-based...
agent servers, with no need to implement new systems and thereby incur further development/maintenance costs. Publisher is available in a software-as-a-service model or a traditional licensing model. CSC has taken a leadership role in the development of standards to advance the biopharmaceutical industry as a whole. The firm is involved in industry groups and is an active member of standards bodies — including the CIP4 organization — to support new publishing standards. In addition, CSC has earned industry certifications such as ISO Quality certifications and is a Microsoft Gold Certified Partner.

Key Features and Functions
Powerful, report-level publishing capability offers (1) flexible structures for the creation of tables, figures, listings, and tables of contents; (2) metadata stamping; and (3) large-scale paper dossier output, including PDF, JDF, and PostScript. Publisher has been upgraded to improve the publishing support of attributes required by regulatory bodies in the United States, Europe, Australia, and Asia to support CTD, ACTD, Generic, Hybrid/NeeS and Reports submissions.

Working alongside eCTDXPress — a solution for creating and managing electronic submissions in eCTD format — companies can significantly enhance productivity gains in what has become an increasingly complex regulatory environment.

Working Simultaneously on Multiple Submissions
The ability to work simultaneously on multiple submissions by creating a Publication Template is a great way for a company to save time when working on multiple submissions with similar formats. In addition to publication settings, a user can create templates that redefine publication structure, sections, tables, headings, and footers. Once a template has been created, Publisher will display the template in the virtual folder structure. Whenever a new publication is created, the user has the option to apply the template attributes to the new publication. Publications can be created easily for annual reports, study reports, NeeSs, and more.

Publisher Guides Users to Smooth Non-eCTD Submissions
- With its increased automation and electronic capabilities, Publisher eliminates or eases manual processes and duplication of work, such as document compilation, reviews, data entry, publishing of attributes such as tables of contents, bookmarking, and hyperlinks.
- Publisher's intuitive user interface has the look and feel of a desktop application with common metaphors such as outline structures. The interface can be customized to suit preferences, layouts, and regional non-eCTD settings. Built-in templates, tools, and automatic updates of multicountry requirements are included.
- Integration with document management systems such as Microsoft SharePoint Server provides users with greater control over regulatory content and access to powerful features, including the abilities to automate non-eCTD building processes, to control information rights, and to easily manage and publish metadata in any paper or electronic submission format.
- No more starting from scratch: submissions for one drug or one country can be reused and edited for another drug or another country.

Meeting NeeS Requirements
Companies can meet the NeeS and paper requirements that are still business critical to European customers. New functionality highlights include:
- Automatic creation of tables of contents with the appropriate entries to conform to NeeS guidance; also offers increased flexibility in the creation of paper output
- Document-level scaling control for flexibility in output creation, specifically for paper output
- The ability to process virtual bookmarks and hyperlinks — a feature that will assist publishing teams with creation of compliant navigable electronic output
- A bolstered XML-parsing engine that enhances eCTD import capability in order to simplify the transition from a full eCTD to NeeS format — particularly important to organizations using document management systems

Maximizing an Exclusivity Window by Submitting Simultaneous Applications
- Companies can work on multiple submissions with either identical or different formats — from one application. CSC can install all applications on one box, and it will process multiple non-eCTD submissions at the same time. Publisher automatically updates and adjusts file names based on regional requirements for NeeS formats or paper formats.
Submission dossiers for one country can be cloned quickly and easily for other countries via a seamless transfer of data, links, and formats from one submission to another. The dossier can be easily adapted by local operating companies.

SharePoint Server offers a central platform for global collaboration with all of the stakeholders involved in the development of a compound. Users have full access to SharePoint collaboration tools to work on submissions 24 hours a day.

Gain one global view of all submissions across regions with a single tool.

**Powerful, Report-Level Publishing Capability**

Publisher is not just for regulatory submissions; it’s for other professional publication-ready documents as well. Create documents such as annual reports, business plans, white papers, and report-level publishing.

Publisher is the most powerful publishing tool on the market. Its performance has been enhanced to improve such publishing attributes as table-of-contents generation, volumization, and custom publishing.

Users can easily generate tables of contents, tables, listings, and figures from within Publisher. There is greater functionality for report-level publishing specific to the requirements of individual countries and regions.

Enhanced attribute mapping carries document-management-system attributes in publication outline.

Users can queue documents directly to other CSC submission products and tools for enhanced options. Easily Upgrade to eCTD Submissions

A company can purchase Publisher as an end-to-end solution along with the other products in the suite, or as a standalone application. As business requirements change or the network or user base grows, the company can easily add on other regulatory products to scale its submission solutions over time.

To accommodate the need to submit to any country in eCTD format, a company can easily upgrade and combine Publisher with CSC’s eCTDXPress to create, publish, manage, and validate multimarket eCTD submissions.

**Better Global Submission Support**

Publisher’s performance has been improved to increase functionality on a global level, including global collaboration through SharePoint Server and 24 language versions.

Publisher is updated automatically as regional submission guidances change, with no user action required and without the need to install and qualify expensive software patches.

Performance upgrades have been made to support report-level publishing requirements for U.S., European, Australian, and Asia Pacific non-eCTD submissions.

Publisher has the proven ability to support the publishing requirements of large-scale paper submissions to emerging countries.

**Publisher: Best Performance for the Price**

A Web-based system architecture makes multiregional or global deployments of Publisher easier to use and less expensive than other, traditional applications because it eliminates installation and maintenance.

Shared functionality across Publisher and other regulatory products reduces the installation footprint when a company adds other components.

Publisher’s standards-based, Web architecture reduces the complexity and cost of typical infrastructure design and enables users to integrate with other document management systems — such as EMC Documentum, Microsoft SharePoint, and Open Text Livelink — to lower the total cost of ownership.

Publisher lowers deployment costs by reducing the validation time in Implementation Qualification (IQ) and Operational Qualification (OQ).