

S-Cubed[®] Templates

Start Authoring the Right Way

THE PERFECT STARTING POINT

Medical Writers and Regulatory Affairs Specialists can start authoring the right way by using Datafarm's S-Cubed Templates designed with formats based on the Common Technical Document (CTD) Module 1 through Module 5, Investigational New Drug (IND), or the Clinical Trial Application (CTA). Conforming to regulatory guidelines, Datafarm's S-Cubed Templates deliver the perfect starting point to write structured, compliant submission content.

Designed by experienced regulatory professionals, easy-to-use S-Cubed Templates reduce the time manual formatting requires, allowing end-users to create consistent, industry compliant documents without the need for extensive in-house training.

FOCUS ON CONTENT NOT FORMAT

Specifically designed for authors, S-Cubed Templates come with preset heading styles including CTD numbering, tables, guidelines, and instructional notes, allowing end users to focus on the content rather than the formatting.

The S-Cubed Templates' customized toolbars support both Microsoft® Word® 2003 and Word® 2007. Complete with Word 2007 ribbon support, heading styles, numbered lists, table formatting, symbols, and many other features, the toolbars enable users to create well formatted documents at the touch of a button. In addition, the toolbars comply with industry guidelines helping ensure users work in accordance with their organization's standard operating procedures.



The S-Cubed Template Customized Tool Bars.

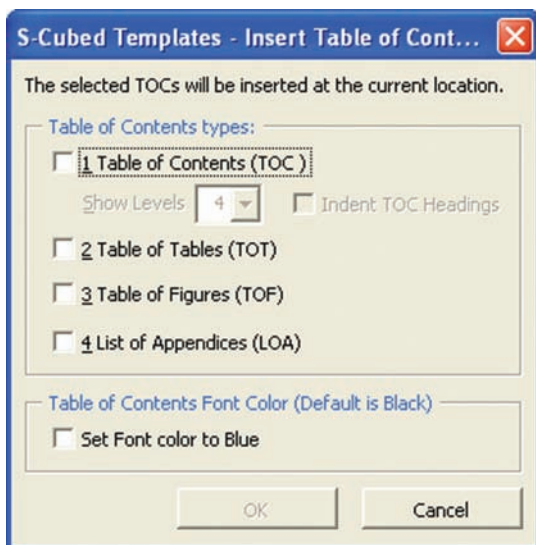
EDIT QUICKLY AND EFFICIENTLY

Changing document properties can be time consuming and can often lead to vital information being invalid or omitted, thus causing serious validation issues. With a single entry into the document properties tool, users can accurately change important information, such as product name, dosage form, and study name, throughout the entire document.



CREATE A TABLE OF CONTENTS IN SECONDS

The S-Cubed Templates' Table of Contents tool is a simple and efficient way to create consistent formatting in seconds. With the ability to automatically create a table of



Quick and Easy Table of Contents Creation.

contents, this feature reduces the manual effort usually required, allowing users more time to ensure the content is correct without having to worry about the formatting.

Users simply fill in desired options and build tables with a consistent, compliant format.

CREATING TABLES HAS NEVER BEEN EASIER

Content authors can spend hours editing tables, ensuring that the font size conforms to the ICH standard requirements, without getting the desired results. The S-Cubed Templates' Tables Toolbar makes it easy to fill out all aspects of a table, including the

ENSURING FORMATTING CONSISTENCY

A major concern to most authoring groups is formatting consistency. The S-Cubed Templates' simple-to-use numbering list feature allows users to quickly set numbering styles and ensure that all authors conform to the same numbering sequences.

1. Numbered List
 - a. Alpha List
 - Bulleted List
 - i. Roman List

EASILY COMBINE MULTIPLE SOURCES

When creating a single document based on a variety of individually authored components, there can be many different formats that need to be integrated. Datafarm's S-Cubed Templates help users easily manage unformatted text from different sources using the "paste unformatted text" function. When importing text from another source into the working document, S-Cubed Templates adopt the current document's format. This ensures that all text is formatted consistently so that the document appears to have been written by one author.

S-CUBED® - WHEN IT IS THIS EASY AND EFFECTIVE, WHY CHOOSE ANYTHING ELSE?

S-Cubed Templates are part of the S-Cubed suite of software that integrates to provide a complete electronic submission solution. The S-Cubed suite includes state of the art modules that deliver comprehensive authoring, publishing, compilation, review, printing and complete lifecycle management of the submission throughout the entire drug development process. Datafarm partners with all clients utilizing S-Cubed and will help ensure that regulatory affairs delivers compliant applications to the global regulatory agencies today and in the future.

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.

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