

Omnicia Announces the Release of OmniTemplate™, an Innovative CTD Authoring Package

October 12, 2005—Omnicia, Inc., a leader in submissions publishing software and consulting services, introduced the latest addition to its product offering: OmniTemplate.

OmniTemplate is specifically designed for BioPharma authors who create critical regulatory submission documents based on the ICH Common Technical Document specifications.

OmniTemplate increases document creation activity through its innovative approach to the overall management of Microsoft Word documents and templates. OmniTemplate not only reduces the amount of time spent creating and formatting documents, it reduces the arduous task of managing hundreds of templates, allowing authors and publishers to concentrate on document content and format.

OmniTemplate is an authoring package that can be customized to fit your company culture. It comes with a Master Template, that governs the basic design and structure of the documents, and also includes toolbars and pull-down menus for easy access to automated MS Word features.

OmniTemplate includes a Master Style Guide—a user’s manual for creating well-formatted documents and Content Templates for authoring eCTD, eNDA/eBLA, eIND, 510K, PMA, Amendment, Supplement, Report, Protocol, IB, and SOP documents.

OmniTemplate comes with time-saving tools to simplify formatting tasks: auto-generation of overall Tables of Contents, Lists of Tables, Figures, and Appendices; creation and splitting of tables; auto-insertion and conversion of landscape/portrait pages, auto-conversion of US Letter-sized paper to A4 and vice versa; application of pre-defined styles, and much more.

When it comes to the CTD, any company or vendor with enough time and money can build the hundreds of individual templates necessary to comply with the ICH CTD granularity requirements. Based on our years of experience in the industry, we realized a different approach was required. Thus, OmniTemplate contains only ONE template while meeting ICH CTD specifications. This means ONE template to install, maintain, and secure, instead of HUNDREDS.

“With our direct experience in publishing submissions and working closely with authors, we had an edge on our competition,” said Reuben K. Jenkins, President and CEO of Omnicia. “Our product makes not only preparing a CTD easier, but management of the entire process simpler to control.”

“We leaned hard on our development team’s decades of combined experience in desktop publishing and preparing submissions, including CTDs and eCTDs, for the US, Canada, and EU,” said Peachy Dimanlig, Chief Operating Officer. “Being the first wasn’t our goal. We wanted to design and build a truly useful, manageable tool, not a concoction of retro-fitted templates with new packaging.”

Omnicia was founded in October of 2001 and is a privately-held corporation. After working for years as the publishing team for a major pharmaceutical company, the founders decided that less costly, more efficient systems and products were needed in the submissions publishing arena. By combining professional services and product software development, Omnicia was able to continue to stay close to the changing needs of its clients while applying the “lessons learned” to improving its product offering. For details on Omnicia’s products and services, please visit our web site at www.omniciainc.com.