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■ Does your authoring process
■ produce electronic submission-
ready deliverables?

Unifying **Clinical Data** and **Submission Strategy**
for the **Global Life Sciences Industry**

Breakthrough Outsourcing

World-Class Consulting

Game-Changing Software



Octagon
Research Solutions, Inc.[®]
Don't **Compromise.**

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StartingPoint[®]

Implementing document authoring standards can be a daunting task, even for the most savvy word processing professional. Emerging global standards, such as the eCTD (electronic Common Technical Document) are not simple and require a professional level of automation and intelligence. If your organization creates well-styled source documents early in the process, recurring time and resource savings appear throughout the entire submission development lifecycle. Conversely, if you don't implement authoring standards, the entire process becomes flawed resulting in increased costs of authoring, review, publishing and reuse.

Octagon's commitment to optimizing processes and minimizing rework is evident in its global submission document authoring template suite, **StartingPoint**[®]. StartingPoint enables rapid deployment of authoring standards across functional areas to facilitate efficient authoring of all components of the eCTD. Templates include instructional text from the International Conference on Harmonization (ICH) guidance documents as well as automation of frequently used authoring functions.

Over 240 separate content templates enable authors to work at the granular level required to support eCTD.

StartingPoint simplifies the authoring process by providing:

- Predefined heading styles, fonts, margins and table formats
- Support for auto-numbered heading styles, which facilitate author cross-referencing tasks
- Quick access buttons for commonly used tasks such as inserting captions, cross-references and symbols
- A Document Validation button that helps authors quickly identify invalid styles, fonts and many other formatting errors
- A Document Information button that enables authors to quickly populate information they use repeatedly in a document, e.g., Manufacturer or Indication
- A global configuration file that allows an administrator to pre-configure document information values that apply across multiple documents, such as Sponsor Name, thus ensuring consistent naming
- A suite of over 240 content templates for the US and Europe (including ANDA submissions), each relating to a specific CTD section, with instructional text that can be turned on or off at will
- Extensive automated table functionality, including easy insertion and management of table footnotes
- Physician Labeling Rule (PLR) functionality allowing for flexibility to formatting full prescribing information into a one or two column format allowing authors to edit in a single column, but produce two column format for final deliverable

The latest version of StartingPoint includes:

- Enhanced Document Validation functionality, including:
 - An expanded list of errors that are highlighted
 - A new 'Report Generation' mode that enables the user to generate a comprehensive report of all errors found in the document
 - A 'Replace All' feature allowing replacement of all instances of erroneous styles with one button push
- Significantly improved document reformatting support, with a 'Replace Styles' button that allows the author to map and convert each existing non-StartingPoint style in a document to a specified StartingPoint style
- The ability to convert existing text, tables and figures from portrait to landscape orientation
- Substantially improved documentation, including a new Administrator and Super User Manual, plus 'Frequently Asked Questions (FAQ)' available from within MS Word
- Several new and enhanced content templates, including:
 - 1.2 Reviewer Guide
 - 1.16 Proposed Risk Evaluation and Mitigation Strategies (REMS)
 - 1.16 Risk Evaluation and Mitigation Strategies (REMS) Supporting Document

Octagon understands the challenges of implementing organizational global authoring standards. We also understand how the implementation of such standards can become a catalyst for change. Initial training, user guide and validation support documents are included.

For more information, please visit www.octagonresearch.com or **contact us** at 610.535.6500.

www.octagonresearch.com

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EDC OPERATIONS: Mountain View, CA

EU HEADQUARTERS: London, UK