

A large, stylized green chevron graphic pointing to the right, composed of two parallel lines that meet at a point on the right side.

High performance. Delivered.

Submission Authoring Templates StartingPoint

StartingPoint allows rapid deployment of authoring standards across all functional areas to facilitate efficient formation of submission documents.

Accenture Life Sciences
Rethink Reshape Restructure...
for better patient outcomes

Accelerated R&D Services
The Science of Getting Products
to Patients Faster

Business Problems and Challenges

Implementing document authoring standards can be a daunting task, even for experienced professionals. Global standards, such as the Common Technical Document (Paper CTD or eCTD) are complex and require a significant level of automation and expertise. If you do not implement authoring standards from the onset, the entire process can be flawed, resulting in increased costs associated with authoring, review, publishing and reuse of submission documents.

StartingPoint Submission Authoring Suite

To help fulfill this critical requirement, Accenture has harnessed its submission experience to offer StartingPoint, which is a collection of standardized content templates and custom authoring & formatting functions that facilitate the efficient creation of submission-ready regulatory documents that comply with all ICH and regional structure and formatting requirements.

The StartingPoint product reflects our deep domain experience working with document authors as well as working on an estimated 450 major planned submissions and an estimated 30,000 life cycle maintenance submissions.

StartingPoint eases the user experience by automating both the complex as well as routine word processing tasks. The suite improves the entire authoring process by providing tools to help ensure the quality of the structure and format of the document at any point in the process.

With StartingPoint, life sciences organizations can leverage authoring standards to create quality and consistently formatted source documents early in the submission lifecycle, have their authors focus on creating content, minimize rework and optimize time-critical processes, while keeping pace with industry change.

StartingPoint Capabilities

Advantage and Benefits to Sponsors/Users

Over 450 content templates	CTD Templates for US, Europe, and CA which have been created and developed with industry Best Practice in mind Medical Device templates (includes templates for IDE, 510(k), PMA, PCA, E. C. Technical File, and CSDT)
Step-by-Step Instructional text – from ICH and regional Guidelines	Templates come with step-by-step instructional text to establish alignment with ICH and regional guidelines
Sample text from our Regulatory Affairs group	Suggested predefined text, suitable for submissions based on our long history as a Regulatory operator
Automated creation of navigational aids	Helps publishing tools to automatically create bookmarks and hyperlinks in the PDF version of documents Helps reduce the arduous task of manually creating agency-required electronic navigation aids for an electronic submission
Predefined Heading Styles, Fonts, Margins and Table Formats	Establish a consistent look and feel across all submission documents
One common toolbar on the Microsoft® Word Ribbon	Assists with the execution of commonly used tasks such as inserting captions, cross- references, landscape pages and symbols
Physician Labelling Rule (PLR) Functionality	Allows authors to edit the Full Prescribing Information in one column format and produces the Highlights section in two column format for the final deliverable
Document Information Fields	<ul style="list-style-type: none">• Allows values to be utilized across multiple templates to establish consistency of content throughout all created documents.• Allows an Administrator to pre-configure document information values that apply across multiple documents, such as 'Sponsor Name', establishing consistent naming conventions
Automated Table Functionality	Easily generates new tables, including easy insertion and management of table headings and footnotes across multiple pages
Document Validation Functionality	<ul style="list-style-type: none">• Helps authors to quickly identify and fix invalid styles, fonts and many other formatting and submission compliance errors• Includes report generation mode that enables users to produce a comprehensive report of all errors found in a document• 'Replace All' feature allows replacement of all instances of erroneous styles with one keystroke
Document Reformatting Support	'Replace Styles' function that allows authors to map and convert each existing non-StartingPoint style in a document to a specified StartingPoint Style
Reference Building	Establishes the ability to build and maintain a literature reference section within a template, as well as create in-text citations
Documentation Support	<ul style="list-style-type: none">• Administrator and Super User manuals• Real-time technical support and training available• Help and FAQ available from within Microsoft® Word

Contact us

For more information about how Accenture is helping companies increase R&D effectiveness and efficiency, please visit www.accenture.com/lifesciences or contact:

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About Accenture

Accenture is a leading global professional services company, providing a broad range of services and solutions in strategy, consulting, digital, technology and operations.

Combining unmatched experience and specialized skills across more than 40 industries and all business functions—underpinned by the world's largest delivery network—Accenture works at the intersection of business and technology to help clients improve their performance and create sustainable value for their stakeholders. With more than 394,000 people serving clients in more than 120 countries, Accenture drives innovation to improve the way the world works and lives. Visit us at www.accenture.com.

About Accenture Life Sciences

Accenture's Life Sciences practice is dedicated to helping companies rethink, reshape or restructure their businesses to deliver better health outcomes and drive shareholder returns. We provide consulting, outsourcing and technology around the globe in all strategic and functional areas—with a strong focus on R&D, Sales & Marketing and the Supply Chain. We have a long history of working hand in hand with our clients to improve their performance across the entire Life Sciences value chain. Accenture's Life Sciences practice connects more than 10,000 skilled professionals in over 50 countries who are personally committed to helping our clients achieve their business objectives and deliver better health outcomes for people around the world.