



Authoring Templates Created *By* Writers *For* Writers



Key Benefits

- Create compliant submission-ready documents consistent in presentation and appropriate in content the first time around
- Reduced internal delays and review periods
- Updates as per new guidance
- Onboarding and training, including manual practice guides
- Technical support

A Springboard to Submission Success

Creating submission-ready regulatory documents consistent in presentation, appropriate in content, and formatted to be eCTD compliant the first time comes with challenges.

Delays are inevitable when you consider:

- The amount of training authors require to efficiently use Microsoft Word
- The ever-changing ICH and regulatory authority guidance and specifications
- Imminent changes in presentation and formatting compliance as documents develop

To address these challenges, Synchrogenix paired its technical experts with its regulatory writers and editors to create a **comprehensive eCTD Authoring Template Suite, the only template suite created *by* writers *for* writers.**

Synchrogenix's GlobalSubmit eCTD Authoring Templates come preloaded with:

- Proper formatting
- Document granularity
- Agency-specific guidance in hidden text offering expert advice
- Best practices to guide sponsors to a successful submission

Why Choose Synchrogenix's GlobalSubmit Authoring Templates Over the Competition?

Our authoring templates are the **only templates built by regulatory writers for regulatory writers** based on decades of experience planning, writing, and editing hundreds of global submissions. We also ensure compliance by reviewing our templates regularly to ensure consistency with new guidance.

The numerous features included, such as the ability to integrate document changes and incorporate added text in a different color, makes writing tasks much easier to perform and ensures efficiencies between writing and regulatory operations teams.

Spend More Time Writing and Less Time Tweaking

Toolbar

- A specialized toolbar containing symbols and shortcuts makes inserting headings, table of contents, and symbols simple. (Figure 1)
- The toolbar also allows for easy table creation and automatic formatting.

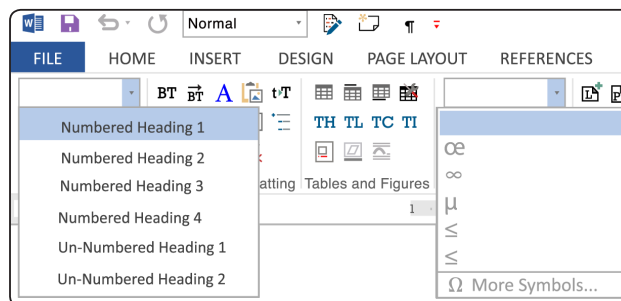


Figure 1

Hidden Text

- Hidden text provides both regulatory guidance, as well as best practices and expert advice from our writers and editors, including interpretations of requirements and strategic suggestions. (Figure 2)
- The hidden text easily disappears with a click of a button.

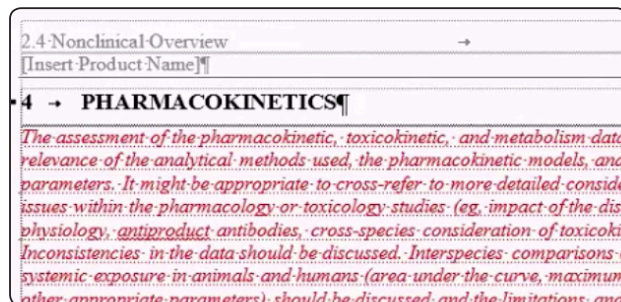


Figure 2

Sample Tables and Text

- Sample tables and standard text are included where appropriate to streamline writing efforts.

Reduce Re-work and Avoid Lengthy Delays

With Synchrogenix's GlobalSubmit eCTD Authoring Template Suite, you can easily create compliant, submission-ready documents consistent in presentation and content the first time around.

Purchase the Suite today to receive:

- 240+ Common Technical Document (CTD) templates and links to forms and other applicable guidance providing the most current information available
- Access to expert advice
- Installation and User guides, onboarding and training, including manual practice documents and individualized Q&A session
- Technical support
- Updates per new guidance
- Peace of mind

For more information, visit our website at www.synchrogenix.com or email contactus@synchrogenix.com.

Synchrogenix - Regulatory and Communications Strategy, Science, and Solutions

Synchrogenix provides regulatory and communications strategy, science, and solutions to life science companies worldwide. Our regulatory expertise and innovative technology bridges the full regulatory continuum to propel treatments to the market by meeting the needs of all stakeholders and improving public health outcomes.