

Octagon Releases Updated **SUBMISSIONS TEMPLATE**



The new release combines user-requested features with other innovative enhancements that will simplify the tedious formatting tasks associated with traditional authoring methods, says John Lawrie, VP of Process Solutions at Octagon.

Octagon has unveiled StartingPoint 2.2, the most recent version of its global template suite that supports global submission standards and incorporates region-specific solutions.

StartingPoint 2.2 template suite facilitates rapid authoring standards across functional areas to assist efficient authoring of all components of the eCTD (electronic common technical document). The software includes instructional text from the International Conference on Harmonization guidance documents, as well as automation of frequently used authoring functions.

"With the recent FDA CDER announcement regarding the withdrawal of three

electronic submission guidances, eCTD submission document authoring, review, and approval processes and standards have become even more critical," says John Lawrie, VP of process solutions at Octagon.

Features of the suite include the addition of EU Content templates for Module 1, and a physician's labeling rule button, which enables the easy generation of the compliant two-column format required by the FDA.

The solution also offers a one-button feature enabling users to toggle between U.S. letter and A4 page sizes without affecting pagination, thus facilitating submission document creation processes for global companies planning to submit in EU and U.S. regions.