

Prolexys Case Study: A “Learn as You Grow” Outsourcing Strategy



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Prolexys Pharmaceuticals, Inc. is a biopharmaceutical company focused on discovering small molecule drugs that act at novel therapeutic targets. The company's therapeutic focus is on cancer and cardiovascular indications. When the Prolexys team decided to begin the transition to the eCTD format for electronic regulatory submissions, they knew their lean, 29-person company would be stressed by the daunting tasks of learning new submission processes while simultaneously implementing new eCTD tools. Rather than forcing the organization into a radical change, Prolexys opted to outsource their first eCTD IND. The team understood that there were new technical or operational components to the eCTD format but also understood that at the end of the day, it was a regulatory submission that deserved regulatory attention. This submission would require a partnership with a full-service organization that offered both Regulatory Affairs and Regulatory Operations support throughout the project.

Prior to beginning the project, the Prolexys team diligently investigated alternatives and recommended the eCTD format to senior management. The team weighed the benefits and risks of an electronic submission compared to a paper submission. Electronic submissions clearly offered reduced cost compared to producing and storing paper as well as immediate, multi-user access to the submission for internal team members. No one was interested in the prospect of managing paper. The biggest risk seemed to be the fact that the team had never created a submission in the eCTD format.

The final decision to submit an IND in eCTD format was based on both short and long-term benefits and the understanding that the company wanted to transition to eCTD at some point in the near future. The team felt that an IND was preferable to an NDA as the first project since the manageable size would give them a chance to learn without the pressure of processing large volumes of information. The risk of this approach was minimized again by the Prolexys team's outsourcing strategy. The team selected Octagon as their submission-outsourcing partner. This strategy enabled them to take advantage of the safety net of Octagon's vast eCTD expertise while also allowing them to use the project as an introduction to the eCTD submission process. By utilizing Octagon's Regulatory Operations and Regulatory Affairs expertise, the risk of missing the submission deadline or submitting in a non-compliant format was negated.

As the project kicked off, the combined Prolexys/Octagon team worked closely to develop a content plan for the submission. They quickly developed processes to support the transfer, review and finalization of submission documents and procedures for addressing any issues that were identified as documents were being processed. The Octagon team quality checked the submission components and identified issues using ViewPoint®, Octagon's enterprise submission process management solution. Once issues were identified, the Prolexys team members were immediately notified through the system and were able to review and respond using ViewPoint's web-based reviewer tool. This issue management process provided instant updates from both teams and the interactions allowed the combined teams to efficiently address issues and process many documents in a short timeframe.


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Because Prolexys wanted to increase their organizational understanding of eCTD, on-the-job knowledge sharing became a very important aspect of this submission project. The initial kick off meeting included formal eCTD training which was reinforced throughout the project with informal discussions concerning the “how and why” of the eCTD structure and meta data. Frequent communication facilitated the sharing of best practices and improved understanding of the subtle nuances surrounding the eCTD submission process.

The final submission was submitted on time and the Prolexys team joined the ranks of competitive companies operating in the eCTD environment in order to gain efficiencies and reduce costs over time. Looking back on the successful completion of the project, *Tracy Erkkila noted, “It was great to collaborate with Octagon as the submission outsourcing partner. The Octagon team members were professional, competent and responded quickly to our requests. The entire experience was positive. I am very glad we chose the eCTD option over paper and now I can't imagine ever going back.”*

Prolexys used this project to leapfrog into the world of eCTD submissions. Their success was based on a methodical evaluation approach, good planning, a strong strategic outsourcing partnership that complemented their internal resources and a strong team vision toward electronic efficiencies. The Prolexys success story is a great example of a “Learn as You Grow” strategy that enabled a small company to make big strides in the transition to eCTD.

Submission Statistics:	
Submission Type:	IND in eCTD Format
Size of Submission:	.88GB
Total Number of PDF Files:	804
Total Number of Hyperlinks:	35486
Total Number of Bookmarks:	33960



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