CERTARA®

CASE STUDY:

Prelude Therapeutics reduces their quality control (QC) process for regulatory submissions from hours to minutes with Certara's GlobalSubmit eCTD Software

In 2019, Prelude Therapeutics, a small cancer drug discovery company, implemented Certara's GlobalSubmit submissions management software for their electronic common technical document (eCTD) submissions. The regulatory team at Prelude Therapeutics is very lean and responsible for more than 30 submissions annually; therefore, the utmost efficiency in publishing, checking the validation criteria, and reviewing eCTDs is required.

The company found that their eCTD publishing process was not agile enough to meet their needs to implement updates quickly to submissions and provided limited reviewing capabilities through a third party. Without eCTD viewing software, they were unable to review the full scope of their submissions, hindering an effective review process. These challenges resulted in the decision to bring on GlobalSubmit eCTD software to make their regulatory submissions process more efficient.

Following the initial in-depth training provided by Certara, user acceptance testing (UAT) and validation, GlobalSubmit eCTD software was implemented into the regular review process. Hyperlinks and bookmarks are seamlessly created, and quality check (QC) is performed quickly and efficiently using the LINK and CROSSCHECK functionality in GlobalSubmit PUBLISH. With GlobalSubmit VALIDATE, more than 200 error conditions are checked, eliminating the risk of technical rejection. As a result, the QC process for each submission has been reduced from hours to minutes, saving their regulatory team considerable time.

> **For a small team that has limited time to compile and double check a submission, GlobalSubmit is a really good platform because it is all integrated, including CROSSCHECK and VALIDATE. So, you know when you generate the submission that it is compliant, and you don't need another tool for validation**
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> **Jessica Pung, MS, RAC**
> Associate Director of Regulatory Operations, Prelude Therapeutics

For other stakeholders involved in the review process, GlobalSubmit WebReview provides a simple, easy-to-use interface to quickly search through applications and approve specific submission content. With GlobalSubmit eCTD software, the team appreciates that they can review the backbone of the regulatory submission, not just the folder structure, and that updates to eCTD requirements are automatically applied to the software and checked in real-time with live validation, eliminating the inefficiencies of finding technical issues. Since implementing GlobalSubmit eCTD software, Prelude Therapeutics has saved a considerable amount of time in their QC process and has become more efficient with their regulatory submissions.

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About Certara

Certara, a global leader in biosimulation, accelerates medicines using biosimulation software and technology to transform traditional drug discovery and development. Its clients include 1,650 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 61 countries.

For more information visit www.certara.com or email sales@certara.com.