

Outsourcing eCTD Submission for a Small Biotech: Helping a Startup Biotech Navigate High-Stakes FDA Submissions



AT A GLANCE

Our client, a small biotech startup, needed to outsource their eCTD submission. The CMO was tasked with identifying a regulatory submission partner capable of delivering high-quality submissions within tight deadlines to maintain shareholder trust and avoid impact to their public reputation.

CHALLENGES

The client's small size meant minimal internal resources for regulatory submissions, but meeting timelines was critical. The CMO had seen how large vendors often lacked responsiveness—but this was an essential element for a small team that relied upon quick and responsive support. What the client needed was flexibility and reliability. Furthermore, they needed a partner in whom they could confidently trust without risking submission failures.

OUR APPROACH

From the outset, eCTD Submit was confident they would deliver—in fact, their co-founder assured the client that eCTD Submit would assume the cost of an alternate solution if the initial submission should fail. The client was granted unfettered access to key team members, including direct contact with the project manager. During document quality control (QC), the Navigator tool coupled with regular quality reviews ensured compliance and accuracy at every step. And with real-time updates and proactive issue resolution, this trust and transparency made eCTD Submit function as a true extension of the client's team.

THREE KEY POINTS

1

Reliable and responsive

Communication in real time created a strong working relationship.



2

Cost-effective and high-quality

Premium submission quality without premium pricing.



3

Integrated team

eCTD Submit acted as a true partner, unafraid to advise or challenge client strategy.

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SOLUTIONS

The security and compliance provided through eCTD Submit's eCTD management system maintained strict adherence to FDA requirements, delivering peace of mind to the client's leadership. And where there may have been gaps in the client's internal capabilities, eCTD Submit's scalable and flexible support model with both submission tools and review processes tightened the QC and submission process to avoid errors. For smaller organizations like the client's, outsourcing your eCTD publisher with eCTD Submit consistently provides a smooth submission process ensuring accuracy and speed while mitigating critical error.

WHO WE ARE

We've managed thousands of successful applications. When you work with eCTD Submit, you experience direct access to trusted experts in eCTD submission. With user-friendly templates, compliant submissions are simple for even first-time users. And you can easily transfer your existing applications into our Navigator system without losing data in transition.


Our clients continue to return to eCTD Submit, even as they move between organizations, a testament to the high levels of trust and satisfaction with our services.



On our high-quality standards and process:

"The quality review process is ongoing on a continuous basis... like a well-oiled machine. They ensure quality is held to a rigorous standard."

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