

48-Hour Turnaround Time: Achieving Faster eCTD Submissions with eCTD Submit



AT A GLANCE

A major cell therapy organization faced the challenge of submitting multiple response documents to the FDA within a very short timeframe following five rapid interactions. Leveraging eCTD Submit's regulatory expertise, efficient processes, and intuitive software, the team delivered flawless submissions in just two days, exceeding the client's expectations.

CHALLENGES

The client needed to prepare a large, complex submission within days after receiving numerous FDA response requests. Typically, submissions of this magnitude take weeks, generating significant anxiety about meeting such an accelerated deadline.

OUR APPROACH

eCTD Submit quickly assessed the project's scope and reassured the client of their ability to meet the deadline. Through seamless collaboration, advanced publishing tools, and expert project management, all FDA response documents were successfully submitted within 48 hours.

The client's feedback highlighted eCTD Submit's efficiency: "Your publishing time is half of what we've experienced with other providers."

THREE KEY POINTS

1

Two-Day Turnaround

Ensure critical deadlines and submissions are completed on time with eCTD Submit's expertise and adaptable solutions.

2

Comprehensive Document Review

Our eCTD NavigatorSM tool ensures efficient document review.

3

Error-Free Quality Control

eCTD Submit's expertise and diligent document review results in accurate submissions the first time around.

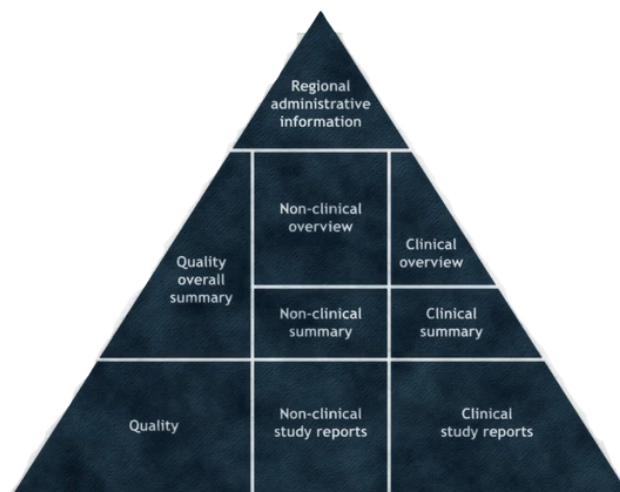


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SOLUTIONS

In this case, eCTD Submit’s ability to handle complex, time-sensitive submissions with ease solidified a long-term collaborative partnership with the client, a testament to the trust and reliability eCTD Submit consistently provides.



WHO WE ARE

At eCTD Submit, our deep experience in eCTD submission publishing avoids the delays and hang-ups that all too often occur with other publishing vendors who struggle to meet short timeframes and sudden deadlines. We’ve managed thousands of successful applications; when you work with eCTD Submit, you experience direct access to trusted regulatory experts and publishers who are able to quickly understand your unique needs.

With user-friendly templates, compliant submissions are simple for even first-time users. And you can easily transfer your existing applications into our eCTD NavigatorSM system. With our intuitive web-based eCTD NavigatorSM, you’ll have immediate access to all your submission documents.

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

CONTACT US TODAY

 +1 973-396-4956

 ectdsubmit.com

 info@ectdsubmit.com