

# A Decade of Reliable eCTD Management



## AT A GLANCE

With a collaborative working relationship spanning over 10 years, this client has utilized eCTD Submit's bespoke eCTD submission services across four different organizations, delivering consistent, error-free FDA submissions at each. The client cites eCTD Submit's unwavering flexibility and thorough quality control (QC) as reinforcing the trust that's only found in a publisher of eCTD Submit's caliber. Finally, eCTD Submit's quality eCTD management system's efficient review process, enhanced communication, and effortless user experience have made it a mainstay for the client.

## CHALLENGES

Prior eCTD publishing vendors had struggled to meet this client's submission needs due to incompatible processes. Impact to the client included high cost, overage fees, and constant delays. As a result of these negative experiences, the client knew exactly what they were looking for: a flexible, and responsive partner, with an intuitive eCTD management system, one that enabled easy document access/viewability and efficient QC processes.

On the cusp of our initial engagement, the client faced tight timelines, thousands of pages, and a long list of last-minute changes to be made before their official submission.

## OUR APPROACH

Working closely with the client, eCTD Submit created a tailored submission plan that balanced flexibility with rigorous quality standards. Our eCTD Navigator delivered seamless, centralized document review capabilities which enabled the client to review their submissions exactly as the FDA would see them and work ahead of potential formatting issues to drive high-quality final submissions and avoid costly delays. eCTD Submit's ability to function as an extension of the client team improved the strategic insight necessary towards staying ahead of deadlines with confidence.

## THREE KEY POINTS

1

### Flexible and Fast Turnaround Times

eCTD Submit consistently meets tight deadlines and adapts to last-minute changes

2

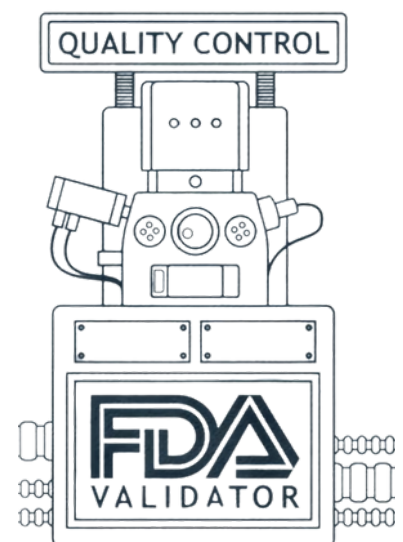
### High-Quality, Reliable Outputs

Commitment to quality, rigorous internal checks, and reduced review burden

3

### Intuitive Navigator Tool

Ease of use, transparency, agency-perspective view



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## SOLUTIONS

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eCTD Submit's quality support and reliable timeframes secured prompt submissions for this client despite the last-minute pressures, avoiding overage fees and keeping their project on schedule. eCTD Submit's deep submission expertise and collaborative focus supported on-schedule submissions even with minimal lead time. The intuitive workflow of the eCTD Navigator tool improved QC processes and empowered client teams to catch and address document errors far ahead of deadline.

The collaboration between eCTD Submit and the client grew into a trusted partnership, and today, the client knows they can always count on eCTD Submit to deliver their submissions on time.

## WHO WE ARE

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


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.



### On the Navigator tool's impact:

*"When I got access to their Navigator, it was kind of like, this is amazing...It gives you exactly what you need and provides you an interface where you can actually access the documents in a meaningful and useful way."*

## CONTACT US TODAY

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