Streamlining Regulatory Submissions: eCTD Submit Enhances Speed and Simplicity

AT A GLANCE

When a client—a Senior Vice President of Regulatory Affairs—transitioned to a new role, eCTD Submit was still his first choice for smooth regulatory submissions. This time, for a quick FDA submission turnaround and accommodation of security requirements, eCTD Submit's timely, high-quality service and user-friendly eCTD Navigator tool once again proved to be invaluable.

CHALLENGES

In the client's previous roles, handling submissions with other eCTD systems had introduced hurdles such as inefficient quality control (QC) processes, slow publishing, and cumbersome tools that hindered real-time communication with the publisher. It was clear that finding eCTD submission experts with a high degree of flexibility and technical expertise was essential to meet tight timelines, especially across multiple time zones.

OUR APPROACH

Throughout their work together, the partnership was built on proactive communication, speed, and user-friendly solutions tailored to specific submission needs. The instantaneous review of key documents enabled through the web-based eCTD Navigator tool was both easy to use and enabled the client to input direct feedback to eCTD Submit. Notified instantly, eCTD Submit responded immediately and the client and eCTD Submit completed the submission without any delays. Additionally, eCTD Submit's flexibility in accommodating the client's unique security requirements enabled the client to use their own hosted solution, which allowed the client to maintain control over their own sensitive files while ensuring their data met regulatory compliance.

THREE KEY POINTS

1 **Time Zone Advantage**
eCTD Submit's East Coast location provides a practical advantage for EU clients: extended workdays and fast turnarounds, with completed documents ready the following morning.

2 **Ease of Use and Real-Time Feedback**
The eCTD Navigator's web-based access and intuitive interface allowed the client to review and provide feedback directly in the tool, avoiding the hassle of offline exchanges.

3 **Reliable Speed and Flexibility**
Exceptional turnaround—delivering hundreds of pages within 2 business days—meant submissions stayed on schedule, even with last-minute changes.

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SOLUTIONS

With eCTD Submit's cloud-based eCTD Navigator tool and responsive eCTD submission experts, this client streamlined their regulatory submission processes by enabling a rapid turnaround time without compromising quality on the client's behalf. The eCTD Navigator tool's capacity for direct feedback online improved collaboration for speedy turnaround, as well. And for data security, eCTD Submit isn't limited to any one solution; the agreed upon security arrangements ensured the client's sensitive data stayed protected and remained in control of by the client's hands. These eCTD submission experts were and still are an extension of the client's team, working to provide the reassurance of high-level expertise at every submission.

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. With our intuitive web-based eCTD Navigator, you'll achieve diligent and complete QC review of all your relevant documents while remaining comfortably within budget.

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 ease of use and real-time feedback:
"You can just literally view things at the drop of a hat... Feedback comments back through the software; I've never seen that in any other software."

CONTACT US TODAY

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