GLOBAL
REGULATORY WRITING & CONSULTING

CASE STUDY

RegOps Submission Project Management: Things aren't always what they seem

Product Type: Initial Investigational New Drug (IND) Submission

Product Life Cycle Stage: Phase 1

We support Medtech and Biopharma innovators with strong, collaborative partnerships, tailored regulatory consulting and writing services, and deep strategic expertise.

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GLOBAL'S MEDICAL WRITING CAPABILITIES

Create and manage timelines for the functional area submission components as well as the overall submission.

Project management including facilitate team meetings to keep team son track towards timelines.

Create and manage **risk registers** and support due diligence activities by performing **inventory and gap assessments** of regulatory files.

Publish eCTD submissions including assembling sections using eCTD - compliant software, performing quality checks of the full submission, and transmitting through FDA's ESG portal.

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ABOUT THE CLIENT

A new client requested publishing services from GLOBAL's Regulatory Operations (RegOps) Team for their Initial Investigational New Drug Applicaiton (IND). The client was up against a tight deadline and only had one week to complete the publishing process.

ABOUT THE PROJECT

During the project scoping meeting, the Submission Project Manager discovered the Sponsor's final documents from their authoring team did not meet eCTD standards. Non-compliance with eCTD standards can increase the likelihood of Information Requests and could put the Sponsor at risk of validation errors or submission rejection. The Submission Project Manager shared the risks of submitting an initial IND with improper formatting and the associated corrective actions that FDA could require. The Scope of Work (SOW) was expanded to include converting their document into a properly formatted FDA-compliant submission and publishing the IND. Although the scope of the SOW significantly increased, the timeline for the project stayed firmly at one week.

REGULATORY OPERATIONS OVERVIEW

Submission Project Management
Our submission project managers work closely with clients to build and manage submission timelines, track source content (e.g., protocols and reports), develop eCTD sections, workflows, and actions, handle issues, facilitate, decisions, and coordinate with eCTD publishers.

eCTD Publishing
Our eCTD publishers will work with the project team to develop submission strategies and ultimately transmit submissions through FDA's ESG portal.

GLOBAL SOLUTIONS

The Submission Project Manager quickly established the project timeline and assembled the GLOBAL project team between GLOBAL's RegOps, CMC and Medical Writing teams. Using our matrix team approach, each department has a lead point of contact and additional team members were staffed to provide support (e.g., additional authors, QC reviewers, etc.).

The success of this submission relied on clear and regular communication. Our project team messaged daily via Teams and scheduled ad hoc meetings to keep momentum going during this fast-paced project. Additionally, the Submission Project Manager provided regular status updates to the Sponsor.

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GLOBAL SOLUTIONS

Ultimately, GLOBAL executed the project using the company's core values.

Collective Intelligence	The Submission Project Manager collaborated with the new client and shared industry knowledge to ensure an FDA-compliant submission.
Agility	One the new scope was known, but the timeline could not change, the team was able to pull in appropriate resources to complete this task.
Inclusiveness	Each functional area at GLOBAL was included in this project to ensure a complete IND was provided to the FDA.
Integrity	GLOBAL was open and honest with the Sponsor as to the time and cost this would take for "all hands-on deck" work to be completed in the one-week timeframe.
Curiosity	GLOBAL learned of this new product and their goals to ensure a streamlined approach and deliverable.
Sanctuary	The GLOBAL Submission Project Manager spoke clearly and confidently about the regulations to the Sponsor and was fully supported by both management and her peers to complete this project.

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OUTCOME

Even against the tight deadline, our project team successfully delivered an FDA-compliant submission to the Sponsor and our Submission Project Manager published the initial IND. The Sponsor was exceptionally happy with the work that the team produced and has continued its partnership with the RegOps Team to publish addition amendments.

CONCLUSIONS

In the drug development process, a sponsor company cannot rely on the innovation of their product alone. Regulatory submissions have legal requirements and failure to comply with eCTD guidance can lead to the need for corrective actions or the submission being rejected.

By leveraging her industry knowledge and experience, GLOBAL's Submission Project Manager was able to help the Sponsor pivot in the direction of compliance with FDA regulations. However, it cannot be overstated how important it is to find and resolve potential validation errors as soon as possible.

CONCLUSIONS CONTINUED

Sponsors should consider implementing a comprehensive submission plan early in their authoring process to maintain regulatory writing best practices and ensure comprehensive reviews are built into their submission timeline.

Additionally, by meeting with the client to fully scope this project, our Submission Project Manager made sure she understood the client's needs and used the meeting as an opportunity for them to align on terminology. When it comes to submission project management, many terms seem interchangeable but are nuanced. This alignment on terminology between publishers and sponsor is important, especially for new biotechs filing their first asset who may not be familiar with the regulatory landscape.

Lastly, the biggest lesson learned is built into the foundation of our company as one of our core values - agility. Regulatory submissions are living documents and timelines, requirements, and clients' expectations can change at any time. Publishers should be prepared to pivot to meet these unexpected changes.

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