GLOBAL
REGULATORY WRITING & CONSULTING

CASE STUDY

Sequence/Serial Numbering for an Initial IND

Project Type: IND Submission

Product Type: Pharmaceutical

Product Lifecycle Stage: Initial Application

GLOBAL'S REGULATORY CMC CAPABILITIES

Regulatory CMC Strategists to help navigate the complex regulatory landscape

CMC Technical Experts to guide process, formulation, and analytical development

Quality Experts to support phase-aligned cGMP compliance

Writers & Document Specialists to author submission-ready regulatory and technical documents

We build and train teams to maximize efficiency and quality.

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ABOUT THE CLIENT

A mid-size pharmaceutical company requested to have an initial IND submitted to the FDA with serial and sequence numbers of “0000”.

The client’s regulatory lead reached out to GLOBAL’s submission manager to request this format, as she noticed the numbering between the company’s submission number and the FDA referenced submission number were not the same. GLOBAL’s submission manager knew that an initial (without previous pre-IND work) Investigational New Drug application required the sequence number to be 0001 and, per FDA Form 1571 instructions, the serial number would be 0000.

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ABOUT THE PROJECT

A company's approach to regulatory submissions is often influenced by their legacy processes. However, FDA regulations and ways of working change over time, and many companies may not realize changes have taken place. Fortunately, Global is here to help!

Prior to eCTD electronic filings, submissions were sent to the FDA with the same details; 0000 would be listed on the cover letter and 0000 would be allocated on FDA Form 1571. After the FDA implemented its electronic filing system, the two were decoupled. This allows for pre-IND submissions to begin with 0001 in the eCTD software when an FDA Form 1571 is not required. This process was widely adopted but often companies push back to keep the numbering the same. To match the numbers, a communication with your regulatory project manager at the FDA is needed.

Submissions to FDA go through their Electronic Submissions Gateway (ESG). Our submission manager had extensive experience with ESG and knew that it is not correct to submit an initial Investigational New Drug application via eCTD with a sequence number of “0000”.

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ABOUT THE PROJECT CONTINUED

Additional review of the FDA's guidance documents and a communication with the FDA revealed conflicting information to the company's policy.

The regulatory landscape for eCTD submissions is ever-changing and complex. After the review of FDA's guidance documents, the submission manager determined that more clarity was needed to help best guide the client.

GLOBAL SOLUTIONS

GLOBAL's submission manager requested that the regulatory lead reach out to the FDA project manager for guidance. Their response indicated what GLOBAL's submission manager had known:

- The eCTD sequence number for an original submission must be "0001".
- The serial number on FDA Form 1571 should be "0000".

This feedback confirmed the importance of clarifying FDA guidance, which will be even more important during the transition to eCTD 4.0.

OUTCOMES

The submission manager educated the project team on the differences between serial number (the number listed on FDA Form 1571) and sequence number (the number given to the eCTD submission).

The initial IND was successfully submitted to the FDA with a sequence number of “0001” and a serial number of “0000,” in compliance with FDA guidance. Since the client’s legacy process was different from this guidance, clear identification of both the serial numbers and sequence numbers was required on both the internal document management system and the accompanying cover letter. The clear identification of the numbers was needed for the initial IND as well as any future IND submissions.

CONCLUSIONS

When it comes to FDA submissions, even what seems like "small" clerical errors can be cumbersome for the submission lifecycle. While it seems unharmonious for the serial and sequence numbers to be different, this follows FDA guidance. Failure to comply with any FDA guidance puts the sponsor company at risk of validation errors or submission rejection. This can ultimately affect timelines and create unbudgeted expenses. Partnering with a regulatory firm with extensive experience and a thorough understanding of FDA guidance and the eCTD regulatory landscape is critical to the success of your submission.

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