Regulatory Operations Support of a Client's First New Drug Application to the FDA

The Situation

DLRC supported a small to medium size Novel Anti-Viral Therapies company by publishing and delivering a full first-time NDA submission to the FDA, executed as a rolling submission across two sequences. The work spanned document publishing, submission build, eCTD submission publishing, and production of a raw-data additional hard drive.

DLRC's Solution

DLRC's Regulatory Operations team partnered with a Novel Anti-Viral Therapies company to deliver a complex, fast-track New Drug Application (NDA) submitted to the FDA as a rolling, two-sequence dossier. Using advanced publishing expertise and industry-standard tools, the team prepared more than 2,200 documents to full submission-ready standards, ensuring every component met FDA eCTD requirements. A shared, real-time content plan enabled seamless coordination between DLRC and the client, supporting transparent tracking of progress and rapid issue resolution. The second sequence alone exceeded 17 GB, reflecting the scale and technical demands of the project.

In parallel, Regulatory Operations coordinated with a third-party vendor to generate a download of raw data packaged onto an external drive. Checksums were created to ensure data integrity and verify compliance with all FDA requirements. The USB, along with the associated verification, was delivered to the FDA on the same day without disrupting the agreed fast-track timelines.

This coordinated effort resulted in a fully compliant, high-quality NDA submitted on schedule, providing the client with a smooth and well-managed first-time submission experience.

The Outcome

DLRC successfully delivered two fast-track NDA submission sequences to the FDA on time and within budget, transitioning smoothly into the Information Request phase.

The project was underpinned by a shared, real-time content plan that enabled rapid query resolution and clear visibility of progress for both DLRC and the client. Regular partner meetings ensured expectations were aligned and potential risks were addressed early, supporting a controlled and collaborative submission process.

This structured approach helped maintain momentum through a complex, high-volume NDA and positioned the client for an efficient review phase.

The FDA Information Request phase is now ongoing.

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