




BLA and Assay Device Turnaround: Complex FDA Resubmissions



 [DLRC Group](#)
 hello@dlrcgroup.com
 www.dlrcgroup.com

The Situation

DLRC Inc. has successfully partnered with a long-standing client, a medium-sized pharmaceutical company, to strategically address and overcome a Refuse to File (RTF) decision for a biologic. Collaborating closely with DLRC Inc., the company aimed to address FDA concerns without overhauling its entire regulatory strategy.

The resubmission process presented a complex challenge, requiring careful interpretation of FDA feedback and thoughtful preparation to address only the relevant comments while maintaining data integrity within limited timeframes. In addition, the project utilised an in-house assay to validate the biologic's efficacy. As part of the strategy, DLRC Inc. supported a Pre-Sub and medical device submission in parallel, ensuring both components would be approved alongside the resubmission.

Throughout this strategic collaboration, DLRC Inc. demonstrated its expertise in navigating complex regulatory hurdles, ensuring a smooth path forward for the resubmission and future approvals.

DLRC's Solution

To overcome these complex challenges, DLRC Inc. embraced a collaborative approach, seamlessly integrating project management, regulatory strategy, and regulatory operations teams. This dynamic partnership played a pivotal role in meeting the stringent demands of the project.

A cornerstone of DLRC's approach was proactive, transparent communication with the client, third parties, and regulatory authorities. This proactive engagement led to the development of a well-structured and coordinated regulatory submission strategy. Working alongside the client, DLRC helped identify necessary updates for the Biologics License Application (BLA) submission. The FDA recognised these changes as integral to validating the resubmission and subsequently agreed to proceed with the review process.

As the resubmission progressed, DLRC expanded its support to manage the biologic's review, including supporting the preparation of response packages to the FDA's extensive information requests, often under short deadlines. DLRC's rigorous quality system ensured full document traceability, version control, and streamlined submission management, enabling smooth execution and organisation across multiple teams.

The scope of DLRC's role grew even further with the medical device submission, which became an essential component of the BLA review. DLRC worked closely with the client to guide interactions with both CDER and the CDRH, supporting Pre-Sub and Q-Sub meetings while ensuring alignment between the FDA review team and the medical device process to finalise all aspects of the BLA submission.

When the FDA issued a Complete Response Letter, DLRC guided the client through the agency feedback, providing strategic insights and operational leadership to prepare a Class 1 resubmission. DLRC supported the client with multiple FDA meetings, the generation of documentation updates, and the delivery of a fully compliant resubmission package under highly compressed timelines. Throughout the accelerated Class 1 review, DLRC continued to support the client's rapid turnaround of information requests through efficient project management and publishing capabilities, ensuring timely, accurate responses, which included a particular focus on the US Prescribing Information.

The Outcome

DLRC Inc. has successfully navigated a complex submission process across multiple U.S. review boards (CDER and CDRH), showcasing the versatility, expertise, and collaborative strength of our team. This milestone, marked by the FDA's approval of the BLA in the United States, underscores DLRC's commitment to regulatory excellence and to delivering high-quality support for our clients.

Beyond meeting the regulatory milestones, this success highlights DLRC's ability to efficiently manage and streamline multi-faceted, high-stakes projects. Most importantly, to assist in the advancement of an important therapy for US patients with previously unmet medical needs, reinforcing the meaningful impact that effective regulatory partnerships can have on patient outcomes.

The success of the U.S. resubmission has further propelled the client's ambitions, as they now set their sights on expanding the biologic into Canada. With this new opportunity in mind, the client has entrusted DLRC Inc. with providing strategic and operational support to navigate the Canadian regulatory landscape. Building on the momentum of our partnership, DLRC is poised to continue delivering critical insights and seamless execution to help the client successfully expand into international markets, ensuring alignment with global regulatory requirements and driving continued success beyond the U.S..