

CASE STUDY

Regulatory Readiness Reimagined: How Bracken Helped a Biotech Restore Regulatory Continuity

THE SCENARIO

A mid-stage biotech company developing a novel therapeutic candidate was preparing for an upcoming BLA submission. With a complex regulatory history spanning multiple years and contributors, the company recognized that internal knowledge gaps and lack of document organization could present significant roadblocks as they approached key regulatory milestones. Seeking to streamline their submission process and identify any potential gaps or weaknesses, the company turned to Bracken for support.

THE STRATEGY

Bracken partnered with the company to conduct a thorough audit and reconstruction of their FDA-facing documentation, while putting sustainable processes in place to ensure future readiness. Our approach focused on three critical areas:

- **Forensic Regulatory Reconstruction**

Bracken conducted a comprehensive review of prior FDA interactions, pulling together fragmented communications, submissions, and agency feedback to reconstruct the company's regulatory history. This work enabled the team to confidently identify addressed and outstanding issues and commitments.

- **Document Management Strategy**

We developed a centralized document tracking system, customized to the company's internal workflows, to serve as a living content log. This included FDA communications, cover letters, submission modules, and rationale for decisions made across development phases.

- **Institutional Knowledge Transfer**

Bracken facilitated the onboarding of new regulatory team members by providing historical context and organizing content into actionable checklists and documented processes. This process ensured continuity and reduced time spent rediscovering past work or redoing submissions.

THE RESULTS

Bracken's engagement enabled the company to transform their regulatory operations and submission readiness:

- A comprehensive list of submission components, mapped to FDA expectations, was developed, clearly identifying both strengths and unresolved gaps.
- Regulatory team efficiency increased, with less time spent tracking down documents or revisiting old decisions.
- The company avoided duplication of effort by leveraging existing FDA feedback and prior communications to guide new submissions.
- New team members were brought up to speed faster, thanks to structured content logs and contextual documentation support.

This project highlighted the value of regulatory documentation not just as a compliance necessity, but as a strategic asset. By restoring continuity and embedding best practices, Bracken helped the company position itself for success, both in the near future and as it scaled toward commercialization.

