ELIQUENT®
LIFE SCIENCES

ELIQUENT Outcomes

From CRL to Clarity.
CMC Strategies for Emerging Biologics Developers

ELIQUENT's CMC Solutions are designed to help life sciences companies overcome complex regulatory challenges and accelerate development of advanced therapies. In this ELIQUENT Outcome, explore how our integrated CMC solutions guided a global innovator through a critical regulatory setback.

Background

A global life sciences company with an established track record in therapeutic innovation sought to expand into biologics but faced significant hurdles due to limited internal expertise in this area. The complexity of biologics development, combined with heightened regulatory expectations and limited internal expertise, created challenges in advancing their program.

Challenges

After receiving an FDA Complete Response Letter (CRL) citing multiple deficiencies for their first submitted Biologics License Application (BLA), the company turned to ELIQUENT for guidance on a response strategy and support for interactions with FDA. The company faced:

Complex CRL: The CRL included a variety of comments on deficiencies in microbial control strategy, reference standard, and analytical methods—critical elements of a strong CMC package.

Expertise Gaps: Recognizing gaps in technical expertise—particularly in regulatory strategy, process design, microbiology, and assay development—the company sought ELIQUENT's specialized CMC support.

Evolving Biologics Landscape: Biologics represent one of the fastest-growing areas in life sciences, yet the regulatory environment is still adapting to the complexity of these products. Regulatory authorities are continuously refining expectations for control strategies, comparability, and analytical methods. For companies new to biologics, this creates additional uncertainty and risk.

Objectives

The objectives of the engagement included addressing the immediate regulatory challenges, while also building a stronger, future-ready foundation for the client's biologics program.

Strategic Response: Developing and implementing a clear, CMC-driven strategy to respond to FDA feedback.

Foundation Building: Strengthening regulatory, technical, and quality foundations to address expertise gaps.

Regulatory Navigation: Guiding the client through complex FDA interactions with targeted CMC support.

Sustainable Framework: Establishing a framework for ongoing biologics development and compliance.

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 Our **Solution**

ELIQUENT's CMC experts guided the client through multiple FDA interactions, helping to transform regulatory feedback into a clear path forward.

Our team provided end-to-end support—including drafting and reviewing meeting packages, analyzing data, preparing for and participating in meetings, and shaping technical strategy—to ensure alignment with FDA expectations.

With deep CMC expertise, the ELIQUENT team enabled the client to approach FDA interactions with confidence, backed by well-prepared packages, clear strategy, and actionable insights. As a result, the client gained actionable feedback from FDA that enabled them to advance product development with a viable plan to address the CRL and move the development program forward.

 **Value** Delivered

ELIQUENT delivered both immediate regulatory solutions and lasting value across the product lifecycle—helping the client accelerate progress while mitigating future risks.

Regulatory Clarity: A structured response strategy that addressed FDA's concerns and restored development momentum.

CMC Expertise On-Demand: Access to deep technical knowledge in microbiology, process validation, comparability, assay development, and regulatory strategy.

Confidence in FDA Interactions: Preparation and support for successful Type A, C, and D meetings, including data review, mock sessions, and feedback interpretation.

Strengthened Development Program: A more robust foundation for future submissions, including BLA review, non-clinical study assessment, and inspection readiness.

Long-term Partnership: Expansion of scope beyond the CRL to broader CMC support, underscoring ELIQUENT's role as a trusted advisor throughout the product lifecycle.

ELIQUENT **CMC Solutions**

ELIQUENT delivers comprehensive CMC – Chemistry, Manufacturing & Controls – solutions that connect regulatory strategy, quality execution, and technical governance. Whether you're preparing your first IND, scaling for commercial launch, or navigating post-approval changes we provide the integrated support to keep you moving forward with confidence.