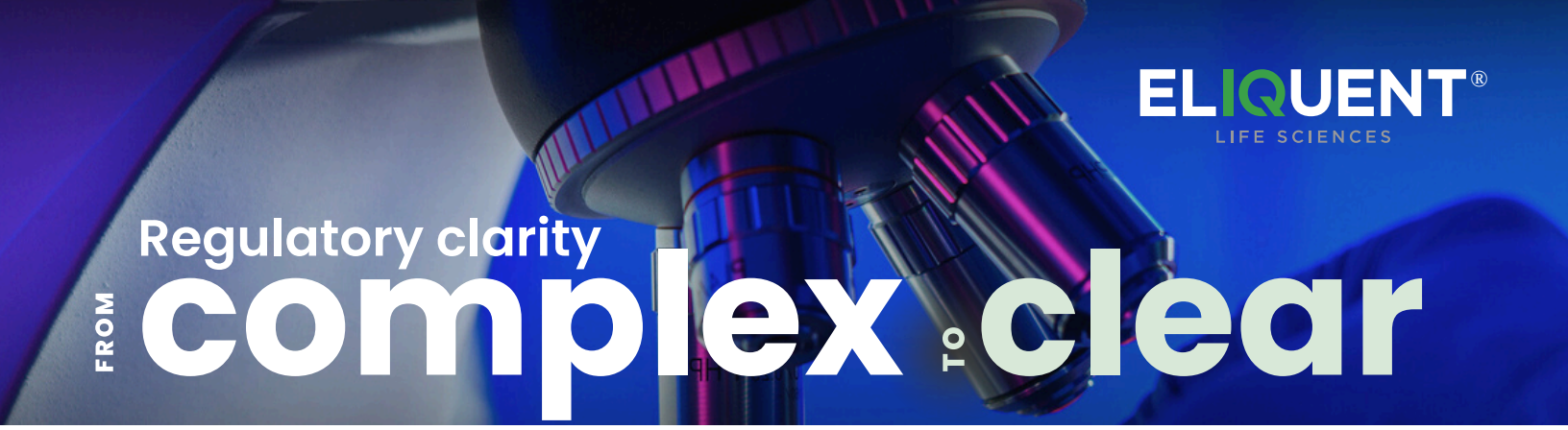

ELIQUENT Life Sciences brings clarity to regulatory complexity.
We are expert consultants delivering the answers and solutions that life sciences innovators need to gain and maintain market authorization for their products.

CMC **Strategy & Submissions**

Biotech companies face intense pressure to move quickly from promising clinical data to regulatory submission. Compressed timelines, lean teams, and evolving requirements often leave organizations without the internal expertise to build a complete, submission-ready CMC package. The result: increased risk of delays, deficiencies, or setbacks that can stall development, jeopardize approval, and erode investor confidence.

From Module 3 authorship and gap resolution to clinical hold and Complete Response remediation, ELIQUENT's team of former regulators and industry leaders provides the strategic and technical expertise needed to achieve regulatory success.

Expert Support for **Stronger Submissions**

ELIQUENT's CMC Strategy and Submission Solutions deliver end-to-end support for CMC regulatory submissions, helping clients navigate complexity and reduce risk. From pre-clinical development through commercialization and post-market maintenance - we ensure clients can move forward with confidence.

Our CMC team leverages deep expertise across modalities and regions to manage the full lifecycle of CMC submissions, including meeting packages, INDs, BLAs, and MAAs, ensuring technical consistency, regulatory alignment, and timely execution.

Clients partner with ELIQUENT to successfully align regulatory roadmaps with development milestones, strengthen filing packages, accelerate timelines and position products for global success. *ELIQUENT's CMC Strategy and Submission Solutions include*:

Module 3 Authorship & Review

End-to-end support for clinical and commercial applications across global markets.

Submission Gap Closure

Identify and address delays, deficiencies, or setbacks to ensure readiness.

Regulatory Hurdle Resolution

Effective responses to clinical holds and Complete Response Letters.

Strategic **Agency Engagement**

Leverage former regulators to secure feedback at critical milestones.

Change Management Strategy

Develop strategies to manage post-approval changes and maintain global compliance.

Comprehensive **Capabilities**

ELIQUENT delivers end-to-end support for CMC regulatory submissions, helping clients navigate complexity and reduce risk.

Our CMC expertise is strengthened by integrated nonclinical, clinical, and project management support, enabling seamless coordination across all disciplines of an application.

This multidisciplinary approach allows us to prepare and submit complete regulatory dossiers on behalf of our clients, supporting efficient agency engagement and accelerated development timelines. Areas of expertise include:

- Analytical comparability to assess manufacturing changes
- Biosimilar development including analytical similarity studies
- Process validation design
- Shipping validation
- Viral clearance studies
- In-use compatibility studies
- Reference standard qualification & management
- Microbial & aseptic control strategy
- Stability studies
- Analytical method development, validation, and transfer for product release and characterization
- Technology transfer strategy and change management

The ELIQUENT **Advantage**

Our approach reduces risk and accelerates timelines — delivering measurable value to clients. From first draft to final submission, ELIQUENT's CMC Strategy & Submissions team delivers:

Fewer costly delays through proactive planning and remediation

Stronger filings built on regulatory and technical expertise

Faster path to market with aligned strategy and execution

ELIQUENT®
LIFE SCIENCES

From Complex **to Clear**

Our CMC Solutions support life science innovators tackling complex submission challenges by reducing risks and keep development moving forward.

Clinical Hold **Resolution**

How targeted gap analysis, Module 3 restructuring, and strengthened stability justifications helps keep submissions on track and moving forward.

The Challenge. Biotech companies advancing novel biologics may face clinical holds triggered by incomplete stability data or gaps in Module 3 documentation.

Our Solution. ELIQUENT addresses these challenges through targeted gap analysis, stronger stability justifications, and restructuring of Module 3, supported by focused preparation for agency engagement.

Outcome. By resolving deficiencies early and aligning with regulatory expectations, companies can lift holds more quickly, resume trials on schedule, and protect investor confidence.

Global Expansion Under Pressure

How region-specific Module 3 authorship, proactive gap closure & strategic agency engagement enables timely, compliant submissions across multiple markets.

The Challenge. Organizations moving from U.S. development into global submissions often encounter compressed timelines and limited in-house expertise.

Our Solution. ELIQUENT supports clients with region-specific Module 3 authorship, proactive gap resolution, and strategic agency engagement to clarify expectations across markets.

Outcome. With these steps, companies achieve timely, compliant submissions worldwide, minimizing regulatory questions and accelerating progress toward approval.

Remediation for **Advanced Modality**

How fit-for-purpose comparability frameworks, enhanced analytical methods, and focused regulatory preparation enable confidence and reduced delays for CGT developers.

The Challenge. Developers of cell and gene therapies frequently face regulatory obstacles related to comparability and potency data.

Our Solution. ELIQUENT bridges a path forward with fit-for-purpose comparability frameworks, enhanced analytical methods, and thorough preparation for regulatory meetings.

Outcome. By addressing regulatory concerns effectively, sponsors can submit with confidence, reduce delays, and maintain momentum toward approval.