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.

Due Diligence Solutions

ELIQUENT understands the complex regulatory environment in which life sciences transactions take place. Our team of experts offers a rare blend of perspectives developed as leaders in both the public and private sectors. This wealth of knowledge and depth of experience equips clients with a trusted partner when considering life sciences transactions.

ELIQUENT's due diligence services are more than a compilation of public data – we go a step further by enabling the vast institutional knowledge of our regulatory experts to provide in-depth analyses tailored to our clients' specific needs. Our multidisciplinary team performs risk assessments that take into account business objectives, transaction timelines, and the industry and regulatory landscape. The end result is an unbiased expert analysis of both expected and unexpected regulatory risks.

Unlocking Success

ELIQUENT's due diligence solutions are tailored to the unique needs of the life science sector - empowering clients to confidently navigate opportunities. Our comprehensive services support strategic decision making for both **buy-side** and **sell-side** transactions.

Buy-Side Transactions

Investors leverage ELIQUENT's collective capabilities to navigate life science opportunities and achieve strategic objectives.

Scientific Rigor

With experience across the landscape of therapeutic areas and modalities, the ELIQUENT team provides the technical and scientific expertise investors need when considering a life sciences transaction.

Risk Mitigation

Investing in the life science arena comes with inherent risks. We go beyond identifying risks by providing strategic recommendations to mitigate them effectively, safeguarding your investments.

Market Intelligence

ELIQUENT's industry knowledge and regulatory expertise offers invaluable market insights, enabling you to anticipate trends, assess competitive landscapes, and capitalize on emerging opportunities.

Sell-Side Transactions

ELIQUENT provides clarity and an objective viewpoint, thereby maximizing value in a transaction, and empowering companies to make informed decisions.

Program Roadmap

ELIQUENT partners with companies to maximize returns by developing a roadmap focused on optimizing commercial assets, identifying areas for improvement; and prioritizing value enhancements.

Risk Assessment

Our in-depth assessments go beyond identifying regulatory risks – the ELIQUENT team delivers strategic and technical recommendations for system-wide quality and regulatory enhancements.

Industry Insights

ELIQUENT provides companies with critical insights by monitoring and analyzing the life sciences sector for emerging trends, evolving regulatory reforms, and changes to the competitive landscape.

Strategic & Technical Guidance

ELIQUENT's due diligence services include research and analysis of the following potential data sources:

Medical Product Development
Evaluation of clinical development plans, including review of clinical and nonclinical data, FDA correspondence, safety reporting, and sponsor proposals for future clinical studies.

Regulatory Submissions
Review of pending product submissions to assess completeness and approval prospects, including FDA information requests, mid and late-cycle meetings, advisory committee outcomes, labeling negotiations, and inspectional results.

Distribution & Supply Chain
Assessment of import-export practices, supply chain audit reports, outsourcing arrangements, and distribution procedures.

Reporting Requirements
Confirm that the target company has complied with all requirements for registration, authorization, filing, and listing associated with approved products, including user fee payments and fulfillment of postmarket obligations.

Adverse Event Reporting
Review of adverse event reports (AERs) and good manufacturing practice complaints to ensure that the target company has taken appropriate measures for review and investigation.

Regulatory Pathway Evaluation
Determine eligibility for special designation(s), including priority review, fast track, accelerated approval, breakthrough therapy designation, and regenerative medicine advanced therapy designation.

Compliance Status
Analysis of target company's FDA compliance and enforcement history, including a review of FDA correspondence relating to compliance matters and identification of outstanding or pending compliance and remediation actions.

Preclinical & Clinical Quality Systems
Assessment of compliance with FDA current good laboratory practice (GLP) and good clinical practice (GCP) regulations.

Quality Manufacturing
Evaluation of the target company's compliance with FDA quality and manufacturing regulations related to inspections, standard operating procedures, quality assurance activities, and relevant contract manufacturers.

Marketing & Promotion
Evaluation of promotional practices and marketing materials, including labeling claims, promotion of unapproved products or off-label uses, and related FDA correspondence or enforcement actions.

Unmatched Expertise

ELIQUENT's unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly throughout the product lifecycle. Together, we create a full-service model that equips clients with a premier regulatory resource.

Regulatory Affairs
ELIQUENT's premier team of life science experts work as teams specializing in drugs and biological products, medical devices and combination products, and advanced therapies. Together, the regulatory affairs team provides strategic and technical guidance on product development, regulatory review, and postmarket requirements across therapeutic areas, modalities, and global markets.

Quality, Compliance & Manufacturing
ELIQUENT provides services that are recognized as best in class by companies seeking to strengthen their quality management systems. Experts specialize in corporate quality and compliance systems; FDA inspections, communication, and enforcement processes; and the complete spectrum of compliance and enforcement-related actions.

Talent Solutions
ELIQUENT's comprehensive capabilities are amplified by a network of ready to deploy professionals with an expansive range of expertise. The hand-picked global consultant network supports and enhances ELIQUENT's due diligence solutions by delivering the expertise, credentials, and language- or region-specific skill set clients need to unlock success.

The ELIQUENT Difference

From thought to finish, concept to commerce, and strategy to execution - ELIQUENT Life Sciences is the singular regulatory resource that clients around the world trust. To learn more about our comprehensive service offerings, visit our website or contact a member of our team at info@eliquent.com.