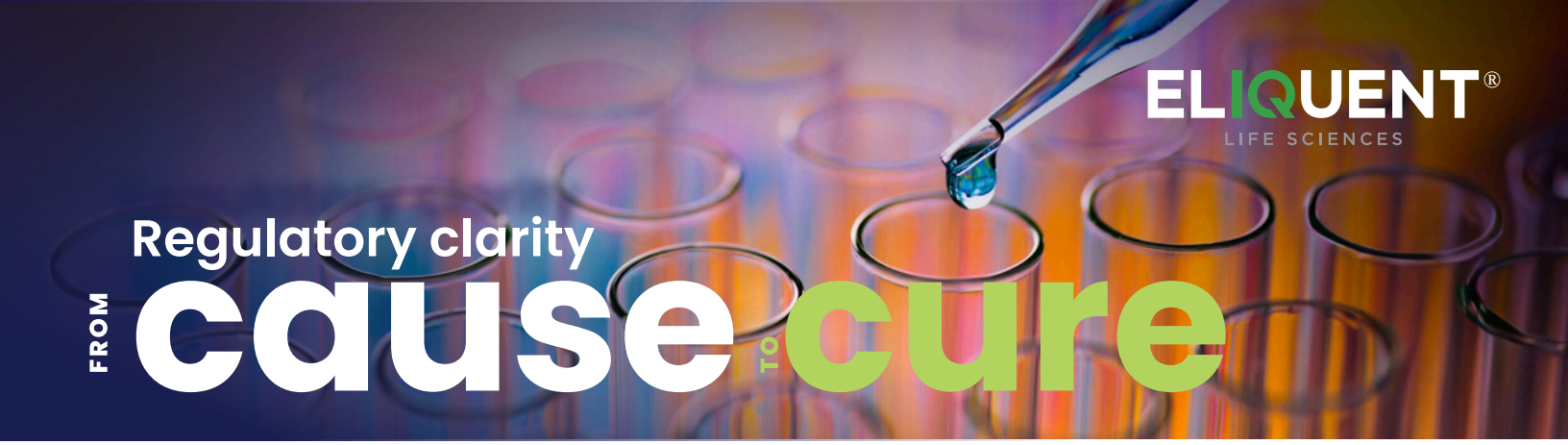

ELIQUENT Life Sciences brings clarity to regulatory complexity. We are expert consultants delivering the answers and solutions that life sciences innovators need to gain and maintain market authorization for their products.

Drug & Biological Product Solutions

To ensure success in today's rapidly evolving biopharmaceutical industry, companies must recognize and be prepared for a dynamic regulatory landscape. Guided by decades of experience, ELIQUENT's team of experts guides clients through the complete regulatory process, from the earliest stages of product development, through the regulatory review process, to marketing authorization and compliance with postmarket requirements and quality systems.

Strategic & Technical Capabilities

ELIQUENT redefines regulatory consulting with a full-service approach and comprehensive solutions that bridge the spectrum of regulatory challenges. Our integrated suite of solutions aligns with your goals to unlock regulatory success.

Pipeline Review & Optimization

Our team of regulatory experts evaluate and prioritize development pipelines to identify valuable portfolio opportunities and to understand and effectively manage regulatory risks.

Clinical Programs

With decades of hands-on experience, ELIQUENT professionals provide best-in-class scientific and regulatory guidance on nonclinical, preclinical, and clinical programs across all therapeutic areas.

CMC Strategy

ELIQUENT's highly experienced team of specialists strengthen CMC packages by facilitating risk-based evaluations that enable effective design and implementation strategies.

Pathway Decisions & Eligibility

ELIQUENT experts work with companies to develop comprehensive regulatory strategies that take into account special designation eligibility and the pathway selection for a successful result.

Regulatory Meetings & Communications

ELIQUENT's team of respected professionals bring an unmatched level of credibility and trust when interacting with global regulators and guiding companies on the regulatory pathway.

Regulatory Submissions

ELIQUENT applies extensive regulatory perspective to develop and implement actionable strategies that optimize a product's regulatory submission and enhance agency interactions.

Expert Training

ELIQUENT's customizable training programs equip teams and employees with the tools and skills to maintain global regulatory processes and build a common culture of accountability.

Lifecycle Support

ELIQUENT's integrated solutions equip innovators with strategic insight and actionable strategies that span the product lifecycle and unlock regulatory success.

Pathway solutions

As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. Clients turn to ELIQUENT for objective guidance across the regulatory pathway, to market approval, and beyond.

Nonclinical

Phase-specific nonclinical support:

Study design & data analysis, with expertise in toxicology, pharmacokinetics & pharmacodynamics

Risk management support, including laboratory controls and Good Laboratory Practices (GLP)

Preclinical

Real-world preclinical guidance:

Pipeline review & optimization

Study design & development

Product classifications

Expedited pathway guidance

Regulatory submission support, including dossier writing and application assembly

Clinical

Strategic & technical direction:

Clinical study support, including:
CRO selection
Protocol writing
Biomarker/endpoint selection

On-site clinical execution

Pre-Approval Quality System Compliance

Regulatory **Submissions**

Valuable & objective guidance:

Regulatory submission support, including:

Dossier writing and review

Application assembly & submission

Regulatory meetings and communications

Pre-approval inspections and response to deficiencies

Post-Approval **Distribution**

Customized solutions:

Quality system design, optimization & implementation

Good Manufacturing Practices (GMP) Consulting

Inspectional readiness

Post-approval commitments

Marketing, labeling, and promotional practices

Lifecycle **Support**

Actionable & proven strategies:

Regulatory communications & engagement strategies

Inspectional readiness

Regulatory policy guidance

Customized training programs

Remediation solutions

Due diligence & regulatory risk assessments

Full-Service Support

ELIQUENT is a trusted partner to global life science innovators. Our unique platform goes beyond traditional consulting to deliver end-to-end solutions. No matter your pathway position, regulatory requirements, global market or therapeutic area – ELIQUENT's integrated solutions align with your regulatory goals to unlock regulatory success.

Regulatory Affairs Solutions

From the earliest phases of innovation through regulatory submissions, to post- approval support, our robust blend of technical skill and clinical expertise guide companies to approval and beyond.

PV+ Safety Solutions

With an approach that includes both strategic direction and hands-on global support, ELIQUENT's customized pharmacovigilance solutions empower companies to operate with confidence.

Quality & Compliance

Our team of highly specialized quality & compliance experts build customized solutions that equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Remediation Solutions

ELIQUENT's Remediation Solutions address challenges head-on, providing the expert guidance life science innovators need to bring your operations back into compliance and securing your path forward.

GxP Implementation

ELIQUENT's team of respected professionals, along with a network of ready to deploy global experts, possess the unmatched ability to solve the most technical challenges on a global scale.