ELIQUENT™ LIFE SCIENCES

Regulatory clarity FROM idea TO impact

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.

Regulatory Affairs Solutions

In the complex life sciences landscape, where innovation meets regulation, a trusted regulatory partner is paramount. Guided by decades of regulatory and clinical experience, and firmly grounded in the principles of public health, ELIQUENT's team of regulatory experts is unmatched. No matter the therapeutic area, modality, or market, our premier team of life science experts have the specialized skills to guide life science innovators **from idea to impact**.

Drugs & Biologics Products

ELIQUENT's team of experts provide strategic and technical guidance on drugs and biologics from product development to regulatory review and beyond post-market requirements.

Combination Products

Unlock the full potential of your combination product. Our team supports companies developing combination products with expert guidance throughout the product lifecycle.

Advance Therapies & CGT

Our team of regulatory and clinical experts apply their specialized skillset to move complex autologous or allogeneic therapies through the regulatory process to manufacturing and beyond.

Devices & Diagnostics

Leverage the extensive experience and expansive technical skill of the ELIQUENT team as you navigate the process of bringing new devices and diagnostics to market and manufacturing them to quality standards.

Unmatched Expertise

ELIQUENT brings the unmatched expertise that companies need when navigating today's evolving regulatory environment. Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to unlock excellence throughout the product lifecycle.

Drugs & Biological Products

Areas of expertise:

- Monoclonal Antibodies
- Enzyme Replacement Therapies
- Biosimilars
- Tissue-Based Therapies
- Vaccines

Advanced Therapies & CGT

Areas of expertise:

- Gene therapy
- Somatic cell therapy
- Tissue-engineered therapies
- Combined advanced therapies

Devices & Diagnostics

Areas of expertise:

- Class I, II, and III devices
- Digital Health
- Molecular Diagnostics
- Immunoassays
- Laboratory Tests
- Companion Diagnostics

Combination Products

Areas of expertise:

- Single-entity, co-packaged, and cross-labeled products
- Drug-coated devices
- Drug delivery systems
- Companion Diagnostics

To approval and beyond

ELIQUENT guides innovators on their path to approval and beyond. As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. ELIQUENT's highly specialized experts provide both strategic direction and hands-on execution services to to support clients from the earliest phases of development to post-approval regulatory support.

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 deacdes of hands-on experience, ELIQUENT professionals provide best-in-class scientific and regulatory guidance on nonclinical, pre-clinical, 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.

Marketing, Promotion & Labeling
Our team of skilled advisors provide specialized support and strategic direction on labeling requirements, promotional materials, and marketing programs.

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

Full-Service Support

The combined achievements and substantial qualifications of the ELIQUENT team enables a full-service engagement that delivers end-to-end support. Our unique platform goes beyond traditional consulting to deliver end-to-end solutions.

Regulatory Affairs Solutions
From the earliest phases of innovation through regulatory submissions, to post-approval support, ELIQUENT's robust blend of technical skill and clinical expertise guide companies to approval and beyond.

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

Quality & Compliance
ELIQUENT's team of highly specialized compliance experts build customized solutions that equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Remediation Solutions
Our team of respected quality experts and global specialists bring an unmatched level of credibility and trust when interacting with regulators and guiding companies to remediation solutions.

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.

To learn more about ELIQUENT's comprehensive service offerings, visit www.ELIQUENT.com or contact a member of our team at info@eliquent.com.

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