
ELIQUENT™
LIFE SCIENCES
Regulatory clarity –
From thought to finish.

Who is ELIQUENT?

We are expert consultants delivering the answers and solutions that life sciences innovators need to gain and maintain market authorization for their products.

From thought to finish, concept to commerce, and strategy to execution — ELIQUENT redefines regulatory consulting with a full-service approach and comprehensive solutions that bridge the spectrum of regulatory challenges.

Singular Regulatory Resource

ELIQUENT is the singular regulatory resource that clients around the world trust. 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.

Unprecedented Assembly

ELIQUENT's foundation is built on experts with the foremost strategic and technical skill. Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to deliver objective, reliable guidance across the product lifecycle.

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Why ELIQUENT?

Unmatched Expertise

With **decades of experience**, ELIQUENT experts have directly influenced significant policy decisions and regulatory actions through their service at global regulatory authorities. ELIQUENT brings the unmatched expertise that companies need when navigating today's evolving regulatory environment.

Combined Qualifications

ELIQUENT experts demonstrate unequaled levels of skill in their regulatory specialties. The team's **combined achievements** and substantial qualifications enable a cross-functional, full-service engagement that delivers best-in-class insight and solutions that bridge the **spectrum of regulatory challenges**.

Wealth of Experience

ELIQUENT's team of experts includes former leaders and regulatory professionals from the FDA and international regulatory bodies; top global pharmaceutical, biotechnology and medical device companies; leading law firms; and the top U.S. biotechnology trade organizations.

Global Scope

Our premier team of regulatory experts have served in senior positions at **global regulatory authorities** and throughout industry. 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.**

We are a **premier team** of regulatory experts with the unmatched ability to solve the most **technical** challenges on a global scale.

Our integrated suite of services address the **entire product lifecycle** with best-in-class insight and and solutions that bridge the **spectrum of regulatory challenges**.

Together, **we unlock regulatory success.**

The ELIQUENT Difference

350+

years of collective experience at

FDA

& global regulatory authorities.

Specialized

We specialize in life sciences. No matter the pathway or complexity of your challenge, our premier team of life **skills** to help.

Skilled

Our **unprecedented assembly** of global regulatory experts set the industry standard. Our breadth of skill and depth of knowledge is **unmatched** in the life sciences industry.

Scope

Our capabilities run deep – the ELIQUENT team offers a **rare blend** of knowledge spanning therapeutic areas, regulatory pathways, quality systems, and global markets.

Scale

Our carefully **curated network** of global experts enables the right team, with the right expertise, at the right size in the right location to **meet your needs**.

Speed

When time is of the essence - whether over the phone or across the globe – our **agile expert teams** are ready for your most complex challenges.

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Full-Service **Support**

ELIQUENT's integrated suite of solutions **enables a full-service engagement** that delivers **end-to-end support**.

Our full-service solutions include:

- Regulatory Affairs
- Pharmacovigilance
- Quality & Compliance
- Remediation Solutions
- Talent Solutions

Full-Service Support

The combined achievements and substantial qualifications of the ELIQUENT team enables a **full-service engagement** that delivers **end-to-end support**. Together, we unlock regulatory excellence.

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

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

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.

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

Whether you need a team of one or 100+,ELIQUENT's **talent solutions** gives you the ability to rapidly scale your team to the right size, with the right level of expertise, in the right locations.

Full-Service Support

Regulatory Affairs Solutions

Guided by decades of regulatory and clinical experience, and firmly grounded in the principles of public health, ELIQUENT's team of experts is unmatched. Clients count on us to provide objective advice and valuable insight throughout the product lifecycle.

ELIQUENT's full-service regulatory affairs solutions include:

Pipeline Review & Optimization	Skilled evaluation and prioritization to effectively manage regulatory risk
Clinical Programs	Specialized guidance and strategic design of nonclinical, pre-clinical, and clinical programs
CMC Strategy	Risk-based design and effective implementation of phase-appropriate CMC solutions
Pathway Decisions	Expert support on product classifications, special designations, and expedited program pathways
Regulatory Meetings & Communications	Actionable strategies and insight for milestone meetings and regulatory communication
Regulatory Policy Guidance	Customized solutions to understand, implement, and comply with regulatory policies and programs
Marketing, Promotion & Labeling	Strategic direction on labeling requirements, promotional materials, and marketing programs
Lifecycle Support	Valuable expertise throughout the product lifecycle, including post-approval requirements and commitments

Full-Service Support

Pharmacovigilance Solutions

ELIQUENT's comprehensive capabilities are the gold-standard in pharmacovigilance. Our industry-recognize experts optimize practices to ensure consistency, compliance and operational efficiency, while aligning with evolving global demands. **ELIQUENT's full-service pharmacovigilance services include:**

Global Support	Trusted guidance when navigating and complying with global pharmacovigilance regulations
Adverse Event Reporting	Systematic identification, objective analysis, and strategic guidance responding to unintended occurrences
Regulatory Reporting	Technical skill and institutional knowledge of complex regulatory reporting obligations
Signal Detection	Expert development and implementation of detection processes, including reporting and risk communication
Risk Assessment & Management	Proactive identification, assessment and planning to manage potential risk and ensure regulatory compliance
Post-Marketing Surveillance	Established network experts to support commercial product safety systems and reporting functions
Risk Communications	Strategic development of communications plans to address emerging safety concerns and instill confidence in the market
Clinical Trials Safety Oversight	On-demand resources to support safety monitoring before and after regulatory approval

Full-Service Support

Quality & Compliance Solutions

A strong quality program is a cornerstone of regulatory success. With decades of experience and a track record of success, ELIQUENT is the industry leader in quality and compliance capabilities. Our team of unmatched experts guide companies to sustainable quality and regulatory excellence. **ELIQUENT full-service quality and compliance solutions include:**

Quality Systems	Objective evaluation and expert direction on quality system design, optimization & implementation
Inspectional Readiness	Customized strategies to prepare for inspections and align with regulatory expectations
Compliance & Enforcement Actions	Proven expertise when responding to regulatory compliance & enforcement actions
Supply Chain Optimization	Skilled support to evaluate and strengthen supply chain management practices
Good Clinical Practices	Risk-based methodology applied to the design and improvement of clinical quality systems
Laboratory Controls & Data Integrity Systems	Tailored solutions to ensure data integrity and manufacturing performance
Regulatory Meetings & Communications	Valuable guidance on regulatory communications, meetings, and correspondence
Consultation, Training & Regulatory Guidance	Strategic insight and actionable strategies spanning the product lifecycle

Full-Service Support

Remediation Solutions

ELIQUENT's team of respected professionals, along with a network of ready to deploy experts, work with companies to investigate, identify, resolve, and prevent both acute and systemic issues at regulated facilities. Together, we equip clients with the informed, objective guidance to detect and solve compliance problems earlier and more effectively. **ELIQUENT's full-service remediation solutions include:**

Compliance Assessments
Strategic and technical evaluations to identify areas of non-compliance & mitigate other potential risks

Rapid Response
Immediate deployment of compliance experts to provide valuable on-site support when time is of the essence

Customized Solutions
Actionable remediation plans to correct known problems, prevent future occurrences, and meet regulatory expectations

Comprehensive Communications
Valuable direction when interacting with and effectively responding to regulatory communications

Corrective Action Plans
Design and enable action plans that are both effective and sustainable for your business

Implementation Expertise
Tailored support to implement both acute and systemic improvements across facilities and product lines

On-Demand & On-Site
Skilled resources ready to support implementation plans, sustain compliance, and respond to evolving demands

Maintenance & Monitoring
Uphold the integrity of implemented practices with ongoing monitoring and maintenance

Third-Party Reporting
Trusted third-party reporting of progress against improvement commitments

Full-Service Support

Expert Training

ELIQUENT experts provide in-person and remote training services to empower both leadership teams and employees with the skills and tools to create pragmatic problem-solving processes and maintain adherence to evolving regulatory, compliance, and quality standards. Our training solutions equips internal teams to drive continual improvement and help build a common culture of accountability. **ELIQUENT's full-service training solutions include:**

In-person, virtual & on-demand — Training for teams, private groups, and individuals

Regulatory policies & procedures — Expert instruction on all aspects of regulatory programs across the product lifecycle

Quality Systems — Foundational and in-depth learning programs on quality management systems across the regulatory landscape

Inspectional readiness — Specialized programs to ensure readiness prior to regulatory inspections

Customized training programs — Flexible options to develop training programs on a variety of regulatory subjects

Targeted Solutions

ELIQUENT's integrated suite of solutions enables a **full-service engagement** that delivers **end-to-end support**.

Our targeted solutions include:

- Market Solutions
- Pathway Solutions
- Global Solutions
- Specialized Solutions
- Therapeutic Specialties

Comprehensive Capabilities

ELIQUENT is a trusted partner to global life science innovators. Why? 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 success.

Market Solutions

Guided by decades of regulatory and clinical experience, the ELIQUENT team delivers value to clients in the following markets:

- Drugs & Biologics
- Medical Devices & Diagnostics
- Advanced Therapies
- Combination Products
- Cosmetics
- Radiopharmaceuticals

Pathway Solutions

As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. Clients turn to our team for objective guidance across the regulatory pathway, including:

- Nonclinical, Pre-Clinical & Clinical Support
- Regulatory Submissions
- Manufacturing & Distribution
- Post-market Solutions

Global Solutions

ELIQUENT'S established and growing global presence spans the regulatory process and major markets.

Our premier team of global regulatory experts support the following global markets:

- Global Market Entry
- United States
- Europe
- Asia

Specialized Solutions

ELIQUENT regularly partners with innovators, law firms, trade associations, and other stakeholders to provide specialized solutions that are tailored to the unique needs of the life sciences industry.

- Industry Due Diligence
- Regulatory Policy
- Expert Training
- Regulatory & Medical Writing
- Litigation Support

Market Solutions

In the complex life sciences landscape, where innovation meets regulation, a trusted regulatory partner is paramount. No matter the **therapeutic area**, **modality** or **market**, our premier team of life science experts have the specialized skills to help.

Drugs & Biologics

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.

Areas of expertise:

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

Devices & Diagnostics

Leverage our team's extensive experience as you navigate the process of bringing new devices and diagnostics to market and manufacturing them to quality standards.

Areas of expertise:

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

Advanced Therapies & CGT

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

Areas of expertise:

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

Combination Products

Unlock the full potential of your combination product. ELIQUENT's supports companies developing combination products with expert guidance throughout the combination product lifecycle.

Areas of expertise:

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

Industry Due Diligence

ELIQUENT applies vast institutional knowledge to equip investors with the information needed to ensure life science transactions account for business objectives, regulatory risks, and the industry landscape.

Areas of expertise:

- Product Development and Review
- Quality manufacturing
- Identification of Regulatory Risk

Pathway Solutions

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. 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.

Nonclinical & Preclinical Support

ELIQUENT's customized support guides companies through crucial nonclinical and preclinical development phases with precision and expertise.

Clinical Programs

With a proven track record of regulatory success, our team delivers objective guidance and unparalleled support for your complex clinical program.

Regulatory Submissions

ELIQUENT applies extensive regulatory experience to develop the best regulatory approach for a product and develop a comprehensive strategy to achieve a successful result.

Manufacturing & Distribution

ELIQUENT evaluates and strengthens systems with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while meeting business objectives.

Post-Market & Lifecycle Support

Our industry-recognized experts deliver valuable insight throughout the product lifecycle to ensure sustained post-market vigilance.

Global Solutions

Expertise beyond borders. ELIQUENT'S established and growing **global presence** spans the regulatory process and major markets. Our premier team of global regulatory experts support markets across the U.S., Europe, and Asia.

United States

ELIQUENT is a leading Food & Drug Administration (FDA) regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and medical device companies.

Our experts have shaped the landscape of FDA regulatory policy and strategy for decades. We bring this unrivaled knowledge and unique insight to our work with clients every day.

Europe

The ELIQUENT team applies their deep and diverse knowledge of European regulations to keep clients in lock-step with evolving global standards.

With decades of experience in the European market, our team understands the intricacies of the European Medicines Agency (EMA) and offers tailored solutions to ensure products meet and exceed the needs of our clients.

Asia: Japan & China

ELIQUENT offers regionally specialized solutions for the innovators across Asia. Our comprehensive solutions include:

JAPAN: Guidance to innovators seeking approval in Japan, the third-largest pharmaceutical market in the world.

CHINA: Customized solutions for Chinese innovators seeking authorization in the U.S. market.

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For more information on ELIQUENT, please contact us at **info@eliquent.com.**

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