ELIQUENT

LIFE SCIENCES

ELIQUENT Life Sciences

Comprehensive Capabilities

REGULATORY CLARITY
- thought to finish.

Introducing ELIQUENT Life Sciences.

Setting a new standard for regulatory clarity -
from thought to finish.

ELIQUENT
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Regulatory Clarity

FROM thought TO finish

ELIQUENT LIFE SCIENCES

Introducing ELIQUENT Life Sciences

The Validant Group is now **ELIQUENT Life Sciences.**

Committed to providing the highest quality services to companies navigating the complex regulatory landscape, ELIQUENT's strategic repositioning defines a new global life science leader and sets the standard for regulatory consulting excellence.

Together, the ELIQUENT team delivers comprehensive support to pharmaceutical, biotechnology, medical device, and combination product companies navigating the complex regulatory landscape.

Why ELIQUENT?

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

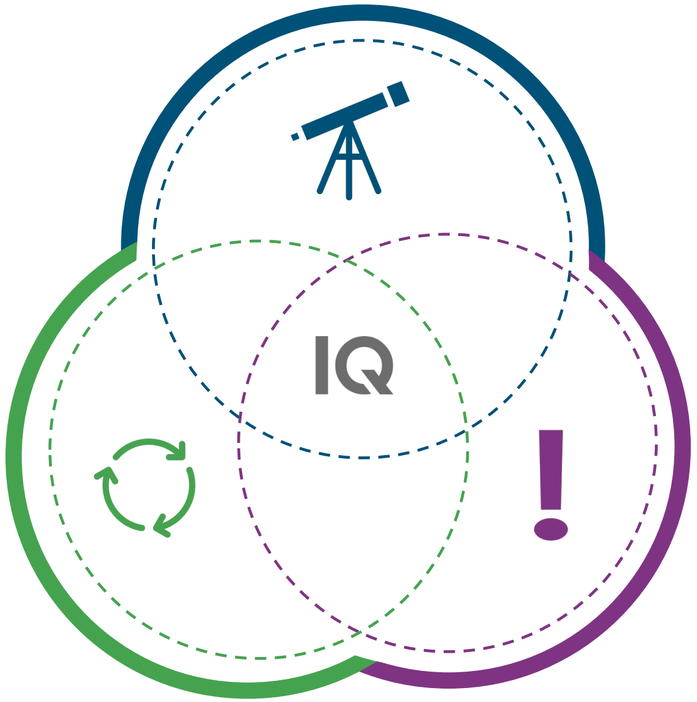
Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to unlock excellence **throughout the product lifecycle**. We are the convergence of global regulatory expertise and technical capabilities **across the therapeutic landscape**.

Together, ELIQUENT redefines regulatory consulting with a full-service approach and comprehensive solutions that bridge the **spectrum of regulatory challenges**.

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.

Clearing the Path to Better Health

Our work clears the path for better health. ELIQUENT Life Sciences is the catalyst for positive in public health. Our collective expertise, unrivaled skillset, and combined capabilities pave the way for transformative ideas to become tangible solutions. From thought to finish, idea to impact, and hurdles to health — **ELIQUENT Life Sciences clears the path to better health.**



We **Believe**

We believe that our clients' projects will advance the health of the world.

We **Devote**

We devote our expertise to enabling efficient and successful life science innovations.

We **Envision**

We envision regulatory challenges as an opportunity to unlock progress.

The ELIQUENT Foundation

ELIQUENT is built on a foundation of expert consultants delivering the answers and solutions that global life sciences innovators need to gain and maintain market authorization for their products.

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.**

350+
years of collective experience at
FDA
& global regulatory authorities.

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The ELIQUENT Team

ELIQUENT Life Sciences is the powerful alliance of five global consultancies working as a collective, **coordinated regulatory team**.

This unprecedented assembly of regulatory experts enables a unique understanding of the life sciences industry and the unmatched expertise companies need when navigating today's evolving regulatory environment.

VALIDANT
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Validant is a full-service life science consulting firm serving developers and manufacturers of pharmaceuticals, biologics, medical devices, and diagnostics worldwide. Validant provides strategy, execution, and ongoing support for a range of regulatory, compliance, and quality needs.

GREENLEAF HEALTH
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Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and medical device companies researching, developing, and manufacturing innovative solutions to pressing global public health challenges.

DR DATAREVIVE
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DataRevive is a regulatory consultancy firm that supports global pharma and biotech clients navigating to the regulatory approval pathway. DataRevive experts deliver CMC, preclinical, clinical, and GxP expertise to innovators seeking product approvals in major global markets.

ORIEL | STAT A MATRIX
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Oriel Stat-A-Matrix is a global leader in training and consulting for business process improvement, regulatory compliance, and quality management systems. Oriel experts support regulatory compliance, product submissions, and processes improvements across the lifecycle.

IDEC
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IDEC offers regionally specialized regulatory guidance and end-to-end product support for pharmaceutical innovators seeking approval in the Japanese market. IDEC experts specialize in product design, market strategy, commercialization, and product management strategies.

RAPPORT
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RApport is a UK based regulatory consultancy supporting global life science innovators. RApport's specialized capabilities provide strategic and technical guidance to companies gaining and maintaining authorization for products in the European market.

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.

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

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.

Comprehensive Capabilities.

Unlocking regulatory excellence.

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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.

Regulatory Affairs — **Pharmacovigilance** — **Quality & Compliance** — **Remediation Solutions** — **Expert Training**

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The convergence of unparalleled global experts working collaboratively to deliver integrated regulatory solutions.

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
- Industry Investors

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 and Lifecycle 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:

- United States
- Europe
- Asia

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

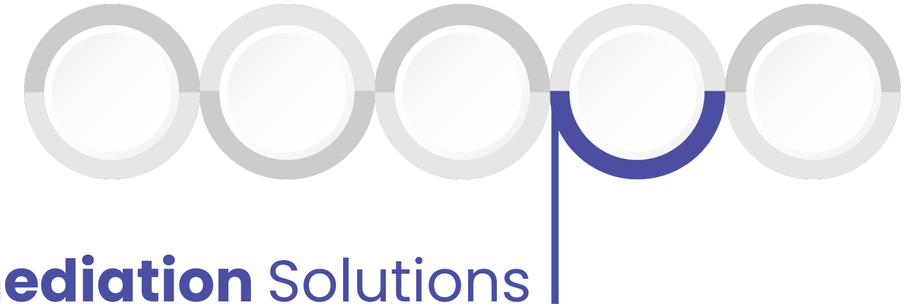
Full-Service Support

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

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

The ELIQUENT Difference

Redefining regulatory support.

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The ELIQUENT Difference

ELIQUENT redefines regulatory consulting with a **comprehensive approach** that bridges the spectrum of global regulatory challenges to provide seamless support.

Specialized
We specialize in life sciences. No matter the pathway or complexity of your challenge, our premier team of life science experts have the **specialized 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.

What sets ELIQUENT apart?

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.**

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Your premier regulatory resource –

from thought to finish.

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