



ELIQUENT

LIFE SCIENCES

Bringing clarity to life sciences complexity



ELIQUENT Life Sciences.

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

Who is ELIQUENT?

ELIQUENT Life Sciences is a leading global regulatory, quality & safety consulting firm delivering integrated solutions across the product lifecycle. We are a premier team of regulatory experts delivering the solutions that life sciences innovators need to gain and maintain market authorization for their products.

Trusted Partner

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.

Integrated Solutions

Our unique platform and team of cross-functional experts deliver integrated solutions that equip clients with a premier regulatory resource.

Together, we redefine regulatory consulting with integrated solutions that unlock success and clear the path to better health.

Why ELIQUENT?

ELIQUENT's full-service platform and team of cross-functional experts deliver integrated solutions that equip clients with a **premier regulatory resource**. Together, we redefine regulatory consulting and clear the path to better health.

Skilled



Our **unprecedented assembly** of global regulatory experts set the industry standard with an unmatched level of skill, capabilities, and insight.

Specialized



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

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 – around the corner or across the globe – our **agile expert teams** are **ready on-demand** for your **most complex challenges**.

Scope



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

425+ years
of combined
experience at **global
health authorities**



John **Taylor**, J.D.
Quality & Compliance
20+ years at FDA



Sandra **Kweder**, M.D.
Drugs & Biologics
33+ years at FDA



David **Elder**
Quality & Compliance
23+ years at FDA



Celia **Witten**
Drugs & Biologics
17+ years at FDA



Mark **Kramer**
Combination Products
17+ years at FDA



Michele **Dougherty**, Ph.D.
Drugs & Biologics
10+ years at FDA



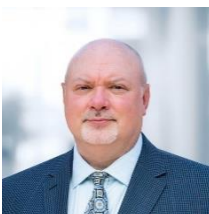
Heather **Rosecrans**
Medical Devices
33+ years at FDA



Kristen **Grumet**
Quality & Compliance
8+ years at FDA



Sarah **McGarry**, M.D.
Drugs & Biologics
18+ years at FDA



Chris **Leptak**, M.D., Ph.D.
Drugs & Biologics
14+ years at FDA



Mike **Ryan**
Medical Devices
21+ years at FDA



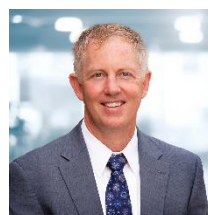
Donald **Ashley**, J.D.
Quality & Compliance
6+ years at FDA



Shelley **Gandhi**
Pharmacovigilance and Safety
19+ years at MHRA



Brian **Mayhew**
Regulatory Policy
4+ years at FDA



Tom **Berry**, Pharm.D.
Quality & Compliance
20+ years at FDA



Steven **Bowen**, Ph.D.
Drugs & Biologics
8+ years at FDA



Lydia **Martynec**, M.D.
Drugs & Biologics
20+ years at FDA



Meredith **Francis**, J.D.
Drugs & Biologics
20+ years at FDA



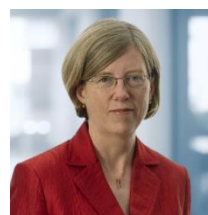
Silvana **Borges**, M.D.
Drugs & Biologics
17+ years at FDA



Grace **McNally**
Quality & Compliance
30+ years at FDA



Robin **Huff**, Ph.D.
Drugs & Biologics
7+ years at FDA



Ann **O'Connor**
Combination Products
17+ years at HPRA



Dawn **Wydner**, Ph.D.
Quality & Compliance
10+ years at FDA



Brooke **Higgins**
Quality & Compliance
23+ years at FDA



Tiffany **Lucas**, Ph.D.
Drugs & Biologics
6+ years at FDA



Maya M. **Davis**, Ph.D.
Quality & Compliance
16+ years at FDA

Trusted Partner

ELIQUENT is a trusted partner to Life Science innovators and currently serves 38 out of the **Top 50 Pharma Companies**.





Integrated Solutions

ELIQUENT's integrated suite of solutions enables a full-service engagement that delivers end-to-end support. **Together, we unlock regulatory excellence.**

Regulatory Affairs

From the earliest phases of development, through regulatory submissions, ELIQUENT guides companies to approval and beyond.

PV + Safety

Customized global pharmacovigilance and safety solutions empower companies to operate with confidence.

Quality & Compliance

Specialized solutions equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Remediation Solutions

Unmatched level of credibility and trust when interacting with regulators and guiding companies to remediation solutions.

Talent Solutions

Network of hand-picked, ready to deploy global experts ensure the right talent at the right place and time.

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 experience, we understand what it takes to bring innovations to market.

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Drugs & Biologics
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Medical Devices & Diagnostics
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Combination Products
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Advanced Therapies & CGT
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Cosmetics
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Radiopharmaceuticals
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Pathway Solutions

Clients turn to our team of former regulators and industry leaders for objective guidance across the regulatory pathway.

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Nonclinical
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Preclinical
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Clinical
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Regulatory Submissions
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Manufacturing & Distribution
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Post-Market Solutions
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Global Solutions

ELIQUENT'S established global presence spans the regulatory process and provides expert support across global markets.

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Global Market Entry
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United States
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Europe
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Asia
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Specialized Solutions

ELIQUENT provides specialized solutions that are tailored to the unique needs of the life sciences industry.

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Industry Due Diligence
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Regulatory Policy
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Expert Training
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Regulatory & Medical Writing
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Litigation Support
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Engineering & Quality Validation
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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 combo 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

Radiopharmaceuticals

ELIQUENT understands and meets the unique challenges and opportunities facing radiopharmaceuticals - complex oversight, short-lived isotopes, evolving global requirements, and cutting-edge scientific advancements.

Areas of expertise:

- Regulatory submissions
- Market Authorization
- Strategy & Development
- Lifecycle Management
- Regulatory Compliance

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 support clients from the earliest phases of development to post-approval regulatory support.



Global Solutions

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

United States

ELIQUENT is a leading FDA regulatory consulting firm. 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.

Global Market Expansion

ELIQUENT provides end-to-end solutions that support companies navigating complex global regulations. Whether launching a new product or expanding into new regions, ELIQUENT works with innovators to mitigate risks, streamline approvals, and maintain compliance across evolving regulatory landscapes.



Europe

With decades of experience in the European market, our team understands the intricacies of the European Medicines Agency (EMA) and offers tailored solutions that keep clients in lock-step with evolving global standards.

Asia

ELIQUENT offers regionally specialized solutions for innovators across Asia. Our team of highly specialized experts partner with innovators to develop a synchronized, global go-to-market approach that unlocks the full potential of the Asia market and leverages the strategic advantages of Japan's regulatory landscape.

Specialized Solutions

ELIQUENT's specialized solutions are tailored to the unique needs of the life sciences industry. Our experts deliver targeted support that helps clients overcome challenges, accelerate timelines, and maintain compliance.

Engineering & Quality Validation

Manufacturing optimization driven by commissioning, qualification, validation, and project management.

Industry Due Diligence

Empowering clients to confidently navigate opportunities with strategic decision making for both buy-side and sell-side transactions.

Regulatory & Medical Writing

From submission to launch, our clear, compliant narratives streamline approvals, reduce delays, and support global regulatory success.

Regulatory Policy & Intelligence

Solutions designed to advance stakeholder engagement, inform policy interpretation, and deliver global regulatory intelligence.

Expert Training Solutions

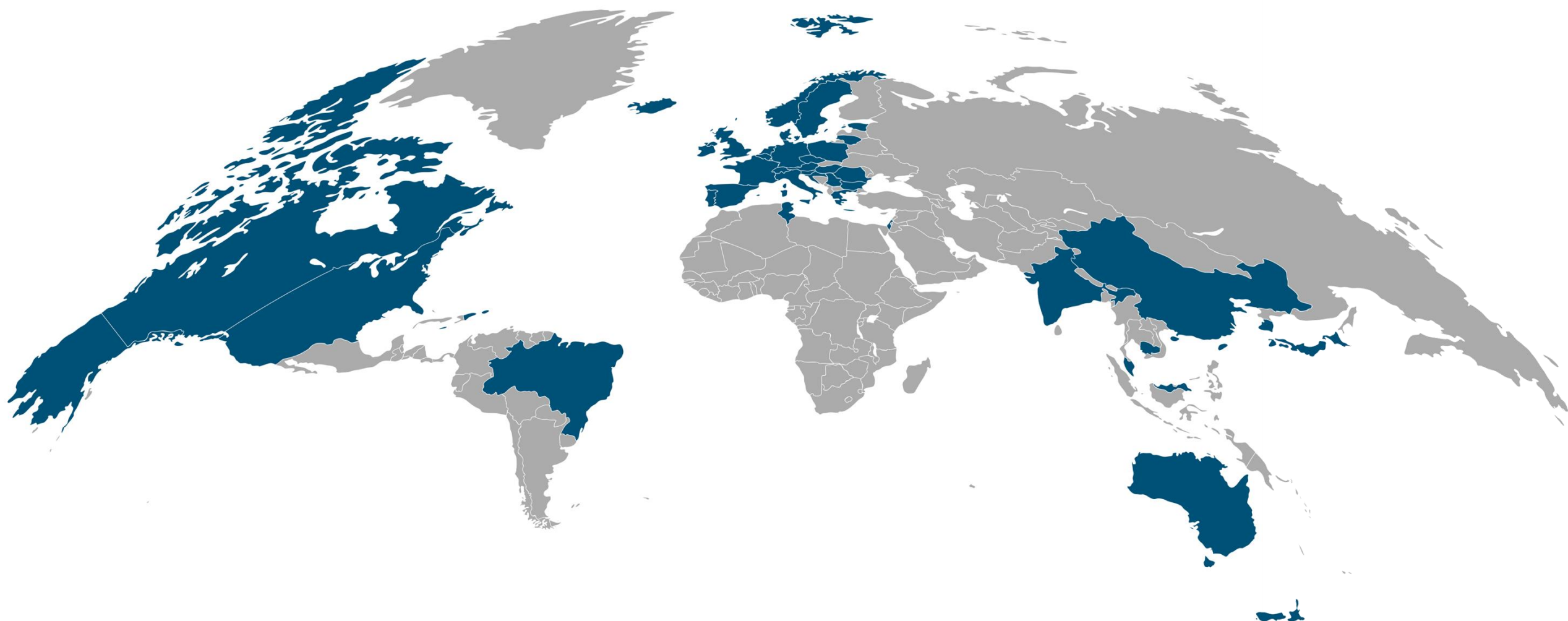
Customized training that empowers teams from the earliest phases of development through post-market support.

Litigation Support Services

Unmatched litigation support and expert witness services to support companies and their outside counsel in the midst of legal disputes.

Expertise Beyond Borders

Since 2022, ELIQUENT has provided expert support to clients across **51 countries** - ensuring seamless market access, regulatory solutions, and compliance worldwide.



 Australia	 China	 Greece	 Japan	 Netherlands	 Singapore
 Austria	 Croatia	 Hungary	 Jordan	 New Zealand	 Slovenia
 Belgium	 Czech Republic	 Iceland	 Korea - South	 Norway	 Spain
 Brazil	 Denmark	 India	 Lithuania	 Poland	 Sweden
 Bulgaria	 Dominican Republic	 Ireland	 Luxembourg	 Portugal	 Switzerland
 Cambodia	 Estonia	 Isle of Man	 Malaysia	 Puerto Rico	 Taiwan
 Canada	 France	 Israel	 Malta	 Romania	 Tunisia
 Cayman Islands	 Germany	 Italy	 Mexico	 Serbia	 United Kingdom
					 United States

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

FROM **c**ause
TO **c**ure



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.



**Regulatory
Affairs**

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 +
Post-market
Surveillance**

With a global 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 **quality & 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 professionals and global experts bring an unmatched level of credibility and trust when interacting with regulators and guiding companies to **remediation** solutions.

**Talent
Solutions**

ELIQUENT's network of hand-picked, ready to deploy global experts gives you the ability to scale your team to the right size, with the right **talent**, 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	Regulatory Meetings & Communications	Actionable strategies and insight for milestone meetings and regulatory communication
Clinical Programs	Specialized guidance and strategic design of nonclinical, pre-clinical, and clinical programs	Regulatory Policy Guidance	Customized solutions to understand, implement, and comply with regulatory policies and programs
CMC Strategy	Risk-based design and effective implementation of phase-appropriate CMC solutions	Marketing, Promotion & Labeling	Strategic direction on labeling requirements, promotional materials, and marketing programs
Pathway Decisions	Expert support on product classifications, special designations, and expedited program pathways	Lifecycle Support	Valuable expertise throughout the product lifecycle, including post-approval requirements and commitments

Integrated Solutions



Pharmacovigilance & Risk Management

ELIQUENT’s pharmacovigilance capabilities are the industry gold-standard. Our expert team optimizes practices to ensure consistency, compliance, and operational efficiency, while aligning with evolving global demands. **ELIQUENT’s full-service pharmacovigilance solutions include:**

Technology Enablement	ELIQUENT modernizes pharmacovigilance systems to align with business goals and ensure scalable, compliant performance.	Operational Harmonization	Our experts drive compliant, scalable safety operations by aligning people, processes, and performance across global teams.
Safety System Modernization	Our team delivers inspection-ready pharmacovigilance systems that streamline data, support oversight, and scale with compliance.	Risk Management	ELIQUENT embeds proactive, lifecycle-wide risk management to strengthen safety strategy and ensure compliance.
Compliance Capabilities	ELIQUENT ensures inspection readiness and practical solutions to keep safety operations ahead of regulatory expectations.	Organizational & Talent Solutions	We build scalable pharmacovigilance teams - equipping your organization to lead in a dynamic regulatory environment.

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

Engineering & Quality Validation

Manufacturing optimization driven by commissioning, qualification, validation, and project management.

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	Corrective Action Plans	Design and enable action plans that are both effective and sustainable for your business
Rapid Response	Immediate deployment of compliance experts to provide valuable on-site support when time is of the essence	Implementation Expertise	Tailored support to implement both acute and systemic improvements across facilities and product lines
Customized Solutions	Actionable remediation plans to correct known problems, prevent future occurrences, and meet regulatory expectations	On-Demand & On-Site	Skilled resources ready to support implementation plans, sustain compliance, and respond to evolving demands
Comprehensive Communications	Valuable direction when interacting with and effectively responding to regulatory communications	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



Talent Solutions

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. When on-site support is needed, ELIQUENT’s Talent Solutions mobilize a tailored team, anywhere in the world, in as little as one week. Our handpicked network ensures the right talent at the right place and time. **ELIQUENT’s full-service talent solutions include:**

Interim Leadership

Enabling organizations to fill temporary leadership gaps with skilled professionals and an eye toward regulatory success.

Project Based Teams

The expertise, leadership, and support needed to successfully execute project-based objectives on time, within budget, and to the highest quality standards.

Contractor Interim Staffing

Designed for organizations addressing *immediate* staffing needs. Our team of experts bridge skills gaps, manage workload fluctuations, and execute specific project initiatives.

FSP Outsourcing

ELIQUENT’s Functional Service Provider (FSP) outsourcing solutions provide organizations with custom solutions that deliver specialized expertise, flexible engagement models, and an eye toward meeting your business objectives.

RPO Solutions

ELIQUENT’S Recruitment Process Outsourcing (RPO) Solutions provide a streamlined recruitment process that attracts top talent and builds high-performing teams capable of driving business success.



Your premier regulatory resource – **from thought to finish.**

ELIQUENT.com