ELIQUENT Life Sciences:

Momentum Through Complexity

ELIQUENT LIFE SCIENCES



What Starts as One Problem Rarely Ends There

Your biggest challenges are where regulatory, quality, and safety intersect.

A first IND submission that surfaces safety signals.	A CRL citing manufacturing deficiencies.
An inspection finding that becomes a safety issue.	A supplier change that reopens past filings.

The faster you can get to an integrated solution, the quicker you can move forward.

ELIQUENT Life Sciences:
Where Momentum Happens

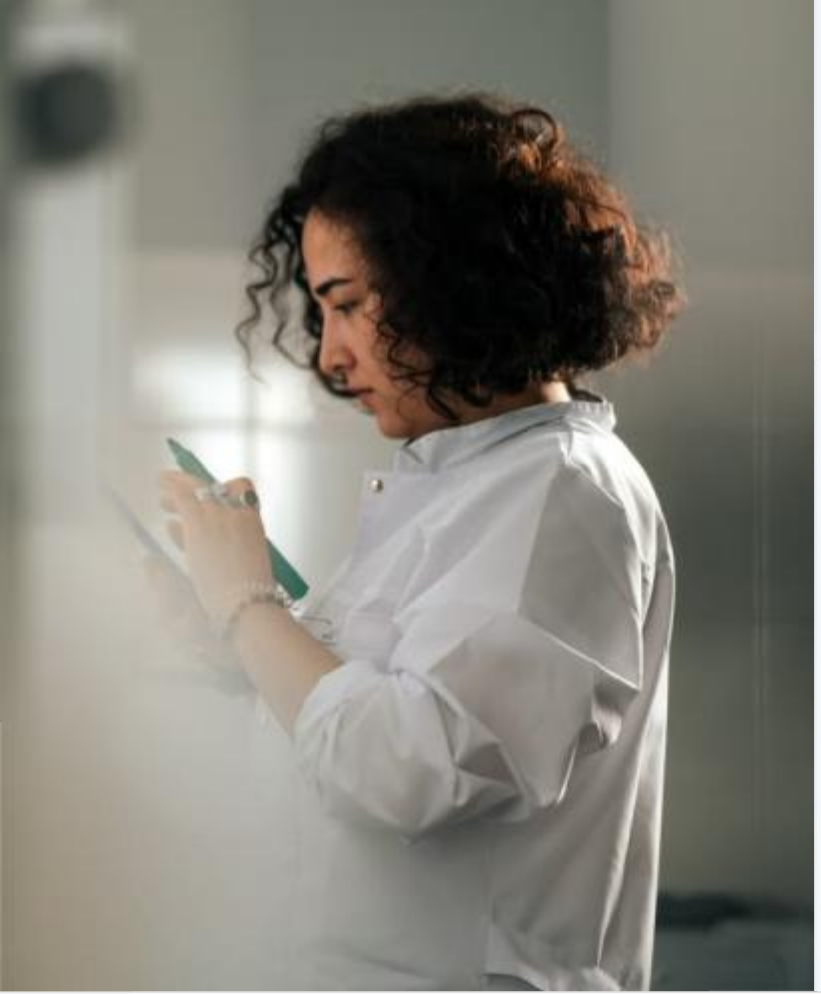
At ELIQUENT, we help life sciences companies solve their most complex challenges. We're one global integrated team of experts spanning regulatory, quality, and safety, here to help you grow and scale at your speed.

One partner from first filing to post-approval, with you every step of the way.

Integrated expertise across regulatory, quality, and safety that brings every part of your strategy together.

A team of regulators, global inspectors, and senior life sciences leaders with 400+ years of regulatory and industry experience who see your challenge from every angle.

Global reach wherever your business takes you, backed by experience with 800+ clients worldwide.



Wherever You're Headed, We Move With You

What opportunity are you currently pursuing?

Advance products from concept to commercialization

Prepare for inspections, audits and remediation events

Ensure quality, compliance, and patient safety

Adopt AI with confidence while maintaining compliance

Navigate global regulatory and market access challenges

Build, scale and optimize manufacturing capabilities

The Depth to Solve Any Regulatory, Quality, or Safety Challenge

ELIQUENT Life Sciences



The partner you want early. The partner you need now.

Our Team of Experts Keeps Your Program Moving

...across sectors

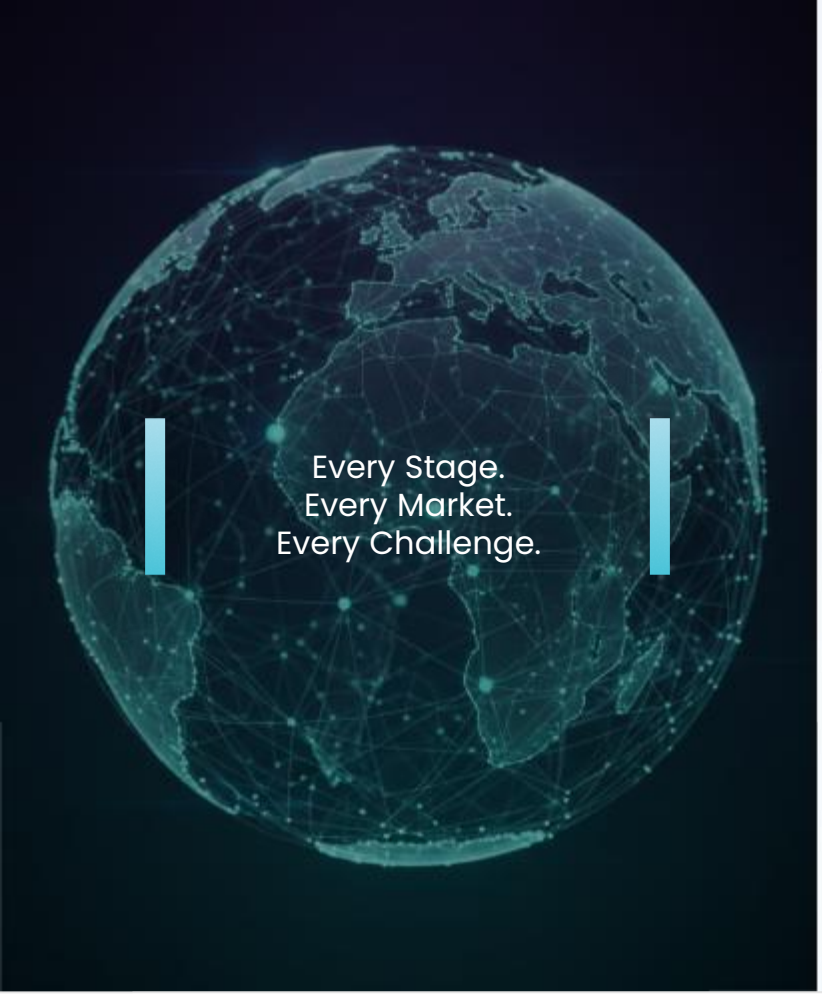
- Global Pharma
- Emerging Biotech
- CDMOs & CMOs
- Medtech & Devices
- Investors & Acquirers

...across modalities

- Drugs & Biologics
- Medtech
- Advanced Therapies
- Combination
- Radio Pharma
- Medical Cosmetics

...across categories

- Rare Disease
- Oncology
- Immunology
- Vaccines
- Cell & Gene
- Biosimilars
- Dermatology



A Unified Global Team

Regulatory, quality, and safety requirements are shifting around the world. ELIQUENT brings the global expertise and agility to keep your program moving wherever it takes you.

Established relationships in the countries you're targeting, giving you access to the right people for your program.

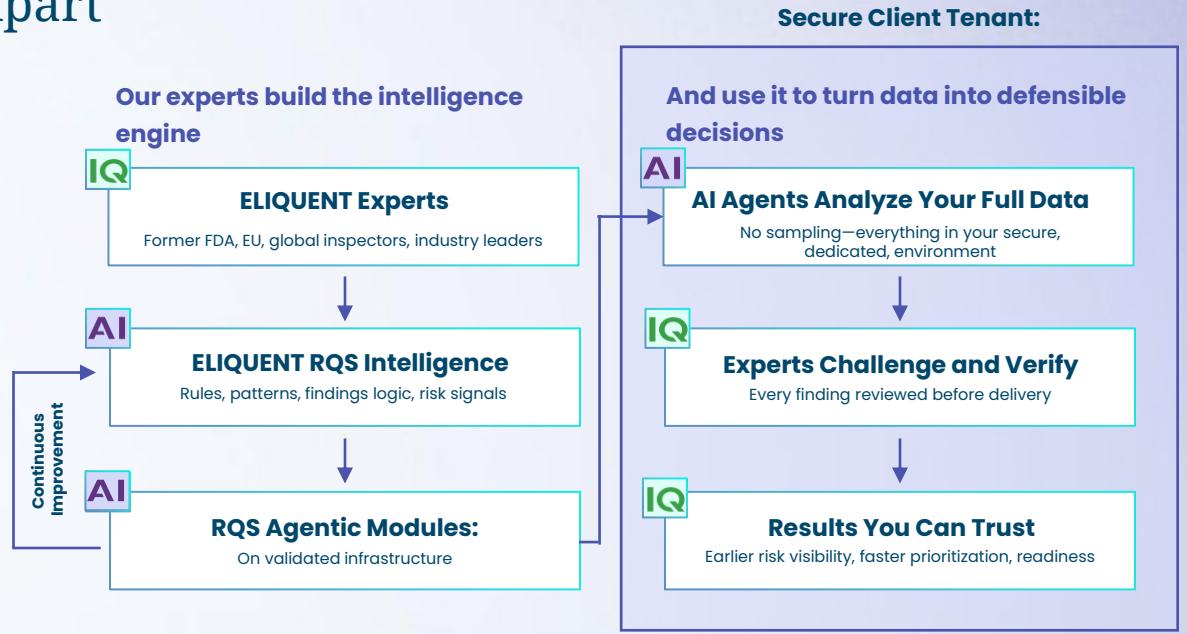
The agility to staff and deliver across regions with speed and consistency, so you can move forward quickly.

Strategies shaped by global health authority guidance, aligning your approach across every market.

Intelligence That Sets Us Apart

ELIQUENT's methodology combines AI agents with the expertise of regulators, inspectors, and industry leaders to help you build, verify, and govern every review.

This means you get earlier visibility into quality and regulatory risk, and faster prioritization and findings your team can act on. And with every review, the system gets smarter, with quarterly updates that incorporate the latest agency guidance and changes across your portfolio to keep it current as your needs evolve.



CASE STUDY 01

Find the Fastest Pathway to Approval

When you're planning a route to your first submission, ELIQUENT identifies the fastest pathway available to your product, builds the pre-IND meeting package, and finds the gaps in your development plan.

ELIQUENT in Action

PROBLEM

A vaccine developer preparing its first mRNA IND faced nonclinical data gaps.

STRATEGIC SOLUTION

ELIQUENT closed the nonclinical gaps and built both the Pre-IND and IND packages.

IMPACT

IND clearance and a smooth transition into clinical development.

COMBINED EXPERTISE

REGULATORY AFFAIRS

QUALITY & COMPLIANCE

CASE STUDY 02

Enter a New Product Category

When you're expanding into a new product modality, ELIQUENT navigates classification and pathway decisions, identifies product precedents, and builds an end-to-end approval and launch plan.

ELIQUENT in Action

PROBLEM

A global biopharma manufacturer and its affiliate needed to meet combination product requirements across the US, EU, and other target markets.

STRATEGIC SOLUTION

ELIQUENT ran a gap assessment, built a full combination product QMS, trained the teams, and delivered two years of remediation and advisory support.

IMPACT

Successful audits and inspections by FDA, BSI, EMA, and Korea's MFDS, plus new market approvals.

COMBINED EXPERTISE

REGULATORY AFFAIRS

QUALITY & COMPLIANCE

REMEDIATION SOLUTIONS

CASE STUDY 03

Expand Labels and Indications

When you're pursuing a new indication, ELIQUENT plans the filing sequence, builds the evidence package, and prepares the labeling and negotiation strategy.

ELIQUENT in Action

PROBLEM

A global immunology biotech needed a new market for its drug after the FDA rejected its US filing.

STRATEGIC SOLUTION

ELIQUENT repositioned Japan as the lead market, steering PMDA consultations to secure orphan drug priority review and J-NDA endorsement.

IMPACT

First-in-the-world approval of the expanded indication in Japan.

COMBINED EXPERTISE

REGULATORY AFFAIRS

PHARMACOVIGILANCE & SAFETY

CASE STUDY 04

Scale Manufacturing Without Supply Disruption

From building and validating quality systems to vetting external manufacturing partners, ELIQUENT ensures your capacity grows without supply chain interruption.

ELIQUENT in Action

PROBLEM

An investor acquiring a manufacturer with prior FDA enforcement actions needed to verify if a proposed third-party partner could safely absorb its operations.

STRATEGIC SOLUTION

Former FDA investigators audited the target's compliance gaps and independently evaluated the proposed partner's facility readiness.

IMPACT

Delivered a clear risk assessment and post-acquisition compliance roadmap to ensure a seamless manufacturing transition.

COMBINED EXPERTISE

REGULATORY AFFAIRS

QUALITY & COMPLIANCE

GxP CONSULTING & IMPLEMENTATION

CASE STUDY 05

Overcome a Regulatory Setback

When an agency raises findings you need to resolve, ELIQUENT conducts a root-cause analysis, implements corrective actions, and provides independent verification.

ELIQUENT in Action

PROBLEM

A global dermatology company contacted ELIQUENT after receiving a Complete Response Letter on its first BLA.

STRATEGIC SOLUTION

ELIQUENT supplied biologics CMC experts, leading four FDA interactions with prepared packages and mock sessions.

IMPACT

A viable, FDA-informed plan to address the CRL and restore development momentum for the project.

COMBINED EXPERTISE

REMEDIATION SOLUTIONS

REGULATORY AFFAIRS

QUALITY & COMPLIANCE

CASE STUDY 06

Access New Global Markets

When you're looking to expand your global footprint, ELIQUENT builds the market-specific strategies and regional capabilities needed to secure rapid global approvals.

ELIQUENT in Action

PROBLEM

A biopharmaceutical firm needed to accelerate market access for a rare disease therapy across emerging GCC and EMEA regions.

STRATEGIC SOLUTION

ELIQUENT developed a market-by-market submission roadmap, implemented custom regulatory tracking tools, and conducted local training to expedite timelines.

IMPACT

Accelerated market entry and approvals in key regions as well as supporting future product launches across broader APAC and LATAM regions.

COMBINED EXPERTISE

REGULATORY AFFAIRS

QUALITY & COMPLIANCE

ELIQUENT Life Sciences

The strategic vision and hands-on execution that keep your products moving toward the patients who need them.

Tell us where you're trying to go and what is standing in the way.



Appendix

Regulatory

Accelerate from pre-market development to post-approval support

ELIQUENT navigates complex global agency requirements to help you move efficiently from early pipeline strategy through market approval and long-term lifecycle management.

Shape pipeline strategy and submission pathways across markets

Prepare for and lead critical agency meetings with former reviewers

Interpret new regulations before they hit your programs

Quality & Compliance

Unmatched expertise from pipeline to patient

ELIQUENT Quality & Compliance fortifies your operational backbone by designing robust quality systems and resolving compliance challenges across your entire product lifecycle.

Qualify suppliers and close gaps across your supply chain

Implement reliable engineering and quality validation processes across your facilities

Strengthen laboratory controls and modernize data integrity systems

Pharmacovigilance & Safety

Safety expertise designed to keep your product moving

ELIQUENT's pharmacovigilance team protects your patients and your product's market standing by modernizing your safety systems and ensuring continuous inspection readiness.

Modernize your safety infrastructure with secure technology enablement and system migrations

Achieve complete inspection readiness by embedding strong compliance capabilities into your workflows

Seamlessly manage post-market safety data

Remediation Solutions

We keep you moving through your toughest regulatory challenges

The veteran remediation leaders at ELIQUENT turn regulatory crises into structured recoveries, executing corrective actions to get you moving forward again.

Execute corrective action plans against your warning letter commitments

Clear validation and documentation backlogs on the agency's timeline

Monitor and report progress with objective third-party verification

GxP Consulting & Implementation

Engineers and former regulators who build it, not just advise it

We bridge the gap between clinical development and commercial scale by designing and building validated, inspection-ready facilities and digital systems.

Design and qualify facilities and equipment for commercial scale

Validate the digital systems your operations depend on

Deploy technical staff into your sites wherever you operate