



# ELIQUENT

LIFE SCIENCES

Bringing clarity to life sciences regulatory 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.

# 375+ 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**



Dan **Schultz**, M.D.  
Medical Devices  
**20+ years at FDA**



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



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



Michele **Dougherty**, Ph.D.  
Regulatory Affairs – U.S.  
**10+ years at FDA**



Kalah **Auchincloss**, J.D.  
Quality & Compliance  
**6+ years at FDA**



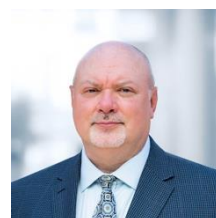
Kristen **Grumet**  
Quality & Compliance  
**8+ years at FDA**



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



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



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



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



Shelley **Gandhi**  
Pharmacovigilance  
**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**



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



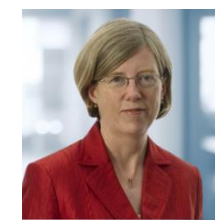
Silvana **Borges**, M.D.  
Drugs & Biologics  
**17+ years at FDA**



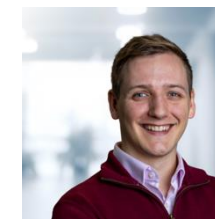
Grace **McNally**  
Quality & Compliance  
**30+ years at FDA**



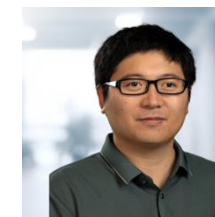
Robin **Huff**, Ph.D.  
Drugs & Biologics  
**7+ years at FDA**



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



William **Tillet**  
Regulatory Affairs - EU  
**2+ years at UKHSA**



Shenggang **Wang**, Ph.D.  
Regulatory Affairs  
**3+ years at FDA**



Vincent **Li**, Ph.D.  
Drugs & Biologics  
**5+ years at FDA**



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



# 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  
.....

Advanced Therapies & CGT  
.....

Cosmetics  
.....

Radiopharmaceuticals  
.....

## **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  
.....

# 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.

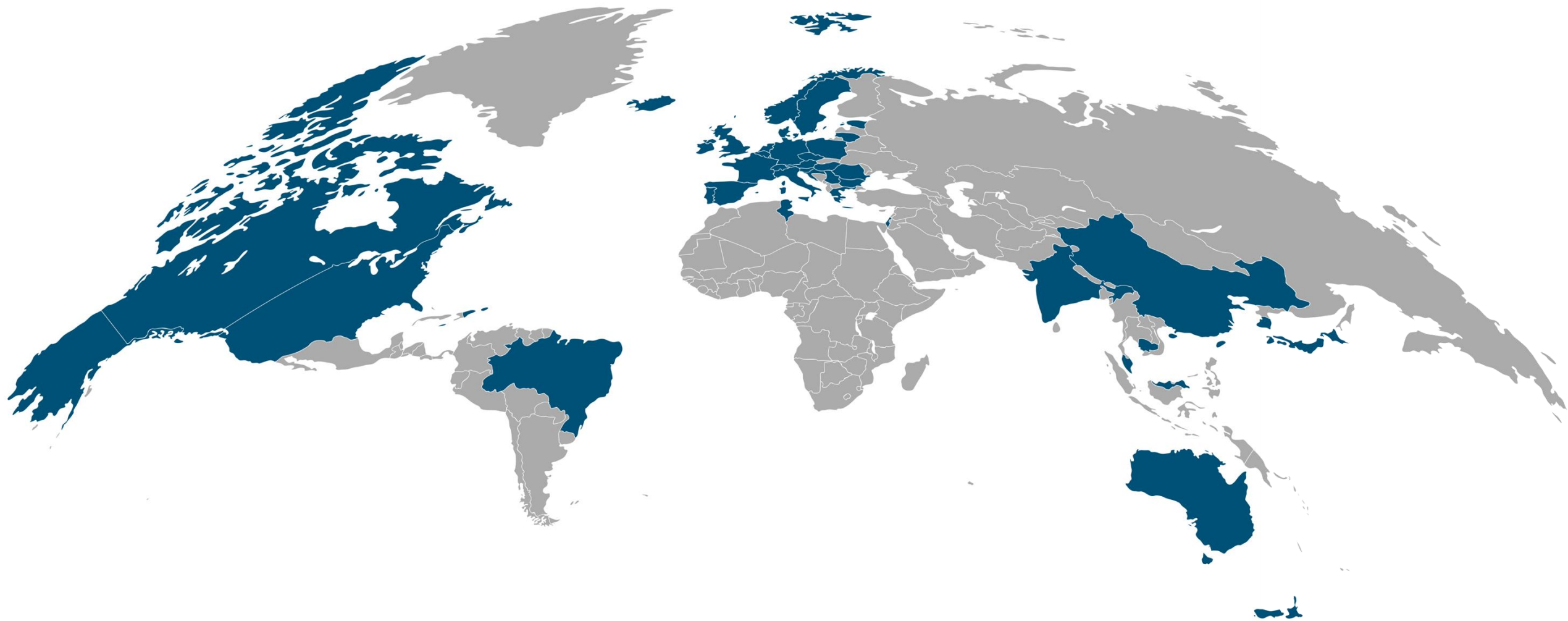
## Asia

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.



# 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

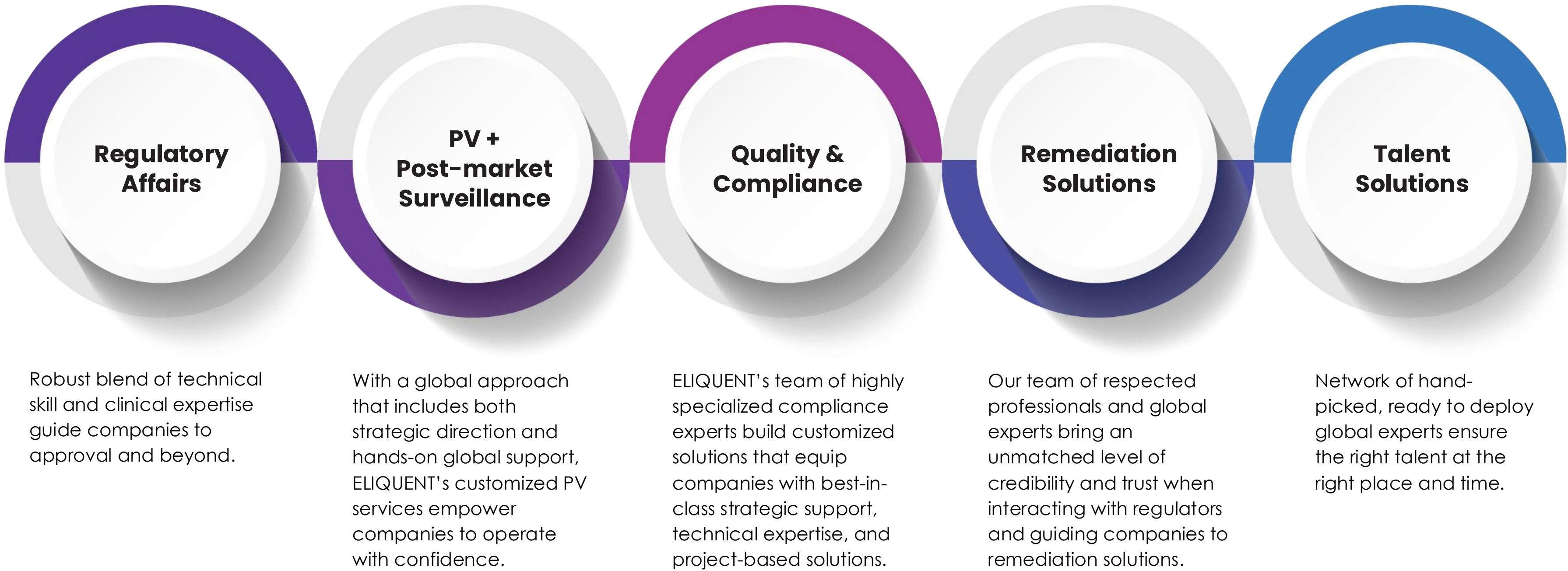
FROM **c**ause  
TO **c**ure





# 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.



# 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:**

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

<b>Compliance Assessments</b>	Strategic and technical evaluations to identify areas of non-compliance & mitigate other potential risks	<b>Corrective Action Plans</b>	Design and enable action plans that are both effective and sustainable for your business
<b>Rapid Response</b>	Immediate deployment of compliance experts to provide valuable on-site support when time is of the essence	<b>Implementation Expertise</b>	Tailored support to implement both acute and systemic improvements across facilities and product lines
<b>Customized Solutions</b>	Actionable remediation plans to correct known problems, prevent future occurrences, and meet regulatory expectations	<b>On-Demand &amp; On-Site</b>	Skilled resources ready to support implementation plans, sustain compliance, and respond to evolving demands
<b>Comprehensive Communications</b>	Valuable direction when interacting with and effectively responding to regulatory communications	<b>Maintenance &amp; Monitoring</b>	Uphold the integrity of implemented practices with ongoing monitoring and maintenance
		<b>Third-Party Reporting</b>	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.