Experience the power of clarity.

ELIQUENT Life Sciences brings clarity to regulatory complexity. We are expert consultants delivering the answers and solutions that life sciences innovators need to gain and maintain market authorization for their products.

Regulatory Writing Solutions

Regulatory and medical writing plays a crucial role in translating scientific data and clinical findings into clear, compliant, and impactful documents. ELIQUENT's highly specialized medical writing team unlocks the full potential of your product's journey by creating a compelling narrative that resonates with regulators and positions your product for success.

Unlock **Excellence**

From streamlining regulatory approvals to enhancing market presence, our medical writing solutions support your regulatory objectives and strengthen your market position.

Strategic Storytelling

ELIQUENT understands that the best stories are built through collaboration. Our medical writers partner with your internal teams to build a story that positions your product for success. This collaborative approach captures your product's journey, prioritizes your business objectives, and builds a compelling narrative that resonates with regulators.

Accelerate Time to Market

Effective medical writing anticipates potential questions or objections from regulators and addresses them within the narrative. By complying with regulatory requirements the first time around, ELIQUENT's regulatory and medical writing solutions streamline the approval process, reduce delays, and accelerate your product's journey from concept to market.

Expand Global Market Entry

Entering global markets involves more than just innovative products - it requires precise, clear, and regulatory-compliant documentation. ELIQUENT's medical writing team distills complex scientific data into accessible, authoritative documents that meet the regulatory requirements of international regulatory bodies.

Unmatched **Expertise**

Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly with our highly skilled medical writing team. Guided by decades of experience, spanning a wide range of therapeutic areas, ELIQUENT's team of respected professionals bring the unmatched expertise that companies need when working directly with global regulators.

Why Collaboration Matters: The collaboration between medical writers and subject matter experts (SMEs) is not just beneficial; it's essential. This partnership bridges the gap between deep scientific knowledge and its articulate expression in regulatory documents, medical literature, and educational materials. Together, the collaborative teams excel at translating complex scientific data into clear, precise, and compelling regulatory documents.

Specialized Solutions

ELIQUENT's Regulatory Writing Solutions are more than compiling and presenting data – our expert team collaborates with innovators and a team of regulatory experts to build compelling stories that guide regulators through an evidence-based narrative. The outcome is a persuasive justification that conveys facts and ultimately supports market entry. ELIQUENT support innovators in the following areas:

Regulatory Documentation

ELIQUENT's regulatory documentation solutions are tailored to meet the stringent requirements of regulatory authorities worldwide. We collaborate with your team to develop scientifically rigorous, accurate documents that are aligned with current regulatory expectations. Our regulatory documentation solutions include:

- Clinical Development Plans
- Clinical & Nonclinical Common Technical Documents (CTD)
- Clinical Study Reports (CSRs)
- Health Authority briefing documents and responses
- Product Labeling and Instructions for Use (IFUs)
- Protocols
- Pediatric Investigation Plans (PIPs) and Pediatric Study Plans (PSPs)

Safety & Pharmacovigilance

ELIQUENT's pharmacovigilance writing services ensure your safety documentation is not only compliant but also strategically aligned to support the long-term safety and efficacy of your product. Our team collaborates to develop a wide range of pharmacovigilance documents, including:

- Risk Management Plans (RMPs)
- Pharmacovigilance System Master File (PSMF)
- Signal Detection Reports
- Development Safety Update Reports (DSURs)
- Post authorization safety/efficacy studies
- Post-Market Safety Reports
- Periodic Safety Update Reports/Periodic Benefit-Risk Evaluation Reports (PSURs/PBRERs)

Comprehensive Capabilities

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

Pathway Solutions

ELIQUENT guides innovators on their path to approval and beyond. As former regulators and industry leaders, our understanding of the complete product lifecycle is unrivaled. ELIQUENT's Medical Writing Solutions align with your products development pathway - from initial drafts to final submissions, we provide end-to-end support throughout the regulatory pathway.

Global Solutions

ELIQUENT understands the unique challenges of navigating global regulatory requirements. Our team of global experts work seamlessly with our medical and regulatory writing team to leverage decades of combined global regulatory experience across the U.S., Europe, and Asia Pacific. Whether you're navigating complex U.S. Food and Drug Administration (FDA) submissions, European Medicines Agency (EMA) clinical trial applications, or preparing for a pre-consultation meeting with Japan's Pharmaceuticals and Medical Devices Agency (PMDA), our medical writing solutions are customized to meet your unique regulatory needs.

Market Solutions

ELIQUENT experts demonstrate unequaled levels of skill in their regulatory specialties. Our team of professional medical writers – working cross-functionally with our regulatory experts - brings a deep understanding of the pharmaceutical, biotechnology, and medical device industries. With extensive experience across therapeutic areas, our writers know how to communicate complex information effectively.