ELIQUENT™
LIFE SCIENCES

Regulatory clarity

FROM hurdles TO health

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.

Pharmacovigilance & Risk Management Solutions

A reliable and effective pharmacovigilance program is more than a regulatory requirement—it is a cornerstone of patient trust and product success. With decades of experience developed as leaders in both the public and private sectors, ELIQUENT's industry-recognized pharmacovigilance and risk management experts serve as trusted partners to global life science innovators. Our team works across the entire product lifecycle to support innovators with precision and expertise – enabling you to navigate global post-marketing surveillance, adverse event reporting, and risk management planning with confidence and clarity.

Strategic & Technical Capabilities

ELIQUENT's Pharmacovigilance and Risk Management Solutions are the industry gold-standard. With an approach that includes both strategic direction and hands-on support, ELIQUENT optimizes practices to ensure consistency, compliance and operational efficiency. Because there is no one-size-fits-all approach, each solution is built to support your regulatory objectives, while aligning with evolving global demands.

Global Support
Navigate and comply with global pharmacovigilance regulations through our expert guidance, ensuring consistent safety standards across all markets.

Post-Market Surveillance
Leverage our network of experts to continuously monitor commercial product safety, detecting and addressing issues as they arise.

Clinical Trials Safety Oversight
Access on-demand resources for rigorous safety monitoring during clinical trials, ensuring safety standards are met from inception to approval.

Risk Assessment & Management
Proactively manage potential risks with our comprehensive assessment and strategic planning services, maintaining compliance and product safety.

Global **PV Training**
Bespoke pharmacovigilance training programs to uphold the highest regulatory standards across diverse global markets.

Regulatory Reporting
Manage complex regulatory reporting obligations efficiently with our expertise, ensuring accurate and timely submissions.

Signal Detection
Implement advanced signal detection processes to identify safety issues early, enhancing patient safety and regulatory compliance.

Adverse Event Reporting
Systematically identify, analyze, and manage adverse events with our strategic support to maintain safety and regulatory compliance.

Risk Communications
Develop and execute communication plans to effectively address safety concerns and maintain market confidence.

QPPV – Qualified Person for PV
Comprehensive QPPV solutions ensure clients meet EU, UK, and regional pharmacovigilance requirements, while safeguarding patient safety.

Unmatched expertise

A globally recognized leader in pharmacovigilance and risk management, **Shelley Gandhi** brings more than three decades of experience to her role at ELIQUENT Life Sciences.

Shelley's extensive professional background includes more than 19 years of service at the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

During her tenure, Shelley served in multiple senior positions, including a role as the UK representative on the European Medicines Agency's (EMA) EudraVigilance Expert Working Group. In this capacity, Shelley was instrumental in shaping key pharmacovigilance processes and systems across Europe.

In her role at ELIQUENT, Shelley's firsthand knowledge of regulatory expectations and her proficiency in navigating complex safety assessments and reporting challenges are invaluable to the long-term success of life science innovators.

About **Shelley**

Follow this link to learn more about Shelley.

Specialized Solutions

ELIQUENT's foundation is built on experts with the foremost strategic and technical skill across markets, pathways, and global regulations.

ELIQUENT's specialized solutions showcase our collective capabilities and combined expertise. Together, we create a full-service model that equips clients with a premier regulatory resource.

Global Safety Advisory Solutions

Designed to support and enhance the safety of your pharmaceutical products from early clinical development through to post-market surveillance with a proactive approach to managing drug safety and regulatory challenges on a global scale.

PV System Optimization

ELIQUENT specializes in designing and optimizing PV systems, ensuring seamless integration during mergers and acquisitions, and enhancing oversight of PV vendors. Our services streamline operations, reduce risks, and improve compliance across all facets of pharmacovigilance.

Safety Operations

ELIQUENT ensures that every level of your organization is integrated and aligned with international safety standards, providing comprehensive support tailored to your specific needs.

Inspection Readiness

With decades of experience and a track record of success, our team of unmatched experts develop customized strategies to prepare for inspections and align with regulatory expectations.

Regulatory & Medical Writing

ELIQUENT's Regulatory Writing Solutions ensure your safety documentation is not only compliant but also strategically aligned to support the long-term safety and efficacy of your product.

Learn **More**

Follow this link for more more PV Solution success.