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.

Laboratory Developed Tests: **LDT Solutions**

For decades, Laboratory Developed Tests (LDTs) have been subject to little regulatory oversight compared to in vitro diagnostic tests (IVDs), allowing laboratories to develop and run these tests unencumbered by FDA regulatory requirements. As LDTs have become increasingly sophisticated and commercially widespread, the FDA has moved to regulate them, applying the same regulatory requirements to LDTs and IVDs.

The FDA's new regulatory framework will have a far-reaching impact for laboratories operating in this space and underscores the critical need for laboratories developing and marketing LDTs to establish robust quality systems that ensure regulatory compliance and product quality.

As the LDT landscape continues to evolve, a trusted partner is crucial to stay ahead of regulatory challenges. ELIQUENT Life Sciences is uniquely positioned to support laboratories during this critical transformation. Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists partners with LDT companies to maintain compliance, ensure product quality, and remain competitive in an evolving regulatory landscape.

Specialized Solutions

As the industry leader in life sciences consulting, ELIQUENT collaborates with clinical laboratories preparing to comply with new regulatory requirements. Our tailored solutions are designed to meet the unique regulatory, quality, and compliance challenges faced by LDT developers. ELIQUENT's LDT services include:

Regulatory Strategy Development

ELIQUENT works in partnership with companies to develop clear and effective strategies to achieve market authorization and regulatory compliance.

Inspection Readiness

ELIQUENT's regulatory experts develop and implement custom strategies that prepare companies for FDA inspectional responsibilities, while aligning with global regulatory standards and expectations.

Consultation & Regulatory Guidance

ELIQUENT's team provides market-leading insight that equips companies with solutions that reduce the risk of non-compliance while enhancing operational efficiency, product quality, and market access.

Labeling & Marketing Compliance

Our deep bench of former FDA officials and industry experts ensure your LDT's labeling and marketing materials comply with FDA regulations.

Expert Training

ELIQUENT experts create training solutions that empower teams to elevate regulatory compliance, drawing from the industry's largest portfolio of quality and regulatory training content.

FDA Submission Support

From preparing pre-submission materials to supporting you through the full FDA review process, our team ensures that your regulatory submission is complete.

Quality Management Systems

ELIQUENT advises laboratories on establishing and maintaining a robust quality system that meets FDA's Quality Management System Regulation (QMSR), ensuring your laboratory is audit-ready and compliant.

Regulatory Engagement

ELIQUENT guides companies through successful interactions with regulators by providing valuable support on regulatory communications, meetings, and correspondence with regulatory authorities.

Supplier Qualification & Management

ELIQUENT assesses and qualifies critical suppliers to ensure they meet FDA requirements for LDTs.

Evidence Development & Management

ELIQUENT supports the generation of analytical and clinical evidence needed for regulatory submissions, including study design, data collection, and management.

Unmatched Expertise

With decades of experience, ELIQUENT brings the unmatched capabilities that companies need when navigating today's evolving regulatory environment. Our team of professionals have directly influenced significant policy decisions and regulatory actions through their service at global regulatory authorities. The team's combined capabilities and experience building effective and sustainable regulatory programs enables a cross-functional, full-service engagement that unlocks regulatory excellence.

Kalah **Auchincloss**

More than 15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.

Maura **Norden**

15+ years of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

Kristen **Grumet**

25+ year career in quality systems compliance management, including 9-years as an FDA Field Investigator specializing in medical devices.

Kate **Leith**

40+ years experience in clinical lab, biologics, and medical device industries, spanning the product life cycle from R&D to customer support.

Full-Service Support

ELIQUENT's team of global experts work cross-functionally to provide a **full-service engagement**. 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. ELIQUENT's comprehensive capabilities include:

Regulatory Affairs Solutions

From the earliest phases of innovation through regulatory submissions, to post-approval support, ELIQUENT's robust blend of technical skill and clinical expertise guide companies to approval and beyond.

PV+ Postmarket Surveillance

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

Expert Training

ELIQUENT's customizable training programs equip teams and employees with the tools and skills to maintain global regulatory processes and build a common culture of accountability.

The **ELIQUENT** Difference

From thought to finish, concept to commerce, and strategy to execution - ELIQUENT is the singular regulatory resource that clients around the world trust. To learn more about our LDT solutions , visit our website or contact bd@eliquent.com.