ELIQUENT
LIFE SCIENCES

Regulatory Clarity from thought to finish

Combination Product Solutions

ELIQUENT Life Sciences brings clarity to regulatory complexity.
We are expert consultants delivering the solutions that combination product innovators need to gain and maintain market authorization for their products. From thought to finish, concept to commerce, and strategy to execution— ELIQUENT Life Sciences is the singular regulatory resource that clients around the world trust.

To Approval and Beyond

As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. ELIQUENT's highly specialized combination product experts provide both strategic direction and technical support from the earliest phases of development to post-approval regulatory support.

The ELIQUENT team has extensive experience with companion diagnostics, drug-coated devices, and a wide range of drug delivery systems including subcutaneous, inhaled, injected, topical, intrathecal, and closed loop. ELIQUENT's comprehensive combination product solutions include:

Product Classification

The ELIQUENT team provides strategic and technical guidance to determine a product's regulatory identity (classification) as a drug, device, biological product, or combination product.

Premarket Pathway

Guided by decades of regulatory experience, ELIQUENT experts provide best-in-class premarket support across all potential pathways, including: NDA, ANDA, BLA, PMA, 510(k), De Novo.

Regulatory Submission

ELIQUENT applies extensive regulatory perspective to develop and implement strategies that optimize a product's regulatory submission and agency interactions at every step.

Quality & Manufacturing

ELIQUENT evaluates and strengthens systems with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while meeting business objectives.

Expert Training

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

Unmatched Expertise

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. Our team of **combination product experts** includes leaders - across medical devices, regulatory policy, and manufacturing quality and compliance. Together, we unlock regulatory excellence.

DAN SCHULTZ, M.D.
Principal, Medical Device & Combo Products
Distinguished 35-year career includes service as Director of the FDA's Center for Devices and Radiological Health.

HEATHER ROSECRANS
EVP, Medical Device & Combo Products
One of the nation's leading 510(k) experts, with an FDA career that spanned more than 30 years and included a pivotal role in developing the FDA's 510(k) program.

MARK KRAMER
EVP, Medical Device & Combo Products
17-year FDA career included establishing and directing the Office of Combination Products and leading interdisciplinary review teams.

BRIAN BURNS
Partner
Extensive background in medical device quality and regulatory strategy, including leadership roles across the medical device industry.

JANET WHIPPLE
Partner
More than 25 years of experience in medical device quality, regulatory compliance, design, and operations.

KALAH AUCHINCLOSS
EVP, Regulatory Compliance
15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.

Full Service Support

ELIQUENT's unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to provide a **full-service engagement** that delivers **end-to-end support**. 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.

Regulatory Affairs

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

Pharmacovigilance & 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

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

Remediation Solutions

Our team of respected professionals and global experts bring an unmatched level of credibility and trust when interacting with regulators and guiding companies to remediation solutions.

Expert Training

Expert Training Solutions

ELIQUENT's customizable training programs are led by industry experts and focus on the complete regulatory landscape, including: drugs, devices, biologics, combination products and quality systems.