

# 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

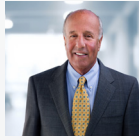
ELIQUENT evaluates and strengthens systems with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while meeting business objectives.

### 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.



## BRIAN BURNS

*Partner*

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



## 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.



## JANET WHIPPLE

*Partner*

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



## 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.



## 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.

