ELIQUENT
LIFE SCIENCES

Regulatory clarity

FROM thought TO finish

Medical Devices & Combination Products

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.

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

To Approval and Beyond

ELIQUENT's in-depth knowledge and understanding of the global regulatory landscape provides clients with a trusted partner when navigating the complex process of bringing medical technologies to market.

Our Medical Device and Combination Products Team guides clients through the complete regulatory process, from the earliest stages of product development, through the FDA review process, to marketing authorization and compliance with postmarket requirements and quality systems.

Regulatory Expertise

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.

Premarket Pathway

Guided by decades of regulatory experience, ELIQUENTexperts work with companies to determine the best regulatory approach for a product and develop a comprehensive strategy to achieve a successful result.

Regulatory Submissions

Our team of respected professionals bring an unmatched level of credibility and trust when interacting with regulators and developing a submission approach that includes both strategic direction and hands-on support.

Marketing & Promotional Practices

ELIQUENT applies extensive regulatory perspective to support companies with marketing and promotional practices, including labeling requirements, DTC advertising, and use of social media.

Quality & Manufacturing

ELIQUENT's team of highly specialized quality and manufacturing experts build customized solutions that equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Unmatched expertise

With decades of experience, ELIQUENT brings the unmatched expertise that companies need when navigating today's evolving regulatory environment. Guided by former FDA and industry leaders, ELIQUENT's Medical Device and Combination Products Team collaborates seamlessly to provide the strategic and technical guidance that unlocks excellence throughout the product lifecycle.

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

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, Quality & Compliance Practice

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

JANET WHIPPLE

Partner, Quality & Compliance Practice

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.

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.

Pathway Solutions

As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. Clients turn to our team for strategic direction and hands-on execution services that support the earliest phases of development to post-approval and beyond.

Market Solutions

Guided by decades of regulatory and clinical experience, our premier team of life science experts have the specialized skills to assist clients across therapeutic areas, modalities and markets.

Global Solutions

ELIQUENT'S established and growing global presence spans the regulatory process and major markets. Our premier team of global regulatory experts support markets across the U.S., Europe, and Asia.

The **ELIQUENT** difference

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 learn more about Eliquent's comprehensive service offerings, visit our website or contact a member of our team at info@eliquent.com.