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.

Medical Devices & Combination Products

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

Our 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.

Comprehensive Capabilities

ELIQUENT redefines regulatory consulting with a full-service approach and comprehensive solutions that bridge the spectrum of regulatory challenges. Our integrated suite of solutions aligns with your goals to unlock regulatory success.

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.

Combination Products

ELIQUENT experts are a valued partner to sponsors when determining how regulatory agencies will likely regulate their combination products throughout the product lifecycle.

Digital Health

ELIQUENT experts provide guidance to clients developing, commercializing, utilizing, and investing in innovative digital health technologies as they navigate the evolving landscape of digital health regulatory requirements.

Premarket Pathway & Submissions

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

Quality & Manufacturing

ELIQUENT's experts build customized solutions that equip companies with best-in-class solutions to ensure their medical devices and combination products are manufactured according to applicable quality standards and regulations.

Marketing & Promotional Practices

ELIQUENT provides companies with regulatory support on product labeling and promotional materials, including direct-to-consumer (DTC) promotion on social media and assistance with remediating alleged promotional violations.

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 Devices 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 Devices & Combination Products
Distinguished FDA career includes service as the Director of the FDA's Center for Devices and Radiological Health (CDRH).

BRIAN BURNS
President, Quality & Compliance Practice
Extensive background in medical device quality and regulatory strategy, including senior roles across the medical device industry.

MARK KRAMER
Principal, Medical Devices & Combination Products
35-year career includes establishing and directing FDA's Office of Combination Products and leadership roles in industry.

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

HEATHER ROSECRANS
EVP, Medical Devices & Combination Products
FDA career that spanned more than 30 years and included a pivotal role in developing the FDA's 510(k) program.

MAURA NORDEN, J.D.
EVP, Medical Devices & Combination Products
15+ years of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

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 sciences 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 our comprehensive service offerings, visit our website or contact a member of our team at info@eliquent.com.