

Regulatory clarity

FROM **idea** TO **impact**

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.

Cosmetics Regulatory Solutions

Since enactment of the Modernization of Cosmetics Regulation Act (MoCRA) in December 2022, regulatory oversight has shifted to emphasize the safety and quality of cosmetics. With FDA's increased regulatory authority, it's critical that cosmetics manufacturers and distributors are informed and prepared for evolving regulatory requirements.

ELIQUENT's in-depth knowledge and understanding of the global regulatory landscape provides clients with a trusted partner when developing and commercializing cosmetic products.

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.

Specialized Solutions

ELIQUENT's specialized solutions showcase our collective capabilities and combined expertise. Our wide-ranging expertise enables us to advise stakeholders implementing and complying with FDA regulations and policies under the Food Drug & Cosmetic Act, including new MoCRA requirements, the Federal Fair Packaging and Labeling Act and related statutes and regulations.

MoCRA Requirements

Clients turn to the ELIQUENT team for strategic direction and technical support on all aspects of MoCRA requirements, including:

Registration & Listing

Adverse Event Reporting

Labeling

Safety Substantiation

Good Manufacturing Practices

Small Business exceptions

Compliance Services

Our premier team of regulatory experts have the specialized skills to support compliance requirements, including:

FDA manufacturing and quality controls

GXP regulations for cosmetics

Compliance Assessments

Gap analyses for inspectional readiness

Evaluate and respond to FDA enforcement and regulatory communications

Regulatory Policy Solutions

ELIQUENT helps clients navigate the emerging regulatory landscape by providing the following:

Guidance on new rules and reports mandated by MoCRA

Regulatory intelligence gathering

Support developing and implementing regulatory policy strategies

Identify engagement opportunities with the FDA and other stakeholders

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 team of respected professionals collaborate seamlessly to provide the strategic and technical guidance that unlocks excellence throughout the product lifecycle.



JOHN TAYLOR

Head, Quality & Compliance Practice

Former FDA senior official held many high-profile positions at the FDA, as well as senior leadership roles within industry.



DONALD ASHLEY

25-year compliance and enforcement career, including six years as Director of the Office of Compliance for the FDA's Center for Drugs.



KALAH AUCHINCLOSS

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.



LIZ OESTREICH

Diverse background provides critical expertise within legal, public policy, and non-profit sectors.

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.