

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 provides guidance to cosmetic manufacturers and distributors, beauty and personal care product companies, trade associations, and other stakeholders implementing and complying with FDA regulations and policies. Our wide ranging expertise enables our team of regulatory professionals to support cosmetic product manufacturers and distributors by providing the following services:

Regulatory Expertise

ELIQUENT helps clients navigate FDA regulatory programs, policies, and procedures, including guidance on the anticipated FDA jurisdictional determination for a product.

Product Labeling & Claims

Guided by decades of regulatory experience, ELIQUENT experts advise manufacturers and distributors on FDA labeling requirements and product claims made on packaging and marketing materials.

MoCRA Requirements

Our team of highly specialized experts counsel companies on all aspects of MoCRA, including new registration and listing requirements, adverse event reporting, safety substantiation, and the FDA's expanded enforcement authorities.

Expert Training

ELIQUENT's customizable training programs are tailored to equip teams and employees with a full understanding of MoCRA requirements and the skills needed to meet and maintain regulatory compliance.

Quality & Manufacturing

With an approach that includes both strategic direction and technical support, our compliance services prepare companies for forthcoming GMP regulatory requirements and FDA guidance for cosmetic manufacturers and distributors.

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.