# Regulatory clarity **thought finish**

**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.

## **Regulatory Policy** Solutions

From the earliest phases of development through manufacturing and distribution, regulatory policy shapes the development, approval, and commercial success of medical products.

ELIQUENT's Regulatory Policy Solutions are designed to support the needs of businesses as they navigate regulatory policies. Our expert team works cross-functionally to assist pharmaceutical and biotechnology companies, medical device manufacturers, patient groups, trade associations, and other stakeholders in communicating effectively about regulatory policy issues and in understanding, implementing, and complying with new or changing regulations, guidances and legislation.

No matter your pathway, regulatory requirements, or therapeutic market – ELIQUENT's integrated solutions align with your regulatory goals to unlock excellence.

## Strategic & Technical Capabilities

ELIQUENT's Regulatory Policy Solutions support clients' participation in regulatory programs and ultimately enhance patient access to innovative medical products. Our regulatory policy team provides advice and recommendations based on their unique blend of institutional knowledge coupled with granular expertise across the product lifecycle.

With an approach that includes both strategic direction and hands-on support, ELIQUENT's regulatory policy solutions optimize practices to ensure consistency, compliance and operational efficiency. Understanding there is no one-size-fits-all approach, each solution is built to support your regulatory objectives, while aligning with evolving global demands.



#### Regulatory Policy Interpretation & Application

ELIQUENT provides unparalleled expertise and strategic insight to organizations navigating emerging regulatory policies and industry trends - ensuring compliance while driving innovation.



#### Advocacy & Stakeholder Engagement

Engage with stakeholders and shape policy outcomes with targeted advocacy and engagement solutions. Our approach drives impactful results and ensures your voice leads the conversation.



#### Regulatory Intelligence

Stay informed with ELIQUENT's expert monitoring and analysis of regulatory and market trends. Our expert insights enable smarter decisions and proactive planning for long-term success.

## Targeted Solutions

ELIQUENT provides the strategic direction and technical expertise that clients count on as they encounter complex regulatory challenges. Our team of industryrecognized professionals empower clients by anticipating policy shifts and maintaining a competitive advantage in a dynamic regulatory landscape. ELIQUENT's strategic and technical regulatory policy capabilities include:

#### Regulatory Policy Interpretation & Application

Evaluate existing and emerging regulatory policies to assess their potential impact, including new guidances, regulations and FDA-focused legislation.

Customized policy proposals on targeted topics with supporting campaigns that align with organizational goals and market objectives.

In-depth analysis and interpretation of targeted regulatory topics, including trend analyses, therapeutic landscapes, policy frameworks, and regulatory actions.

## Advocacy & Stakeholder Engagement

Shape engagements with regulatory authorities through activities such as commenting on notices and proposed policies and guiding participation in Agency meetings such as workshops, PFDD meetings, and Advisory Committee meetings.

Building effective communication strategies for engaging regulators and stakeholders.

Advise on emerging regulatory policy issues relevant to industry working groups and professional associations.

## Regulatory Intelligence

Proactive monitoring of emerging regulatory developments, including new and updated regulations, guidance documents, notices, and related information; health authority meetings, workshops, and public remarks; market news; and industry trends.

Timely insight and analysis of shifting regulatory policies, market trends, and updates from key regulatory authorities.



## Learn More

Follow this link or visit **ELIQUENT.com** for more Regulatory Policy excellence.

## **Unmatched** Expertise

ELIQUENT's unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to support innovators across the product lifecycle.

With decades of experience, our regulatory policy experts offer a rare blend of perspectives developed as leaders in both the public and private sectors. This wealth of experience equips clients with a trusted partner capable of transforming regulatory challenges into catalysts for innovation and market leadership.



A distinguished leader in the regulatory policy landscape, **Brian Mayhew** brings more than two decades of experience to his role at ELIQUENT Life Sciences.

Brian's in-depth understanding of the regulatory landscape is rooted in a diverse career spanning roles across regulated industry and at the U.S. Food and Drug Administration. This unique blend of professional experience enables Brian's distinct perspective on the interplay between regulators and industry.

At ELIQUENT, Brian drives forward-thinking solutions that bridge the gap between regulatory policy and corporate objectives. His unparalleled expertise empowers clients to successfully navigate policy challenges in a complex global market.