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.

Drug & Biological Product Solutions

To ensure success in today's rapidly evolving biopharmaceutical industry, companies must recognize and be prepared for a dynamic regulatory landscape. Guided by decades of experience, ELIQUENT's team of experts 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.

Full-Service Support

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.

Pipeline Review & Optimization
Our team of regulatory experts evaluate and prioritize development pipelines to identify valuable portfolio opportunities and to understand and effectively manage regulatory risks.

Clinical Programs
With deacdes of hands-on experience, ELIQUENT professionals provide best-in-class scientific and regulatory guidance on nonclinical, pre-clinical, and clinical programs across all therapeutic areas.

CMC Strategy
ELIQUENT's highly experienced team of specialists strengthen CMC packages by facilitating risk-based evaluations that enable effective design and implementation strategies.

Pathway Decisions & Eligibility
ELIQUENT experts work with companies to develop comprehensive regulatory strategies that take into account special designation eligibility and the pathway selection for a successful result.

Regulatory Meetings & Communications
ELIQUENT's team of respected professionals bring an unmatched level of credibility and trust when interacting with global regulators and guiding companies on the regulatory pathway.

Regulatory Submissions
ELIQUENT applies extensive regulatory perspective to develop and implement actionable strategies that optimize a product's regulatory submission and enhance agency interactions.

Marketing, Promotion & Labeling
Our team of skilled advisors provide specialized support and strategic direction on labeling requirements, promotional materials, and marketing programs.

Lifecycle Support
ELIQUENT's integrated solutions equip innovators with strategic insight and actionable strategies that span the product lifecycle and unlock regulatory success.

Unmatched expertise

Guided guided by decades of regulatory experience in drug and biological product development, the ELIQUENT team collaborates seamlessly to provide the strategic and technical guidance that unlocks excellence throughout the product lifecycle.

MICHELE DOUGHERTY, Ph.D.

Head of Regulatory Affairs Practice

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

BOB MEYER, M.D.

Principal, Drug & Biological Products

A leader in drug and biological product lifecycle management, with 30 years of regulatory and academic leadership.

SANDRA KWEDER, M.D.

Principal, Drug & Biological Products

Former Deputy Director of the FDA's Office of New Drugs and Deputy Director of the FDA's Europe Office and Liaison to the EMA.

KAREN MIDTHUN, M.D.

Partner, Drug & Biological Products

28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research (CBER)

ANN O'CONNOR

Partner, Quality & Compliance

35+ years experience in senior leadership roles at the Health Products Regulatory Authority (HPRA) and multinational companies.

KURT MOERCK, Ph.D.

Partner, Quality & Compliance

More than three decades of global experience at three of the largest worldwide pharmaceutical companies.

Pathway solutions

As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. Clients turn to ELIQUENT for objective guidance across the regulatory pathway, to market approval, and beyond.

Nonclinical

Phase-specific nonclinical support:

- Study design & data analysis, with expertise in toxicology, pharmacokinetics & pharmacodynamics
- Risk management support, including laboratory controls and Good Clinical Practices (GCP)

Preclinical

Real-world preclinical guidance:

- Pipeline review & optimization
- Study design & development
- Product classifications
- Expedited pathway guidance
- Regulatory submission support, including dossier writing and application assembly

Clinical

Strategic & technical direction:

- Clinical study support, including CRO selection, protocol writing, and biomarker/endpoint selection support
- On-site clinical execution
- Pre-Approval Quality System Compliance

Regulatory Submissions

Valuable & objective guidance:

- Regulatory submission support, including dossier writing and review, and application assembly and submission.
- Regulatory meetings and communications
- Pre-approval inspections and response to deficiencies

Post-Approval & Distribtuion

Customized solutions:

- Quality system design, optimization & implementation
- Good Manufacturing Practices (GMP) Consulting
- Inspectional readiness
- Post-approval commitments
- Marketing, labeling, and promotional practices

Lifecycle Support

Actionable and proven strategies:

- Regulatory communications and engagement strategies
- Inspectional readiness
- Regulatory policy guidance
- Customized training programs
- Remediation solutions
- Due Diligence & regulatory risk assessments