ELIQUENT
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Radiopharmaceutical **Solutions**

Bringing clarity to life sciences regulatory complexity

ELIQUENT Life Sciences.

Setting a new standard for regulatory clarity - from thought to finish.

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Who is ELIQUENT?

ELIQUENT Life Sciences is a leading global regulatory, quality & safety consulting firm delivering integrated solutions across the product lifecycle. We are a premier team of regulatory experts delivering the solutions that life sciences innovators need to gain and maintain market authorization for their products.

Trusted **Partner**

ELIQUENT is the singular regulatory resource that clients around the world trust.

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

Unprecedented **Assembly**

ELIQUENT's foundation is built on experts with the foremost strategic and technical skill.

Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to deliver objective, reliable guidance across the product lifecycle.

Integrated **Solutions**

Our unique platform and team of cross-functional experts deliver integrated solutions that equip clients with a premier regulatory resource.

Together, we redefine regulatory consulting with integrated solutions that unlock success and clear the path to better health.

Why ELIQUENT?

ELIQUENT's full-service platform and team of cross-functional experts deliver integrated solutions that equip clients with a **premier regulatory resource**. Together, we redefine regulatory consulting and clear the path to better health.

Skilled

Our **unprecedented assembly** of global regulatory experts set the industry standard with an unmatched level of skill, capabilities, and insight.

Specialized

We specialize in life sciences. No matter the pathway or complexity of your challenge, our premier team of life science regulatory consultants have the skills to help.

Scale

Our carefully curated network of global experts enables the right **team**, with the right **expertise**, at the right **size,** in the right **location** to meet your needs.

Speed

When time is of the essence – around the corner or across the globe – our **agile expert teams** are **ready on-demand** for your **most complex challenges.**

Scope

Our capabilities run deep – the ELIQUENT team offers a rare blend of knowledge spanning therapeutic areas, regulatory pathways, quality systems, and global markets.

375+ years

of combined experience at **global health authorities**

Michele **Dougherty**, Ph.D.
Regulatory Affairs – U.S.
10+ years at **FDA**

Shelley **Gandhi**
Pharmacovigilance
19+ years at **MHRA**

Grace **McNally**
Quality & Compliance
30+ years at **FDA**

Kalah **Auchincloss**, J.D.
Quality & Compliance
6+ years at **FDA**

Brian **Mayhew**
Regulatory Policy
4+ years at **FDA**

Robin **Huff**, Ph.D.
Drugs & Biologics
7+ years at **FDA**

John **Taylor**, J.D.
Quality & Compliance
20+ years at **FDA**

Kristen **Grumet**
Quality & Compliance
8+ years at **FDA**

Tom **Berry**, Pharm.D.
Quality & Compliance
20+ years at **FDA**

Ann **O'Connor**
Combination Products
17+ years at **HPRA**

Sandra **Kweder**, M.D.
Drugs & Biologics
33+ years at **FDA**

Sarah **McGary, M.D.**
Drugs & Biologics
18+ years at **FDA**

Steven **Bowen**, Ph.D.
Drugs & Biologics
8+ years at **FDA**

William **Tillet**
Regulatory Affairs - EU
2+ years at **UKHSA**

Dan **Schultz**, M.D.
Medical Devices
20+ years at **FDA**

Heather **Rosecrans**
Medical Devices
33+ years at **FDA**

Lydia Martynec, M.D.
Drugs & Biologics
20+ years at **FDA**

Shenggang **Wang**, Ph.D.
Regulatory Affairs
3+ years at **FDA**

David **Elder**
Quality & Compliance
23+ years at **FDA**

Chris **Leptak**, M.D., Ph.D.
Drugs & Biologics
14+ years at **FDA**

Tiffany **Lucas**, Ph.D.
Drugs & Biologics
6+ years at **FDA**

Vincent **Li**, Ph.D.
Drugs & Biologics
5+ years at **FDA**

Mark **Kramer**
Combination Products
17+ years at **FDA**

Donald **Ashley**, J.D.
Quality & Compliance
6+ years at **FDA**

Silvana **Borges**, M.D.
Drugs & Biologics
17+ years at **FDA**

Dawn **Wydner, Ph.D.**
Quality & Compliance
10+ years at **FDA**

Integrated Solutions

ELIQUENT's integrated suite of solutions enables a full-service engagement that delivers end-to-end support. **Together, we unlock regulatory excellence.**

Regulatory Affairs

From the earliest phases of development, through regulatory submissions, ELIQUENT guides companies to approval and beyond.

PV + Safety

Customized global pharmacovigilance and safety solutions empower companies to operate with confidence.

Quality & Compliance

Specialized solutions equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Remediation Solutions

Unmatched level of credibility and trust when interacting with regulators and guiding companies to remediation solutions.

Talent Solutions

Network of hand-picked, ready to deploy global experts ensure the right talent at the right place and time.

Comprehensive Capabilities

ELIQUENT is a trusted partner to global life science innovators. Why? 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.

Market Solutions

Guided by decades of experience, we understand what it takes to bring innovations to market.

- Drugs & Biologics
- Medical Devices & Diagnostics
- Combination Products
- Advanced Therapies & CGT
- Cosmetics
- Radiopharmaceuticals

Pathway Solutions

Clients turn to our team of former regulators and industry leaders for objective guidance across the regulatory pathway.

- Nonclinical
- Preclinical
- Clinical
- Regulatory Submissions
- Manufacturing & Distribution
- Post-Market Solutions

Global Solutions

ELIQUENT'S established global presence spans the regulatory process and provides expert support across global markets.

- Global Market Entry
- United States
- Europe
- Asia

Specialized Solutions

ELIQUENT provides specialized solutions that are tailored to the unique needs of the life sciences industry.

- Industry Due Diligence
- Regulatory Policy
- Expert Training
- Regulatory & Medical Writing
- Litigation Support

Market Solutions

In the complex life sciences landscape, where innovation meets regulation, a trusted regulatory partner is paramount. No matter the **therapeutic area**, **modality** or **market**, our premier team of life science experts have the specialized skills to help.

Drugs & Biologics

ELIQUENT's team of experts provide strategic and technical guidance on drugs and biologics from product development to regulatory review and beyond post-market requirements.

Areas of expertise:

Monoclonal Antibodies
Enzyme Replacement Therapies
Biosimilars
Tissue-Based Therapies
Vaccines

Devices & Diagnostics

Leverage our team's extensive experience as you navigate the process of bringing new devices and diagnostics to market and manufacturing them to quality standards.

Areas of expertise:

Class I, II, and III devices
Digital Health
Molecular Diagnostics
Immunoassays
Laboratory Tests
Companion Diagnostics

Advanced Therapies & CGT

Our team of regulatory and clinical experts apply their specialized skillset to move complex autologous or allogeneic therapies through the regulatory process into manufacturing and beyond.

Areas of expertise:

Gene therapy
Somatic cell therapy
Tissue-engineered therapies
Combined advanced therapies

Combination Products

Unlock the full potential of your combination product. ELIQUENT's supports companies developing combo products with expert guidance throughout the combination product lifecycle.

Areas of expertise:

Single-entity, co-packaged, and cross-labeled products
Drug-coated devices
Drug delivery systems
Companion Diagnostics

Radiopharma-ceuticals

ELIQUENT understands and meets the unique challenges and opportunities facing radiopharmaceuticals - complex oversight, short-lived isotopes, evolving global requirements, and cutting-edge scientific advancements.

Areas of expertise:

Regulatory submissions
Market Authorization
Strategy & Development
Lifecycle Management
Regulatory Compliance

Pathway Solutions

ELIQUENT guides innovators on their path to **approval and beyond**. As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. ELIQUENT's highly specialized experts provide both strategic direction and hands-on execution services to to support clients from the earliest phases of development to post-approval regulatory support.

Nonclinical & Preclinical Support

ELIQUENT's customized support guides companies through crucial nonclinical and preclinical development phases with precision and expertise.

Clinical Programs

With a proven track record of regulatory success, our team delivers objective guidance and unparalleled support for your complex clinical program.

Regulatory Submissions

ELIQUENT applies extensive regulatory experience to develop the best regulatory approach for a product and develop a comprehensive strategy to achieve a successful result.

Manufacturing & Distribution

ELIQUENT evaluates and strengthens systems with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while meeting business objectives.

Post-Market & Lifecycle Support

Our industry-recognized experts deliver valuable insight throughout the product lifecycle to ensure sustained post-market vigilance.

Global Solutions

ELIQUENT'S established and growing **global presence** spans the regulatory process and major markets. Our premier team of global regulatory experts support innovators across the U.S., Europe, and Asia.

United States

ELIQUENT is a leading FDA regulatory consulting firm. Our experts have shaped the landscape of FDA regulatory policy and strategy for decades. We bring this unrivaled knowledge and unique insight to our work with clients.

Global Market Expansion

ELIQUENT provides end-to-end solutions that support companies navigating complex global regulations. Whether launching a new product or expanding into new regions, ELIQUENT works with innovators to mitigate risks, streamline approvals, and maintain compliance across evolving regulatory landscapes.

Europe

With decades of experience in the European market, our team understands the intricacies of the European Medicines Agency (EMA) and offers tailored solutions that keep clients in lock-step with evolving global standards.

Asia

ELIQUENT offers regionally specialized solutions for innovators across Asia. Our team of highly specialized experts partner with innovators to develop a synchronized, global go-to-market approach that unlocks the full potential of the Asia market and leverages the strategic advantages of Japan's regulatory landscape.

Radiopharmaceutical Solutions

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Market Solutions | Radiopharmaceuticals

The radiopharmaceutical industry is experiencing a renaissance, with unprecedented growth resulting from rapid advancements in targeting radiation through new therapies and increasing global investment. As radiopharmaceutical innovation accelerates, so do regulatory complexities.

Lifecycle Solutions

ELIQUENT understands the unique challenges facing global radiopharmaceutical innovators.

Our deep expertise, proven track record, and industry-first approach make us a trusted partner to guide radiopharmaceutical innovators through regulatory, quality, and safety requirements—ensuring efficient approvals and long-term compliance.

ELIQUENT supports innovators bringing products to market by developing a **strategic**, **well-planned** approach that accounts for both **drug** and **radiation regulations**, **nuclear medicine oversight**, and **clinical complexities**.

ELIQUENT guides companies through complex submission processes with **efficiency** and **expertise**. Ou submission and market authorization services support innovators from **early development** through **marketing authorization**.

Once approved, ELIQUENT provides the ongoing **lifecycle maintenance** required for radiopharmaceutical products to ensure continued **post-market compliance** and enable **long-term market expansion**.

Radiopharmaceuticals | Targeted Solutions

ELIQUENT's integrated regulatory, quality, and safety solutions are designed to support companies bringing their products to market and maintaining global compliance. Whether you're developing a first-in-class radiopharmaceutical or managing the post-approval lifecycle of an existing product, ELIQUENT provides the expert guidance to ensure regulatory success.

Regulatory **Strategy & Development**

ELIQUENT guides clients through complexities with the following services:

Tailored regulatory strategies for positron emission tomography (PET) imaging agents, theranostics (therapeutic and diagnostic combination products), and radiopharmaceuticals

Planning and preparation for regulatory agency interactions, including the FDA, EMA, and other global health authorities

Guidance on clinical trial design, regulatory submission pathways, and risk mitigation strategies

Regulatory Submissions **& Market Authorization**

Our regulatory submission and market authorization services include:

Investigational New Drug (IND) application and Clinical Trial Application (CTA) preparation and submissions to initiate clinical studies

Comprehensive dossier development, including Chemistry, Manufacturing, and Controls (CMC), nonclinical, and clinical components

Preparation and submissions for commercialization: Marketing Authorization Application (MAA), New Drug Application (NDA) & Biologics License Application (BLA)

Lifecycle Management & **Regulatory Compliance**

ELIQUENT's full-service approach bridges the product lifecycle to include:

Chemistry, Manufacturing, and Controls (CMC) updates including new manufacturing site additions, post-approval variations, and regulatory supplements to keep products compliant

Labeling and safety updates to meet evolving regulatory requirements

Regulatory strategy for additional indications and global expansion into new markets such as the United States, European Union, and Asia-Pacific

Radiopharmaceuticals | Unmatched Expertise

Trusted **Partners**

ELIQUENT's team of radiopharmaceutical experts - composed of professionals with **firsthand experience in radiopharmaceutical regulatory pathways** – collaborate seamlessly to unlock excellence across the product lifecycle.

Our **proven track record** of success in navigating complex regulatory landscapes makes us a trusted partner for radiopharmaceutical companies seeking strategic guidance, streamlined approvals, and long-term compliance solutions.

Helen **Barker,** Ph.D.

30-years life science regulatory experience

8+ years radiopharmaceuticals experience

Chair of Regulatory/Quality Working Group at Nuclear Medicine, Europe (NMEU)

Radiopharmaceutical industry experience includes role as Global Head of Regulatory

Lorna **Griffin**

40+ years of strategic regulatory experience

10+ years of radiopharmaceuticals expertise

Advisor to numerous start-up companies

Track record of success in strategic development, First in Human support, IND preparation and submission in the US, and CTA approvals in the UK and Europe.

Ifty **Saiyed**

Global regulatory affairs leader

25+ years of experience across multinational pharmaceutical companies, CROs, and international regulatory agencies

Experience spanning a wide range of global regions, including ICH markets, Latin America, and the Middle East

Lydia **Martynec**, M.D.

Distinguished expert in the fields of oncology and nuclear medicine

Professional experience includes 20+ years at the FDA where she served in key review capacities within the Center for Drugs and Center for Biologics.

Experience in diagnostic and therapeutic radiopharmaceuticals

Mike **Edwards**

Seasoned global regulatory professional with roles in large and small pharma

Extensive experience with radiopharmaceutical compliance and product development

Capabilities include new product license and strategic lifecycle management

Emma **Williams**

20+ year regulatory career includes expertise in radiopharmaceuticals

Successful history of accelerating New Active Substance development, steering Marketing Authorization approvals, optimizing portfolio management, and implementing organizational efficiencies.

Radiopharmaceuticals | Specialized Solutions

ELIQUENT understands the specialized regulatory approach required by radiopharmaceuticals - one that accounts for complex oversight, short-lived isotopes, evolving global requirements, and cutting-edge scientific advancements.

Emerging Science **& Innovations**

The Challenge.
Radiopharmaceuticals are advancing rapidly, especially in theranostics, PSMA, and FAP treatments. Companies must anticipate regulatory shifts to prevent approval delays.

Our Solution.
ELIQUENT's deep radiopharmaceutical expertise enables a forward approach that guides innovators to anticipate regulatory shifts and accelerate time to market.

We Deliver.
Deep expertise in next-generation radiopharmaceuticals pathways, including dual-purpose (therapeutic and diagnostic) products

Strategic agency engagement to ensure regulators understand and support new approaches to radiopharmaceutical development

Proactive risk mitigation to address evolving regulatory guidance, dose optimization & clinical endpoint design

Global & Regional **Market Differences**

The Challenge.
Radiopharmaceutical regulations vary across the U.S., EU, and Asia-Pacific, requiring a tailored approach for global expansion.

Our Solution.
Our experts streamline submissions and deliver tailored regulatory strategies to meet global and country-specific requirements.

We Deliver.
With unparalleled expertise, ELIQUENT navigates regulatory submissions across global marketing, including:

U.S. - Investigational New Drug (IND) applications

Europe - Clinical Trial Applications (CTA)

Japan - Pharmaceuticals & Medical Devices Agency (PMDA) processes

Global - Post-approval support to expand already-approved products into new territories

Radiopharmaceuticals | Specialized Solutions

Unlike conventional pharmaceuticals, radiopharmaceuticals present unique regulatory, technical & logistical challenges. Our experience enables us to tackle the most critical challenges in radiopharmaceutical development and compliance.

Emerging Science **& Innovations**

The Challenge.
With regulatory requirements for both health and nuclear safety, companies must coordinate with multiple regulatory bodies.

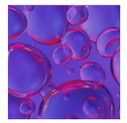
Our Solution.
The ELIQUENT team has extensive experience harmonizing regulatory strategies that align both drug approval requirements and nuclear safety regulations.

We Deliver.
We guide clients to regulatory success with expert knowledge, including:

FDA and EMA radiopharmaceutical guidelines alongside NRC and European national radiation safety requirements

U.S. and Europe-specific Good Manufacturing Practices (GMP) for radiopharmaceutical production to ensure compliance

Country-specific variations in regulatory expectations for the transport, storage, and handling of radioactive materials



Short Half-Life **& Logistics Challenges**

The Challenge.
Radiopharmaceuticals with short half-lives demand precise coordination across manufacturing, distribution, and administration to prevent delays that render them unusable.

Our Solution.
With deep industry expertise, ELIQUENT navigates the unique time constraints of radiopharmaceuticals.

We Deliver.
We manage the complexities of time-sensitive radiopharmaceuticals with solutions that optimize:

Submission timelines to align regulatory approvals with commercial launch readiness

Regulatory strategies for just-in-time manufacturing and decentralized distribution models

Support on compliance with stability testing and shelf-life requirements

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Your premier regulatory resource – **from thought to finish.**

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