ELIQUENT Life Sciences brings clarity to regulatory complexity. We are expert consultants delivering the solutions that life sciences innovators need to gain and maintain market authorization for their products.

Radiopharmaceutical Solutions

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.

ELIQUENT Life Sciences understands the unique challenges and opportunities facing radiopharmaceutical innovators. Our deep expertise, proven track record, and industry-first approach make us the ideal partner to guide radiopharmaceutical innovators through regulatory, quality, and safety requirements—ensuring efficient approvals and long-term compliance.

Strategic & Technical Capabilities

ELIQUENT Life Sciences is a trusted partner to global radiopharmaceutical innovators. Our 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 Submissions **& Market Authorization**

From development to marketing authorization, ELIQUENT streamlines the submission processes with efficiency and expertise. 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), and Biologics License Application (BLA)

Regulatory **Strategy & Development**

Bringing a radiopharmaceutical to market requires an approach that navigates drug, radiation, and clinical regulations. 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 U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and other global health authorities
- Guidance on clinical trial design, regulatory submission pathways, and risk mitigation strategies

Lifecycle Management & **Regulatory Compliance**

Maintaining post-approval regulatory compliance is crucial for radiopharmaceuticals to enable long-term growth. 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

Expert Team

Our team of former regulators, industry leaders, and scientific experts has the hands-on experience and deep knowledge needed to help radiopharmaceutical companies navigate challenges efficiently and successfully.

Helen **Barker**, Ph.d.

30-years of radiopharmaceuticals experience, including role as chair of the Regulatory/Quality Working group at Nuclear Medicine Europe (NME).

Lorna **Griffin**

Highly experienced professional with an excellent track record of more than 40 years in Regulatory Affairs.

Ifty **Saiyed**

Global regulatory leader with multinational career spanning 25+ years across the life sciences industry.

Learn more at
ELIQUENT.com

Specialized Solutions

Unlike conventional pharmaceuticals, radiopharmaceuticals present unique regulatory, technical & logistical challenges. 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.

Dual Regulatory Oversight

Managing Health and Nuclear Regulatory Requirements

The Challenge.
Unlike conventional pharmaceuticals, radiopharmaceuticals fall under both health and nuclear safety regulations, requiring companies to coordinate with multiple regulatory bodies.

Our Solution.
ELIQUENT works with clients to harmonize drug approval requirements and nuclear safety regulations, guiding you through:

FDA & EMA guidelines alongside NRC and EU national radiation safety requirements

U.S. & EU-specific GMPs 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

Precision in Manufacturing & Clinical Trials

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

Our Solution.
ELIQUENT understands the time-sensitive nature of radiopharmaceuticals. Our expert team offers:

Regulatory strategies for manufacturing and decentralized distribution models

Expert guidance on compliance with stability testing and shelf-life requirements

Submission optimization to align regulatory approvals with commercial launches

Emerging Science & Innovations

Staying Ahead of Regulatory Trends for Novel Therapies

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 helps companies anticipate regulatory shifts to prevent approval delays, providing expert guidance throughout the product lifecycle, including:

Deep expertise in regulatory pathways for next-generation radiopharmaceuticals, 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 Market Differences

Varying Regulatory Expectations Across Regions

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

Our Solution.
ELIQUENT delivers tailored regulatory strategies to meet global and country-specific requirements efficiently. Our experts streamline submissions through:

Investigational New Drug (IND) applications in the U.S.
Clinical Trial Applications (CTA) in the EU
Japan's Pharmaceuticals and Medical Devices Agency (PMDA) processes
Post-approval support to expand already-approved products into new territories