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.

Japan Regulatory Solutions

To ensure success in today's global life sciences industry, companies must recognize and be prepared for a dynamic regulatory landscape. Guided by decades of regulatory and clinical experience, ELIQUENT Japan partners with innovators to develop a synchronized, global go-to-market approach that unlocks the full potential of the Japanese market.

Unlock Opportunity

As one of the world's leading economies, Japan offers life science innovators the unique opportunity to expanded market potential within a supportive regulatory environment. Together with ELIQUENT's team of regulatory experts, clients leverage the strategic advantages of Japan's regulatory landscape.

Thriving Pharma Economy

At $95 billion in value, Japan is the third-largest pharmaceutical market in the world, behind only the United States and China.

Growing Market Demand

An aging society and growing life expectancy, combined with Japan's population size, drive demand for medical product development.

Regulatory Optimization

Accelerated approval pathways, including the Sakigake Designation Scheme, have helped expedite the regulatory process.

Support for Innovation

The Japanese government actively fosters an environment of innovation by reducing past barriers and creating incentives for life science innovators.

Global Harmonization

Japan's harmonization with international regulatory standards has simplified the global development process for life science companies.

Enhanced IP Protections

New intellectual property protections benefit life science innovators by safeguarding investments in innovation.

Unmatched Expertise

ELIQUENT's premier team of globally-minded, bilingual experts have the specialized skills to assist innovators across therapeutic areas, modalities, and markets. Clients turn to ELIQUENT for our deep command of Japan's regulatory requirements, and our unrivaled ability to partner and communicate with Japan's local constituencies. This unique blend of strategic guidance and technical skill aligns with your goals to unlock regulatory success.

Japan approval and beyond

ELIQUENT guides innovators on their path to approval and beyond. Our team of highly specialized experts provide both strategic direction and hands-on execution services to support clients from the earliest phases of development to post-approval regulatory support.

Development Strategy Planning
Our team of regulatory experts drive efficiency by equipping innovators with valuable insight and actionable strategies that span the product lifecycle and unlock regulatory success.

Clinical & Nonclinical Programs
With decades of hands-on experience, ELIQUENT professionals provide best-in-class scientific and regulatory guidance on nonclinical 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 dossiers, manufacturing processes and performance qualifications.

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.

Application Preparation & Submission
ELIQUENT applies extensive regulatory perspective to develop and implement actionable strategies that optimize a product's regulatory submission and enhance regulatory interactions.

Market Entry Planning
Our market entry solutions identify strategies for successful commercialization by considering target patient populations, product positioning, and the competitive environment.

Japan Market Alignment
Experienced and bilingual, ELIQUENT supports stakeholders by facilitating collaboration between Japan and global partners creating a strong alignment.

Lifecycle Support
ELIQUENT's team of regulatory professionals bring an unmatched level of credibility and trust when interacting with global regulators and guiding companies on the regulatory pathway.

Full Service Support

ELIQUENT brings the unmatched expertise that companies need when navigating today's evolving regulatory environment. Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to unlock excellence throughout the product lifecycle.

Drugs & Biological Products
Areas of expertise:
- Monoclonal Antibodies
- Enzyme Replacement Therapies
- Biosimilars
- Tissue-Based Therapies
- Vaccines

Advanced Therapies & CGT
Areas of expertise:
- Gene therapy
- Somatic cell therapy
- Tissue-engineered therapies
- Combined advanced therapies

Devices & Diagnostics
Areas of expertise:
- Class I, II, and III devices
- Digital Health
- Molecular Diagnostics
- Immunoassays
- Laboratory Tests
- Companion Diagnostics

Combination Products
Areas of expertise:
- Single-entity, co-packaged, and cross-labeled products
- Drug-coated devices
- Drug delivery systems
- Companion Diagnostics

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 our regulatory solutions for Japan, visit our website or contact bd@eliquent.com.