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.

CMC Solutions

The path from clinical proof-of-concept to global submission is paved with technical, regulatory, and operational complexity. For small and mid-sized biotech companies — especially those working with novel modalities — delays, clinical holds, and inefficient tech transfers can derail momentum.

ELIQUENT Life Sciences delivers comprehensive CMC Solutions that connect regulatory strategy, quality execution, and technical governance. Whether you're preparing your first IND or scaling for commercial launch, we provide the integrated support to keep you moving forward with confidence.

Comprehensive Capabilities

ELIQUENT's strategic and technical expertise spans the product lifecycle — from early-phase development to commercial launch and global post-approval management. With deep knowledge of regulatory expectations, quality standards, and technical operations, we provide the guidance and oversight needed to strengthen CMC development strategies, ensure submission readiness, and maintain compliance worldwide.

ELIQUENT's CMC solutions drive **measurable results** that accelerate timelines, reduce regulatory risk & streamline execution across development pathways.

CMC Strategy **& Submissions**

Strengthen your submissions with expert support.

From Module 3 authorship and gap resolution to clinical hold and Complete Response remediation. Our team has the strategic and technical expertise to ensure regulatory success.

Quality, Compliance & **Inspection Readiness**

Stay ahead of regulatory scrutiny with expert guidance & insights.

From mock inspections and QMS strategies to implementation and remediation, our team of former regulators helps ensure compliance at every phase of the product lifecycle.

Strategy for **Advanced Modalities**

Navigate evolving pathways with confidence.

ELIQUENT's team of CMC experts deliver modality-specific regulatory strategies that accelerate approvals for CGT, RNA, and biologics, with analytics, comparability, and global submission planning.

Tech Transfer & **CDMO Oversight**

Keep transfers and partnerships on track

Our team drives seamless tech transfers, on-site CDMO governance, and risk-based performance monitoring to reduce delays and mitigate risks.

CMC Program **Governance**

Drive complex programs with clarity and control.

Our team drives seamless tech transfers, on-site CDMO governance, and risk-based performance monitoring to reduce delays and mitigate risks.

ELIQUENT®
LIFE SCIENCES

ELIQUENT's CMC Solutions support life science innovators from early-phase planning through post-approval lifecycle management — tailored to fit your team, your modality, and your goals.

The ELIQUENT **Advantage**

Our unique blend of regulatory insight, technical expertise, and cross-functional delivery helps life sciences companies overcome barriers, accelerate timelines, and execute with precision. ELIQUENT's CMC Solutions are driven by:

Deep Bench **Strength**

Our team includes former agency experts, seasoned industry leaders and technical engineers who understand regulatory expectations from the inside out.

Cross-Functional **Delivery Model**

We integrate regulatory, quality, and engineering functions — ensuring technical consistency and executive-level oversight throughout the program.

Novel Product **Specialization**

From CGT to radiopharmaceuticals and RNA-based therapies, we bring the nuanced understanding required for today's most complex modalities.

Global **Perspective**

We help clients navigate evolving requirements across the U.S., EU, and emerging markets, ensuring submission readiness and lifecycle flexibility.

ELIQUENT.com

From Complex **to Clear**

Solving CMC challenges before they slow you down

ELIQUENT's CMC Solutions are built to solve the high-stakes challenges facing life science innovators. Our expert-driven, end-to-end support accelerates timelines, reduces risk, and ensures consistent delivery across every phase of development.

Obstacles in Complex **CMC Submissions**

Compressed development timelines with under-resourced regulatory teams

The Challenge

Life science innovators face pressure to rapidly transition from promising clinical data to regulatory submission — but many lack the internal expertise needed to build a complete, submission-ready CMC package.

Our Solution

ELIQUENT delivers end-to-end support for CMC regulatory submissions, including full-service Module 3 authorship, strategic gap analysis, and proactive remediation of clinical holds or agency comments.

Our experts define regulatory roadmaps aligned with development milestones, guide preparation for agency interactions, and support efficient responses to feedback.

With deep experience across modalities and regions, we help clients reduce submission risk, accelerate timelines, and move forward with confidence.

CDMO Inefficiencies & **Tech Transfer Roadblocks**

Missteps in technical oversight can derail scale-up

The Challenge

Tech transfer to CDMOs is a high-risk, high-stakes process — without strong alignment, thorough planning, and on-site technical oversight, transfers often break down — leading to missed timelines, quality issues, and delays in scale-up or submission readiness.

Our Solution

ELIQUENT's team of experts provide readiness assessments, develop transfer protocols, and provide on-site technical oversight of CDMO activities.

Our governance-driven approach includes real-time performance monitoring and proactive troubleshooting — ensuring accountability, minimizing delays, and enabling smooth, on-time tech transfers and efficient scale-up.

Underdeveloped Quality & **Compliance Functions**

QMS gaps can stall progress and lead to increased risk

The Challenge

Emerging biotechs often lack the deep quality expertise needed to build a compliant QMS and prepare for inspection. Without robust systems and proactive planning, companies risk compliance actions, costly remediation, and program delays.

Our Solution

ELIQUENT quality experts — many of them former FDA and EMA inspectors — provide inspection readiness assessments, mock audits, and QMS strategy implementation. We help build compliant quality systems from the start, close gaps early, and support remediation of known issues to avoid repeat findings and regulatory delays.

Regulatory Uncertainty in **Advanced Modalities**

Modality complexity demands specialized insight

The Challenge

Developers of advanced modalities face complex, modality-specific challenges in analytics, comparability, and regulatory strategy. Limited internal expertise often leads to missteps in control strategy, submissions, and engagement with regulators — resulting in development inefficiencies, delays, and regulatory risk.

Our Solution

ELIQUENT brings hands-on expertise in advanced modalities—spanning CGT, RNA, and biologics—to guide regulatory roadmaps, control strategies, and comparability planning. We navigate global submissions for complex products and define the right path, ensuring confident execution at every stage.