ELIQUENT

LIFE SCIENCES

CMC
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.

425+ years

of combined experience at **global health authorities**

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

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

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

Celia **Witten**
Drugs & Biologics
17+ years at **FDA**

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

Michele **Dougherty**, Ph.D.
Drugs & Biologics
10+ years at **FDA**

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

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

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

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

Mike **Ryan**
Medical Devices
21+ years at **FDA**

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

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

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

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

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

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

Meredith **Francis**, J.D.
Drugs & Biologics
20+ years at **FDA**

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

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

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

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

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

Brooke **Higgins**
Quality & Compliance
23+ years at **FDA**

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

Maya M. **Davis,** Ph.D.
Quality & Compliance
16+ 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
- Engineering & Quality Validation

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.

Specialized Solutions

ELIQUENT's specialized solutions are tailored to the unique needs of the life sciences industry. Our experts deliver targeted support that helps clients overcome challenges, accelerate timelines, and maintain compliance.

Engineering & **Quality Validation**

Engineering optimization and quality validation solutions across computer systems, cleaning programs, and manufacturing processes.

Industry **Due Diligence**

Empowering clients to confidently navigate opportunities with strategic decision making for both buy-side and sell-side transactions.

Regulatory & **Medical Writing**

From submission to launch, our clear, compliant narratives streamline approvals, reduce delays, and support global regulatory success.

Regulatory Policy **& Intelligence**

Solutions designed to advance stakeholder engagement, inform policy interpretation, and deliver global regulatory intelligence.

Expert Training **Solutions**

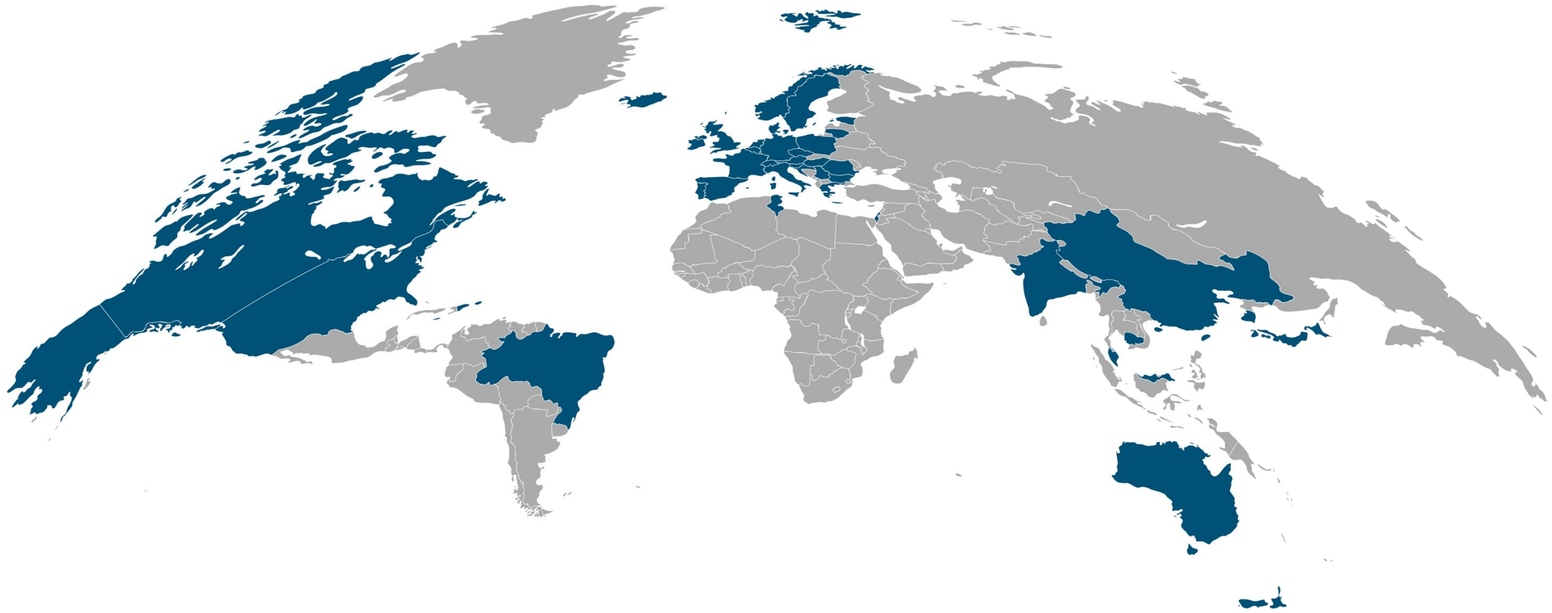
Customized training that empowers teams from the earliest phases of development through post-market support.

Litigation **Support Services**

Unmatched litigation support and expert witness services to support companies and their outside counsel in the midst of legal disputes.

Expertise
Beyond Borders

Since 2022, ELIQUENT has provided expert support to clients across **51 countries** - ensuring seamless market access, regulatory solutions, and compliance worldwide.



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- Portugal
- Puerto Rico
- Romania
- Serbia
- Singapore
- Slovenia
- Spain
- Sweden
- Switzerland
- Taiwan
- Tunisia
- United Kingdom
- United States

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.

CMC

Chemistry, Manufacturing & Controls

Solutions

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Comprehensive **CMC Capabilities**

ELIQUENT 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.

Strategy & **Submissions**

Strengthen your submissions with expert support. From Module 3 authorship and gap resolution to clinical hold and Complete Response remediation. Our team of former regulators and industry leaders works with you to ensure regulatory success.

Strategy for **Advanced Modalities**

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

Tech Transfer **& CDMO Oversight**

Keep transfers and partnerships on track. ELIQUENT 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. ELIQUENT provides phase-based portfolio oversight, integrated cross-functional planning, and technical project management to keep development on track.

Quality, Compliance **& Inspection Readiness**

Stay ahead of regulatory scrutiny with expert support. From mock inspections and proactive gap closure to QMS strategies built by former regulators, we help ensure compliance at every phase of the product lifecycle.

CMC Solutions | Chemistry, Manufacturing & Controls

The path from clinical proof-of-concept to global submission is paved with technical, regulatory, and operational complexity. **ELIQUENT Life Sciences delivers integrated CMC Solutions that connect regulatory strategy, quality execution, and technical governance**.

Proven Results

ELIQUENT's CMC solutions drive **measurable results** that accelerate timelines, reduce regulatory risk & streamline execution for life science innovators navigating complex submission and development pathways.

Scientific, Regulatory & Technical Expertise

Every engagement is rooted in precision, depth, and strategic insight — delivering submission-ready quality the first time.

Speed to Market without Compromise

ELIQUENT reduces time-to-market by 12–18 months through proactive planning and integrated execution.

Risk Reduction Across the Lifecycle

Our team provide continuity and clarity across the product lifecycle - from CRLs to inspection findings and post-approval remediation.

Flexible + Scalable Solutions

We help clients navigate evolving global requirements, ensuring submission readiness and lifecycle flexibility.

CMC | Strategic & Technical Solutions

With deep knowledge of regulatory expectations, quality standards, and technical operations, ELIQUENT provides the guidance and oversight needed to strengthen CMC development strategies, ensure submission readiness, and maintain compliance worldwide.

CMC Program **Governance**

Our integrated solutions for CMC program governance include:

- Phase-based portfolio oversight for complex programs
- Integrated cross-functional planning
- Technical project management & dashboards

Strategy for **Advanced Modalities**

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

- Modality-specific regulatory pathways, including CGT, RNA, and biologics
- Analytics and comparability support
- Global submission planning

CMC Strategy **& Submissions**

ELIQUENT guides clients through submission complexities with the following solutions:

- End-to-end Module 3 authorship for INDs, BLAs & NDAs
- Gap analysis & resolution for regulatory submissions
- Clinical hold & CR remediation support
- Strategic agency engagement to obtain valuable feedback at critical points in your program

Tech Transfer & **CDMO Oversight**

We bring clarity, speed, and value to tech transfer and CDMO oversight through:

- Seamless tech transfers with protocol development and readiness assessments
- On-site CDMO governance and escalation
- Risk-based troubleshooting & performance monitoring

Quality, Compliance & **Inspection Readiness**

Our quality, compliance, and inspection readiness solutions include:

- Mock inspections & proactive gap closure
- QMS strategy supported by former agency experts
- Compliance planning and implementation
- Inspectional issue remediation

CMC Solutions | Unmatched Expertise

Trusted **Partners**

ELIQUENT's cross-functional team of former regulators, industry leaders, and technical experts brings deep knowledge across regulatory, quality, and engineering.

Our 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.

Steven **Bowen**, Ph.D.

FDA tenure of 8+ years includes experience as primary CMC reviewer in the Center for Drugs and senior roles in cGMP inspections and compliance for biologic drugs. Expertise includes scientific training in microbiology and immunology.

Shannon **Chesterfield**

25+ years of experience across the product lifecycle, including sterility assurance, quality systems, inspection readiness, validation, regulatory submissions, global inspections, and commercial launches.

Ifty **Saiyed**

Global regulatory affairs leader with 25+ years in pharma, CROs, and agencies, spanning ICH, Latin America, and Middle East markets, delivering broad and trusted multinational expertise.

Maya **Davis**, Ph.D.

16 years of FDA regulatory experience specializing in CGMP compliance, inspections, and global oversight for pharmaceutical products with senior roles in the Center for Drugs and Office of Regulatory Affairs.

Kathleen **Retterson**

40+ years of leadership in biologics and small molecule development, quality, and manufacturing, with senior roles at Amgen and Genzyme overseeing QA, QC, process development, and supply chain.

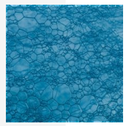
Daniel **Kavanagh**

More than a decade of global CMC expertise helping sponsors compress timelines from development to approval across small molecules, biologics and advanced therapies in the US, EU and key global markets.

Solution Spotlight | CMC Strategy & Submissions

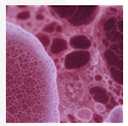
ELIQUENT's CMC Strategy and Submission Solutions deliver end-to-end support for CMC regulatory submissions, helping clients navigate complexity and reduce risk. From pre-clinical development through commercialization and post-market maintenance – we ensure clients can move forward with confidence.

ELIQUENT's CMC Strategy and Submission Solutions include:



Module 3 Authorship & Review

Comprehensive authorship, compilation, and technical review for clinical and commercial Module 3s. Our experts ensure alignment with global requirements and enhance data presentation for high-quality submissions.



Submission Gap Closure

Detailed gap analysis and remediation planning to identify and resolve deficiencies before submission. We strengthen documentation, data integrity, and consistency to deliver submission-ready packages that reduce risk and accelerate approval.

Regulatory Hurdle Resolution

Focused support for clinical hold and Complete Response remediation. Our team develops corrective strategies, authors technical responses, and guides resubmission planning to restore program momentum and maintain credibility with regulators.

Strategic Agency Engagement

Proactive planning and execution for regulatory meetings. Led by former regulators and industry experts, we help shape messaging, prepare briefing packages, and anticipate feedback to drive productive agency interactions.

CMC Strategy & Submissions | Capabilities

ELIQUENT delivers end-to-end support for CMC regulatory submissions, helping clients navigate complexity and reduce risk. Our CMC expertise is strengthened by integrated nonclinical, clinical, and project management support, enabling seamless coordination across all disciplines of an application. **Our areas of CMC Strategy & Submission expertise include:**

Stability Studies
Long-term and accelerated stability studies supporting comparability and shelf-life claims

Compatibility Studies
In-use studies supporting clinical and commercial applications

Viral Clearance Studies
Detailed risk assessments supporting regulatory submissions

Biosimilar Development
In-depth analytical similarity assessments

Technology Transfer
Strategic technology transfer planning, documentation & change management governance

Reference Standards
Qualification, lifecycle management, and control strategy alignment

Analytical Comparability
Programs to evaluate and justify manufacturing process changes

Process Validation
Robust design and lifecycle strategy for consistent product performance

Analytical Method
Development, qualification, validation & transfer for release and characterization

Shipping Validation
Comprehensive protocols to ensure integrity across distribution pathways

Microbial & Aseptic Control
Microbial control, environmental monitoring strategy development & aseptic assurance.

CMC Solutions | From Obstacle to Opportunity

From strategy to execution, ELIQUENT's CMC solutions are built to solve for industry's most complex challenges. Our team of experts provide expert-driven, end-to-end support that accelerates timelines, reduces risk, and turns obstacles into opportunities.

Obstacles in Complex **CMC Submissions**

Compressed timelines and under-resourced regulatory teams

The Challenge.
Biotech companies face intense 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.

We Deliver.
Fewer delays, stronger filings, faster path to market.

CDMO Inefficiencies & **Tech Transfer Roadblocks**

Overreliance on CDMOs and technical missteps can derail scale-up.

The Challenge.
Tech transfer to CDMOs is a high-risk, high-stakes process — especially for small and mid-sized biotechs that depend heavily on external partners. 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.

We Deliver.
Smoother tech transfers, fewer late-stage surprises, and faster scale-up.

CMC Solutions | From Obstacle to Opportunity

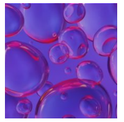
Fragmented CMC **Governance Structure**

Unstructured teams & disconnected efforts leads to missed milestones

The Challenge.
CMC programs span multiple functions, partners, and geographies — making coordination complex and resource-intensive. Many biotechs lack the internal bandwidth or structured oversight to effectively manage activities across IND, tech transfer, and global submissions. Without integrated governance, teams risk poor alignment, missed milestones, and costly delays.

Our Solution.
We provide integrated CMC program governance that includes portfolio oversight, phase-based planning, and technical project management. Through tools like real-time dashboards and scenario planning, we align stakeholders, track cross-functional dependencies, and keep complex programs on schedule — from IND through global submissions.

We Deliver.
Increased visibility, fewer missed handoffs and a more efficient path to submission.



Underdeveloped **Quality & Compliance Functions**

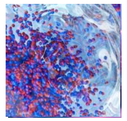
QMS gaps can stall progress and lead to increased risk

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 483s, warning letters, costly remediation, and delays — especially when speed has been prioritized over infrastructure.

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.

We Deliver.
Inspection readiness, improved compliance posture, and peace of mind.

CMC Solutions | From Obstacle to Opportunity



Regulatory Uncertainty in **Advanced Modalities**

Modality complexity demands specialized insight

The Challenge.
Developers of cell and gene therapies, RNA-based platforms, and biologics face complex, modality-specific challenges in analytics, comparability, and regulatory strategy. Limited internal expertise often leads to missteps in control strategy, global submissions, and engagement with regulators — resulting in development inefficiencies, delays, and regulatory pushback.

Our Solution.
We bring deep, hands-on expertise in advanced modalities — spanning CGT, RNA, and biologics — to guide your regulatory strategy, control strategy, and comparability planning.

Our team understands the nuance of global submissions for complex products and helps define the right regulatory path for your therapy, ensuring confident execution at every stage.

We Deliver.
Smarter decisions, higher regulatory confidence, and reduced development risk.

Ready for **Regulatory Clarity**?

ELIQUENT transforms CMC obstacles into opportunities.

Let's partner to accelerate your program, achieve global compliance, and deliver therapies to patients who need them most.

Learn more about our comprehensive CMC capabilities at ELIQUENT.com

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

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