CGT & ATMP Center of Excellence

Guiding advanced therapy programs through complexity, with confidence.

Value Delivery Framework

How we **advise**, **enable**, **implement**, and **sustain** success.

ADVISE

Clarifying complex regulatory, scientific, clinical, quality and safety expectations from early-stage to commercial.

ENABLE

Aligning your product lifecycle, regulatory requirements and business needs into tangible roadmaps and strategies.

IMPLEMENT

Providing expertise and helping hands to execute roadmaps and strategies.

SUSTAIN

Training and supporting everlasting change for our clients to be successful beyond our engagements.

ADVISE

We help organizations **clarify** complex **regulatory**, **quality** and **safety** expectations and best practices.

What You Get

- **Early visibility** into CGT specific regulatory, quality, safety, and operational risk
- **Phase appropriate guidance** aligned to CGT modality, program maturity and development stage
- **Identification of critical decisions** that shape downstream activities
- **Alignment with geographic** and jurisdictional expectations (FDA, EMA, global health authorities)

Why it Matters

Fewer Downstream Remediations

Stronger Submission Positioning

Defensible Regulatory Decisions

Meet the Advisors

- **Former Regulatory Agency Leaders**
- **CGT/ATMP Industry Practitioners**
- **Physicians**

Tiffany Lucas, PhD

Celia Witten, MD, PhD

Shelley Gandi

ADVISE

Areas of Support:

- **CGT and ATMP regulatory mapping (FDA, EMA/EU, PMDA, MHRA)**
- **Expedited Pathway Support (RMAT, PRIME)**
- **CGT IND/BLA Planning & Authorship**
- **Early stage / VC Fund Advisory**
- **CDMO Selection & Oversight**
- **Comparability Support**
- **Program Leadership**
- **CGT-specific CMC Advisory**

Challenge

Early-stage gene therapy sponsor lacked inspection-ready infrastructure and clarity on regulatory expectations.

Solution

Provided CGT-specific regulatory advisory support, including FDA meeting preparation and BLA readiness strategy.

Outcome

Sponsor entered agency interactions aligned, confident, and positioned for streamlined downstream activities.

ENABLE

Our goal is to **align** your product lifecycle, regulatory requirements and business needs into tangible roadmaps and strategies.

What You Get

- **Translation** of CGT and ATMP regulatory and safety insights into one cohesive strategy
- **Design governance and workflows** purpose-built for cell and gene therapy inspection readiness
- **CGT-specific roadmaps** defining what to build and when
- **Scalable frameworks** that support CGT & ATMP complexity

Why it Matters

Reduced regulatory risk

Faster and confident execution

Reduced unplanned costs

Meet the Enablers

- **Quality & Compliance Experts**
- **CMC Experts**
- **Process & Validation Experts**

Javier Cardenas, PhD

Eliza Deriso

Steven Bowen, PhD

ENABLE

Areas of Support:

- **Regulatory Intelligence**
- **Design of LTFU aligned with CGT durability and global expectations**
- **End-to-end risk assessments across development, tech transfer, and scale-out/scale-up**
- **CGT Commercial Readiness Assessments**
- **System and Procedure Development (aseptic processing, COI/COC, decentralized operations)**
- **GMP/GCP Remediation of CGT-specific gaps**
- **Vendor & Partner Compliance critical to CGT ecosystem**

Challenge

A life sciences provider sought to introduce new cell therapy technology but lacked a clear regulatory approach to enable sponsor adoption.

Solution

ELIQUENT assembled a team to assess regulatory, quality, and operational implications, map risks and benefits, and define the requirements needed to facilitate adoption of their technology.

Outcome

Executive leadership gained the clarity to make informed decisions on how to implement innovation in a way that was scalable, compliant, and attractive to sponsors.

IMPLEMENT

We provide expertise and helping hands to **execute** roadmaps and strategies.

What You Get

- **Embedded execution teams** across CGT modalities aligned to accelerated delivery of strategies via FSP, T&M and fixed price delivery models
- **Deployment** of scalable phase appropriate CGT systems, process, and documentation (COI/COC, aseptic processing)
- **Embedded CGT SMEs** for closure of critical gaps in Manufacturing, Quality, Validation, Safety, and Regulatory expectations.
- **Management** of cross-functional execution across complex CGT stakeholder networks

Why it Matters

Reduced execution risk

Streamlined & compliant progress

Flexible resourcing and expertise

Meet the Drivers

- **Program Architects**
- **Modality Experts**
- **Tech Transfer Specialists**

Joey Capone

Whitney Sandberg

Mark Rimbergas

IMPLEMENT

Areas of Support:

- **Authoring eCTD-ready CMC modules for IND/BLA (e.g., cell potency, viral vector characterization)**
- **Quality Systems Implementation (e.g., COI/COC)**
- **GxP Implementation**
- **CGT Audits and Mock Inspections**
- **Specialized Functional Lead Support**
- **CMC Execution & Technical Support (e.g. Comparability, Stability)**
- **Advanced Modalities SME Support**
- **Equipment and Instrumentation Qualifications**
- **Computerized System Validation and Automation**
- **Technical Project Management**

Challenge

Sponsor required comprehensive commercialization support. Initial scope focused on Quality Project Management and Commissioning, Qualification, and Validation (CQV). Mid-project a new geographical jurisdiction necessitated immediate regulatory alignment with an unfamiliar market segment.

Solution

ELIQUENT deployed a multi-disciplinary team of Subject Matter Experts (SMEs) to provide Quality SME leadership as well as regulatory expertise for the right strategy.

Outcome

Immediate integration of experts allowed for a compliant and quick deployment of strategy and ensured integrity throughout the transition.

SUSTAIN

Our efforts bring **everlasting change** for our clients to be successful beyond our engagements.

What You Get

- **Ongoing advisory check-ins** to reinforce regulatory and program decisions
- **Role-based training** to embed CGT and ATMP practices across teams
- **Account-level governance** and continuity support
- **Access to industry expertise and strategic partnerships** as needs evolve

Why it Matters

Continued inspection readiness

Operational Stability

Long Term Cost Control

Meet the Sustainers

- **Trainers**
- **Client Advocates**
- **Partners**

John Love

Erica Squires Midttveit, PhD

Masayoshi Takezawa

SUSTAIN

Areas of Support:

- **Post-Approval CGT Impact Assessments**
- **Regulatory Intelligence on evolving global CGT guidelines**
- **Audit & Inspection Readiness**
- **CGT Commercial readiness assessments**
- **Staff Training & Upskilling for CGT Techniques**
- **CAPA & Deviation Management**

Challenge

A commercial cell therapy sponsor faced rigid, legacy quality structures that hindered critical post-approval facility and cleanroom upgrades.

Solution

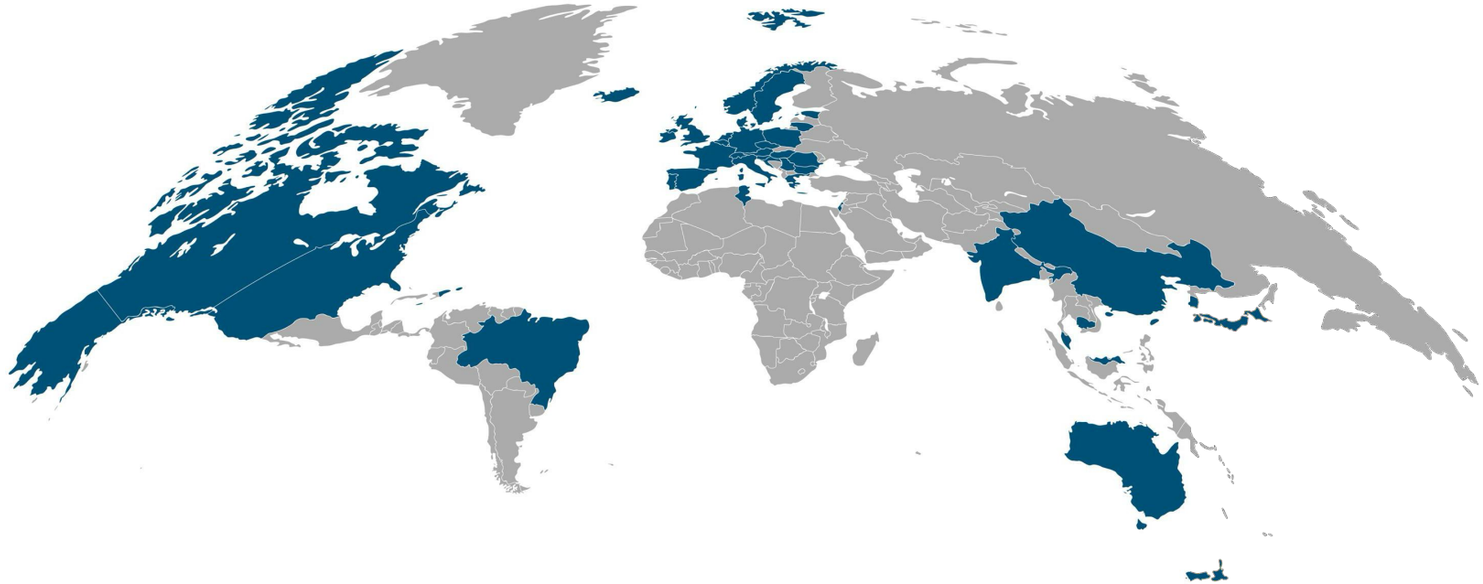
ELIQUENT deployed an expert team to modernize policies and manage end-to-end facility changes while implementing QMS updates for faster process adoption.

Outcome

The sponsor achieved a rapid improvement in turnaround for modifications and seamless regulatory compliance without production delays or downtime.

Expertise Beyond Borders

Since 2022, ELIQUENT has provided expert support to clients across **52 countries** - ensuring seamless market access, regulatory, quality and safety solutions, and compliance worldwide.



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- Switzerland
- Taiwan
- Tunisia
- United Kingdom
- United States

End-to-End CGT & ATMP Tailored Support Across Product Lifecycle

Discovery & Early Development

- Regulatory Strategy
- Platform Risk Assessments
- Safety Consideration (Materials, Vectors, Cell Sources)
- CMC Risk Framing
- Pre-IND / Scientific Advice Meeting Strategy
- Early PV Planning
- Risk Management Strategy
- QMS Roadmaps
- CDMO Selections

Clinical & IND Enablement

- Clinical Safety Oversight Frameworks
- Submission Roadmaps
- IND Development
- CMC Reviews
- Module Authoring
- Agency Response Support
- Risk Management Strategy
- QMS Design
- LTFU & Safety Frameworks
- EU QPPV Solutions

Process Development, Maturation & Scale-Up/Out

- Comparability Planning
- Technology Risk Assessments
- Vendor/CDMO Strategy
- Control Strategy Design
- Procedure Development
- Gap Remediation
- Technology Transfer
- Method Development
- CPV Program Design
- Change Management Frameworks

Commercial Readiness & Launch

- Inspection Readiness
- Global Launch Readiness
- PV & Safety Design
- Filing Preparation
- Submission Support
- CCS Strategy
- Training Support
- GxP Implementation
- Mock Audits
- Labeling & Safety Strategy

Post-Approval & Lifecycle Management

- Lifecycle CMC Strategy
- Maturity Support
- Lifecycle Change Support
- CAPA Management
- Periodic Reviews
- Programs Maintenance
- Mock Audits
- Inspections Support
- QMS Improvements
- Safety, PV, and LTFU Support

ADVISE

Turning complexity into actionable direction.

ENABLE

Aligning strategy with operational execution.

IMPLEMENT

Executing plans with embedded expertise.

SUSTAIN

Building capability that endures.