propharma

CASE STUDY

Accelerating Commercial Readiness for a Novel Cell Therapy Program

Transforming an R&D Organization into an Inspection-Ready Commercial Enterprise

A sponsor developing an advanced cell therapy product was preparing for BLA submission while simultaneously building commercial manufacturing capability. ProPharma's Cell & Gene Therapy Center of Excellence partnered with the organization to align regulatory strategy, mature quality systems, optimize facility readiness, and strengthen supply chain infrastructure, accelerating the path to approval and launch.

Challenge

The client was transitioning from research-focused operations to a commercial GMP environment while advancing toward BLA submission. Significant cross-functional gaps needed to be addressed without compromising submission timelines.

- Aligning CMC documentation and validation activities with BLA expectations
- Maturing QC analytical methods to validation-ready standards
- Designing a facility capable of supporting commercial-scale production
- Implementing inspection-ready data integrity systems aligned to ALCOA+ principles
- Establishing a compliant vendor qualification and cold-chain supply strategy
- Shifting organizational culture from R&D mindset to commercial quality maturity

Solution

ProPharma embedded a cross-disciplinary team directly within the client's departments , implementing a coordinated execution model across regulatory, quality, facility, and supply chain functions.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

www.ProPharmaGroup.com
Info@ProPharmaGroup.com

Regulatory & CMC Alignment

- Defined BLA-enabling regulatory pathway and documentation strategy
- Aligned process and facility validation plans with regulatory expectations Developed milestone-driven commercialization roadmap

Quality & Analytical Advancement

- Defined Quality Manual and Quality organization to support commercialization
- Strengthened QC analytics and method lifecycle management
- Transitioned materials toward compendial-grade standards
- Enhanced analytical control strategies to support validation readiness

Data Integrity & Inspection Readiness

- Implemented Digital Blueprint to implement data oversight
- Implemented ALCOA+-aligned governance framework
- Validated systems, audit trails, and documentation infrastructure
- Increased cybersecurity

Facility & Supply Chain Optimization

- Optimized cleanroom design and manufacturing workflows
- Recommended scalable GMP equipment solutions
- Designed a compliant vendor qualification and risk mitigation framework

Risk Governance & Executive Oversight

- Developed an integrated compliance risk register and mitigation plan
- Conducted FMEA sessions to proactively address failure modes
- Established leadership-level escalation and decision pathways

Result

Through integrated execution and embedded expertise, ProPharma accelerated the client's transition from development-stage operations to commercial readiness while reducing regulatory risk.

- Fully aligned regulatory and commercialization strategy supporting BLA readiness
- Strengthened analytical validation framework
- Inspection-ready data integrity systems
- Optimized facility and equipment design for scalability
- Risk-managed, compliant supply chain infrastructure
- Executive alignment accelerating decision-making and program pace

The organization advanced from facility build-out to BLA submission readiness, with increased confidence in compliance and strengthened operational maturity.

Positioning for Approval and Launch

Advanced therapies require integrated alignment across regulatory, quality, operational, and leadership functions. By strengthening systems, mitigating risk, and accelerating governance, ProPharma positioned the client for a successful BLA submission and scalable commercial launch.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

www.ProPharmaGroup.com
Info@ProPharmaGroup.com