

Cell & Gene Therapy Services

Cellular and regenerative medicine introduces a paradigm shift in healthcare - the promise of using the body's own abilities to grow and heal. Innovation in this area is driving dramatic change in the prevention, treatment and cure of diseases and disorders.

The nature of cell and gene therapies (CGT) requires rethinking traditional pharmaceutical and biopharmaceutical business models and the approach to technical and commercial operations. Geographically dispersed networks of cell collection, processing, manufacturing, and treatment facilities, along with responsibility for Chain of Integrity/Chain of Custody (CoI/CoC) create new demands on the operations network.

Converge understands the risks, complexity, and uncertainty for CGT companies moving from preclinical to clinical development, preparing for commercial product launch, and scaling operations. We extend our clients' reach, close knowledge/skill gaps, and shorten the time required to complete crucial initiatives.

Agile Patient Supply

CGT is truly patient-centric medicine. Treatments are often made either partially or entirely for individual patients, and operations must align with treatment cycles. Scheduling changes at treatment sites drive variability for processing operations, while limited capacity and scarce resources constrain supply. As a result, reliability and agility are critical in supply chain design to minimize risk of disruption, delay, or deviation that directly impacts patients.

In addition, materials often require cold-chain or cryo-preserved shipping, storage, and handling. It is important to design the operations network to balance supply reliability with demand variability, building flexibility into manufacturing and supply chains.

Converge helps emerging companies ensure agile and reliable supply through effective design and execution of supply chain and distribution operations. Our practitioners' cold-chain and specialty logistics expertise supports the scale-up or scale-out of operations for autologous and allogeneic therapies.

Scalable Processing and Operations

CGT treatments involve especially complex processing, with many operations conducted aseptically. Companies begin CMC activities earlier to define critical process parameters and control strategies, and to optimize yields and viability. We help clients stay on track by providing CMC and

manufacturing strategy, leadership, key subject matter expertise, and project management when needed to address challenges and maintain progress.

Since patients and physicians are integral to the CGT supply chain, ensuring vein-to-vein CoI/CoC is essential. This requires infrastructure for tracking and managing the movement and conditions of handling and processing. IT solutions are important components. Converge experts and practitioners support strategies, partner selection and integration to ensure proper CoI/CoC through the entire supply chain and treatment process.

Enhancing Patient Outcomes

Commercial CGT models are service-oriented, requiring alignment between operations, patient supply, and treatment cycles. Our experts can assist with commercialization and integration strategies, build out operations and/or implement supply products, processes, and models that impact outcomes.

A scalable enterprise IT architecture focused on spanning end-to-end patient lifecycle management is important for data collection and monitoring. Our architects and experts lead the development and deployment of new technologies and integration plans that enable maximum flexibility between operating, commercial and business systems.

Our Services

We work independently or with client teams to deliver sound CGT strategy, operational leadership, and execution. Our expertise includes:

- Manufacturing cell processing supply strategies
- CGT manufacturing facility assessment, site selection & conceptual design
- CoI/CoC and digital/IT architecture orchestration
- Manufacturing troubleshooting
- CMC guidance and compliance (cell sorting & processing, process & analytical methods, reports)
- Quality operations
- Shipping & transport strategies/qualification

Converge Consulting serves the Life Sciences industry with strategy, operations, and execution expertise. We collaborate with biotech, pharmaceutical and cell/gene therapy companies to achieve important business objectives. The Converge approach focuses on bridging the gap between sound strategy and reliable execution. www.convergeconsulting.com