



# Your CDMO Partner Advancing Cell Therapies to Patients

Highly Experienced Cell Therapy Team

Dedicated, Integrated Cell Therapy Facility

Full Service Preclinical to Commercial

# Partners for Life

Advancing tomorrow's medicines

#### **Types of Cells We Support**

Cell Derived Therapies – CTL, CAR, TCR, NK and Tissue-Derived Therapies – Mesenchymal Stem Cell, Hematopoietic Stem Cells, Induced Pluripotent Stem Cells.

#### **Process Development and Optimization**

Highly experienced teams support development and optimization of cell therapy processes that meet the needs of our clients, their regulatory phase, and their goals.

#### **Analytical Development and Optimization**

Our scientists can develop, optimize, and validate analytical methods to support client specific assays – including safety and efficacy assays to enable successful transfer to our QC labs.

#### **Tech Transfer / NPI (MSAT)**

The depth and breadth of FDB's MSAT program ensures seamless transfer of knowledge from our customers into the capable hands of our cGMP manufacturing teams.

#### **Clinical and Commercial Manufacturing**

Expansive cGMP manufacturing space complete with advanced technologies and electronic batch records to support clinical and commercial production goals at the highest quality.

Allogeneic & Autologous Cell Therapy Programs World Class Cell Therapy Processes & Technologies Superior Program Management & Quality Control 215+

Years of Collective Leadership Experience in Biotech

2018
Year CA Site Began
Manufacturing Cell

Therapies

LIATE

1000+

Clinical Shipments to Patients in 7 Countries

Commercial Authorization Following EMA Audit for an Allogeneic Cell Therapy Customer

30+
Allogeneic CTL and
CAR-T Lots Produced

**Cell Therapy Experience** 

at California Facility

#### **Supply Chain and Logistics**

Experience-driven strategies and processes that enable program readiness and execution of manufacturing, disposition, and distribution activities. This includes materials supply, assembly, labeling and packaging and cryogenic storage.

#### **Quality and Compliance**

Superior program management, Quality Management System and Quality Control programs designed to ensure product quality meets US and EU regulatory standards, with flexibility to enable clinical and commercial programs.

#### **Strategic Partnerships**

We partner with companies with specialized technical expertise: FUJIFILM Cellular Dynamics for contract development and cGMP manufacture of clinical-grade IPSCs and RoosterBio for process & analytical development of MSCs.

Contact us to get the latest updates on our network and capabilities.

Thousand Oaks, CA, USA Dedicated Cell Therapy Site

Watertown, MA, USA

College Station, TX, USA

Billingham, UK Darlington, UK

### **Cell and Gene Therapy Network**

We offer accessibility and flexibility in the choice of locations and manufacturing scales.



## Contact us to discuss your science.

#### USA

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