

# Strengthen and accelerate your cell and gene therapy expedition with BaseCamp

ElevateBio's cGMP manufacturing business enabling biopharmaceutical partners with turnkey, scalable access to critical capabilities across the full product lifecycle. We are a skilled partner offering the expertise, technologies, and state-of-the-art facilities to provide manufacturing solutions for cell and gene therapies, from preclinical through commercial production.

We support the design, development and manufacturing across cell therapies, viral vectors, and mRNA therapeutics and vaccines.

- CAR/TCR T Cell Therapies
- mRNA Vaccines
- Engineered Cell Therapies
- Gene-Edited Allogeneic Therapies
- In Vivo Car T Therapies
- In Vivo Gene Therapies



### **Our Capabilities**



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

- Provides end-to-end solutions for cGMP manufacturing, warehouse and distribution capabilities
- Operates multiple segregated manufacturing suites for cell therapy products, viral vectors, and mRNA
- Utilizes automated systems for real-time review of process data and release of product



#### Process Development

- Offers robust data supporting a variety of GOIs and viral applications, from CAR-T, TCR-T applications to in vivo viral vectors
- Develops AAV platform processes for a variety of serotypes currently under development
- Offers LentiPeak<sup>™</sup> suspension based lentiviral production platform capable of LVV titers over 108 TU/mL



#### **Analytical Development**

- Develops a spectrum of product specific assays, including cell-based potency assay
- Conducts stability studies in accordance with ICH guidelines
- Offers an established panel of standard assays that are ready to be employed to measure product safety, potency, purity, stability, and identity



#### **Next-Generation Sequencing**

- Offers rapid next-generation sequencing (NGS) services to support all cell and gene therapy modalities
- Leverages advanced technologies and expertise to provide flexibility, customizability, and rapid turnaround times



#### Regulatory and Quality Expertise

- Provides personalized regulatory support across preclinical, clinical, and commercial stages to ensure compliance with regulatory standards
- Delivers expert regulatory submission writing services to support development and regulatory strategy across the full product lifecycle
- Commits to balanced, risk-based quality decisions to help ensure products meet the precise standards expected by industry leaders and health regulators
- Maintains more than 40 state-of-the-art quality control release methods in-house to support in process control and cGMP product release



# BaseCamp Waltham is ICMC<sup>™</sup> Certified for Clinical and Commercial Cell and Gene Therapy Manufacturing Capabilities

BaseCamp Waltham has been certified by the Initiative for Certification of Manufacturing Capabilities (ICMC™) program for our viral gene delivery, non-viral gene delivery, and cell therapy manufacturing capabilities. The ICMC certification is a rigorous audit administered by Dark Horse Consulting Group, that certifies ElevateBio's compliant and scalable manufacturing capabilities for advanced therapies using U.S. and E.U. commercial-level evaluation standards.

#### Our Partners can expect:

- Standardized, reproducible manufacturing processes that have been rigorously evaluated against industry benchmarks
- Reduced regulatory risk
- Accelerated timelines and increased probability of technical success
- Time and resources savings in the development and manufacturing of their therapies

### **Explore BaseCamp Waltham**



BaseCamp Waltham: ~140,000 SQUARE FEET Our flagship cGMP and process development facility in Waltham, MA

#### **GMP Manufacturing**

- 11 Grade B Suites
- 3 Grade C Suites
- Manufacturing Training Lab
- Quality Control Release Testing Labs

www.

#### **Process and Analytical**

- Process Development Labs
- Analytical Development Labs
- Analytical Method Testing Lab

#### Warehouses

- Validated Controlled GMP Warehouse & Storage
- Dedicated GMP Material Receiving
- Dedicated Patient/Donor Material Receiving



## Combining BaseCamp with Life Edit

Powering Cell and Gene Therapy Companies with Integrated Manufacturing and Technologies

ElevateBio Life Edit is our gene editing technologies and R&D business. Through BaseCamp and Life Edit, we deliver unparalleled expertise, capabilities, quality, and high-touch customer service. We have integrated a differentiated set of platform technologies, including full-spectrum gene editing, with industry-leading manufacturing expertise to develop genetic medicines faster and more efficiently, ultimately accelerating their delivery to patients.

### Partner with ElevateBio BaseCamp

Wherever you are in your product lifecycle, we can strengthen and accelerate the development of your transformative therapies with our enabling technologies and unmatched manufacturing capabilities.

WORK WITH US  $\rightarrow$ 

# Expanding our Footprint with BaseCamp Pittsburgh



BaseCamp Pittsburgh: ~125,000 SQUARE FEET

ElevateBio and University of Pittsburgh are partnering to build BaseCamp Pittsburgh at Hazelwood Green