

• SEATTLE
• LONGMONT
• BOULDER

COPENHAGEN •

• HEIDELBERG

• MILAN

CHIBA
YOKOHAMA

Modalities at this site:

Cell Therapy

Viral Vector



LONGMONT FACILITY

A North American Cell and Gene Therapy CDMO Hub

Our AGC Biologics Longmont site capabilities include viral vector development, characterization, and manufacturing in **adherent** and **suspension** environments, along with cell culture and modification development and manufacturing using the latest industry technologies and methodologies. Our scientists here have an established track record of **20+ years of experience** working with complex cell therapy and viral vector products and substances.

Cell and Gene Therapy Services

Our global network that supports Longmont is uniquely positioned with **end-to-end C> services** and commercial manufacturing experience, including pDNA, mRNA, viral vectors, and cell therapies. We have an unmatched track record, including the **first approved ex vivo gene therapy facility in Europe** and we are the only cell and gene therapy CDMO that has brought its own product (Zalmoxis®) to market.





Biopharmaceutical Manufacturing in Colorado

- Cell therapy and viral vector clinical and commercial capabilities with large GMP capacity
- GMP manufacturing suite for cell therapy practice in one centralized location where all processes are managed
- LVV / RVV / AAV offerings in adhesion (up to 200 L) and suspension (up to 2,000 L)
- Platform processes and capabilities for gene modification of HSC (CD34+) and T-cells
- More than 160 in-house analytical tests ensure fast turnaround times
- Dedicated quality control spaces for cellular-based assays, and stability activities, including dedicated suites for microbiology biochemistry

Longmont Suites and Equipment

- Ready-to-use Adherent Platform including, iCELLis® Nano and iCELLis® 500+
- Ready-to-use Suspension Platform including, Sartorius Biostat 25L and 50 L rocker platforms, Sartorius Ambr 250 Modular (PD only), Cytiva XDR-10 (PD only), Cytiva XDR-50 (GMP), and Cytiva XDR-200/500/2000 (Flexible single suite)
- Cell Therapy PD suite and laboratory
- 3 MFG Suites Grade B or C Flexible
- Flexibility for Client Specific Instrumentation
- Future expansion of the facility to 12+ suites possible

Globally Aligned Quality Systems

- Thorough documentation, policies, procedures
- Site-specific processes, specifications, and records
- Backed by a network of seven sites with decades of biologics expertise sharing best practices to meet clinical and commercial requirements
- Regulatory approval expertise

