**COPENHAGEN** •

• SEATTLE
• LONGMONT

HEIDELBERG
 MILAN



Modalities at this site:

Mammalian



## **BOULDER FACILITY**

A Large-Scale Commercial Manufacturing Hub

Our AGC Biologics Boulder site offers a significantly larger production for mammalian-based projects. With our core teams of scientists having **25+ years of experience** in development and manufacturing, we can work with virtually any process, method, or molecule. The Boulder site has experience with multiple mammalian cell types and expression systems.

### **Mammalian Production Systems**

Boulder houses two 20,000 L stainless steel cell bioreactors. The large-volume bioreactors processed under high levels of automation make it well suited for **cost-effective cGMP commercial production** for high-titer processes.







#### **Process Development Services**

- Our expertise in process development and tech transfer enables us to move projects seamlessly into cGMP manufacturing
- High-throughput technologies for process development emphasize characterization, optimization, manufacturability and the robustness of the product yields
- Upstream capabilities that include cultibag bioreactor technology, seed bioreactors up to 2,500 L (stainless steel), and two large stainless steel production bioreactors
- Recovery services that include disc-stack centrifugation, multi-round depth filtration and UF filtration
- Downstream services with large and small chromatography systems, virus inactivation, virus filtration, post-virus chromatography, formulation and BSC and closed filling (bags and bottles)

## **Large-Scale Commercial Manufacturing**

- 2 x 20,000 L stainless steel production bioreactors (17,000 L working volume) with effective size and automation for high-volume commercial production and high-titer antibody processes
- Designed for large-scale drug substance production (up to 10 g/l)
- Large scale volume and high titers mean great cost savings
- · 178,000 sq ft. facility
- Expansion capabilities for 4 more 20,000 L for a total of 6 bioreactors
- Manufacturing success rates that exceed industry standards globally

#### **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

# **Opportunities for Expansion to Meet Project Needs**

- Expansion capabilities for 4 more 20,000 L for a total of 6 tanks
- · Room for two additional downstream lines
- Utilities already configured to support the expansion







agcbio.com

■ contactus@agcbio.com



