AGC Biologics

Mammalian Capabilities

TRACK RECORD

9 commercial mammalian products

150+ mammalian cell culture-based products

Our mammalian CDMO services are based on standard industry systems, with **30 years of scientific expertise**, for production and manufacturing, including batch, fed-batch and continuous perfusion methods.

We offer a variety of flexible single-use manufacturing scales with options for multiple configurations at our sites in the U.S., Europe, and Japan. We also offer large-scale commercial capabilities using **20,000 L** stainless steel reactors at our site in Boulder, CO, USA.

Our quality systems, GMP manufacturing scale, as well as regulatory qualification, allow us to meet demand at any phase.

Unique Benefits

- **Flexible customer-centric processes:** We can accommodate virtually any method or molecule you bring us.
- **Leading pre-clinical track record:** Fast-speed to IND (first-in-human, phase I), market-leading since 2012.
- **Knowledge in the clinic:** A process optimization partnership after phase I that maximizes resources and gets you through clinical stages.
- **Excellence in late-stage:** Our development has supported and carried out scale-down and process characterization studies numerous times with exceptional success.

Cell Line Development & Cell Banking

- In-house proprietary expression platform CHEF1® with **5 commercial products** already in the market and **54 different molecules** produced. Platform includes royalty-free & full documentation for IND filing
- Competitive timelines, getting you to the clinic in as fast as 11 months
- Can work with nearly any molecule, including: mAbs, antibody formats, FC fusion, complex glycoproteins, enzymes, blood borne therapeutics, bi & tri specifics, BITEs, T-cell modulators, growth & blood factors
- Extensive experience with multiple mammalian cell types and expression systems including: CHO DG44, CHO GS, CHOK1, HEK293, NS0, and more
- Single-cell clone selection based on high titer and quality attributes
- Custom CHO cell line, growth media, and production feeds
- Cell line analysis
- cGMP cell banking and storage

Upstream Process Development

- Flexible scale of production
- Clone selection, re-cloning, process optimization, reproducibility
- Best-in-class scale-down models (Ambr250 and bench top bioreactors) Single-use technologies
- Extensive experience of developing in-house and optimizing client processes
- Continuous process validation programs
- Perfusion and intensified fed-batch capabilities
- Consistent scale-up record directly from Ambr 250 and 5 or 10 L to 2,000 L and 20,000 L bioreactors
- Standard process transfer to manufacturing (risk analysis, tech transfer, etc.)

Downstream Process Development

- Harvest that includes traditional depth stage filtration with combinations of different filters
- Single-use Ksep centrifugation system
- Experience with wide diversity of resin types for chromatography
- Single-use protein A purification offers accelerated timelines and lower cost
- Viral removal & filtration
- In-depth analytics to monitor and control processes
- Process validation studies for commercialization

Drug Substance Manufacturing

- 4 facilities around the globe providing pre-clinical to commercial cGMP mammalian manufacturing
- Exceptional scalability with Bioreactor 6Pack System™ single-use suites allowing up to six 2,000 L bioreactors to run in tandem
- Stainless steel commercial manufacturing capabilities up to 20,000 L (vessel volume) designed for high-titers and great cost savings

Comprehensive Analytical Capabilities In-House

- Titer, purity, and identity assays
- Process impurity measurements
- Product aggregation
- Structural characterization
- Product stability and formulation
- Next generation sequencing
- Broad array of characterization assays in-house

Quality Assurance

- Support with regards to regulatory submissions
- Integrated quality systems incorporating US, Japanese, European, and ICH cGMP requirements
- Comprehensive, global quality system
- Regulatory compliance and validation expertise
- History of successful client audits and regulatory inspections

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