AGC Biologics
Your friendly CDMO expert

Viral Vector Capabilities

TRACK RECORD

6 commercial vector approvals

400+ vector GMP batches

AGC Biologics brings technical expertise to develop and optimize every aspect of viral vector gene therapy. Our services range from production of plasmid DNA necessary for the transfection of producing cells to the manipulation and engineering of cells through the use of produced viral vectors. Our technical know-how allows us to bring small-scale processes to scalable industrial manufacturing, ensuring commercial viability. We are the only CDMO site to achieve **FDA & EMA approval** for both LVV & cell drug products.

AGC Biologics has the experience to develop and manufacture **lenti, retro, and adeno-associated viral vectors**. Our ready-to-use platform capabilities are built on Cell Factories (up to 48 L) with iCELLis 500s for **adherent** processes up to 750 L, as well as single-use bioreactors for **suspension** processes up to 2,000 L.

Our quality systems, GMP manufacturing scale, as well as regulatory qualification, allow us to meet both clinical and commercial demand. Moreover, our **custom in-house vector programs** and scale down capabilities provide flexible and cost-effective solutions for process development and pre-clinical studies. We perform **95% of analytical tests in-house** to help bring your product to market as fast as possible.

Tech Transfer & Process Development

- Analytical method & knowledge transfer
- Feasibility studies for new processes with new reagents and materials
- Ready-to-use lentiviral (ProntoLVV™) and adeno-associated viral vector (BravoAAV™) manufacturing platforms with off-the-shelf materials
- Capacity to produce research and non-clinical batches with representative processes at different scales.
- Pilot run to set & define the production methods
- Analytical development for potency & client specific assays
- Process scale down models available for development, optimization and process characterization studies

Upstream Process Development

- **Flexible Production Scale**
  - Cell factories ≤ 48 L
  - Bioreactors: 50 - 2,000 L
- Single-use technologies
- Extensive experience of developing in-house and optimizing client processes
- **Production Systems**
  - Petri dishes
  - Eppendorf bioreactors
  - Cell factory
  - iCELLis 500 system
  - iCELLis Nano system
  - Sartorius STR bioreactors
  - Cytiva XDR bioreactors

Downstream Process Development

- **Separation Chromatography Techniques**
  - Ion exchange
  - Size exclusion
  - Affinity
- **Tangential Flow Filtration**
  - Ultrafiltration
  - Diafiltration

cGMP Manufacturing & Quality Control

- Adhesion production up to 750 L
- Suspension production up to 2,000 L
- Stability studies management (scheduling, testing, documentation & statistical analysis)
- Raw materials release
- Qualification and validation of product-specific analytical methods
- Fill & finish for vials (automatic and manual systems) and bags (manual system)

In-House Analytical Development

Potency Assays

- Infectious viral titer
- Physical viral titer
- Infectivity
- Transgene function
- Vector genome titer
- Capsid titer

- **Chemical/Physical Characteristics**
  - Appearance
  - Osmolality
  - pH
- **Purity**
  - Residual BSA, HCP, and BENZONASE
  - Residual pDNA, host cell DNA, and DNA size, E1A/LTA DNA and total DNA
  - Residual affinity ligand and LTA protein
  - Viral aggregation
  - Full/empty ratio
- **Microbiological Control and Safety**
  - Endotoxin
  - Sterility
  - RCL - molecular and cultural assays
  - Bioburden
  - In vitro adventitious viruses
  - NAT mycoplasma

Quality Assurance

- Support with regards to regulatory submissions Integrated quality systems incorporating US, European, and ICH cGMP requirements
- Analytical method validation and process performance qualification (PPQ) in accordance with applicable guidelines
- QP certification
- History of successful client audits and regulatory inspections
- EMA & FDA approvals

+1 425.485.1900
agcbio.com
contactus@agcbio.com