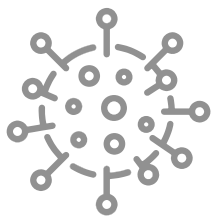




AGC Biologics

Right. On Time.



Viral Vector **capabilities**

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 engineering of cells through the use of produced viral vectors. Our technical know-how allows us to bring small-scale process to scalable industrial manufacturing, ensuring process robustness and commercial viability.

AGC Biologics has the experience to develop and manufacture Lenti and Retro viral vectors. Our ready-to-use platform capabilities are built on Cell

Factories (up to 48L) and Bioreactor (up to 200L) using adherent process, designed entirely in-house. Our quality systems, GMP manufacturing scale, as well as regulatory qualification, allow us to meet both clinical and commercial demand. Moreover, our scale down capabilities provide flexible and cost-effective solutions for process development and pre-clinical studies. Since we perform more than 100 analytical tests in-house, AGC Biologics reduces overall turnaround time. With experience manufacturing three commercial products, we are the only C> CDMO, which has brought its own product to the market (Zalmoxis®).



Tech Transfer & Process Development

- Knowledge transfer from client to AGC Biologics
- Feasibility studies for new processes with new reagents and materials
- Ready-to-use Lenti viral vector manufacturing platforms with off-the-shelf materials (packaging plasmids, master cell bank)
- Transfer of client processes at different development stages from R&D scale to cGMP
- Small-scale setting up experiments for production of research and non-clinical batches
- Small-scale run to certify the quality of the reagents (plasmid DNA, master cell bank, etc.)
- Optimization studies to improve process performance
- Pilot run to set and define the production methods
- LPC and characterization studies
- Comparability studies
- Analytical development for potency and client specific assays
- Qualification of product specific analytical methods before final transfer to QC
- Implementation and optimization of automated assays

Up-Stream Process Development

- Flexible scale of production in Cell Factories up to 48L
- Flexible scale of production in Bioreactor up to 200L
- Single-use technologies
- Extensive experience of developing in-house and optimizing client processes

Production Scale

- Petri Dishes
- Cell Factory
- Pall iCellis Nano system
- Pall iCellis 500 system

Down-Stream Process Development

Separation Chromatography Techniques

- Ion exchange
- Size exclusion
- Affinity
- Ligands

Tangential Flow Filtration

- Ultrafiltration
- Diafiltration

Analytical Methods Development

Performed In-house

Potency Assay

- Infectious Viral Titer
- Physical Viral Titer
- Infectivity
- Transgene function

Identity and Chemical/Physical Characteristic

- Vector Identity
- pH
- Osmolality

Purity

- Residual BSA/HCP/BENZONASE
- Lentiviral Proteins
- Residual LTA protein
- Residual VSV-G/LTA/E1A and Total DNA

Microbiological Control and Safety

- Endotoxin
- Sterility
- Cultural RCL

cGMP Manufacturing & Quality Control

- Ready-to-use in-house platform in Cell Factories up to 48L
- Release, IPC, characterization and stability testing
- Analytical method transfer
- Method validation in accordance with relevant guidelines
- Stability studies management (scheduling, testing, documentation and statistical analysis to support shelf life definition)
- Characterization studies management
- Outsourcing testing management
- Raw materials release

Quality Assurance

- Support with regards to regulatory submissions (IND, IMPD, BLA, MAA)
- Integrated quality systems incorporating US, European, and ICH cGMP requirements
- Comprehensive Quality Agreements
- Regulatory compliance and validation expertise
- History of successful client audits and regulatory inspections
- EU cGMP Certification



AGC Biologics
21511 23rd Dr. SE
Bothell, WA 98021 USA

P: +1 425.485.1900
F: +1 425.486.0300
E: contact@agcbio.com

agcbio.com

©2020 AGC Biologics. All rights reserved. AGC, AGC Biologics, the Leaf logo and other brand indicia and slogans are registered and unregistered trademarks of AGC Biologics in the United States and other countries.