AGC Biologics

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 the manipulation and 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, retro, and adeno-associated viral vectors**. Our ready-to-use platform capabilities are built on Cell Factories (up to 48 L) and Bioreactor (up to 200 L) 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. We perform **more than 160 analytical tests in-house** to help bring your product to market as fast as possible. With experience manufacturing two commercial products, we are a CDMO that brought a product to the market (Zalmoxis), and understand the procedures and complexities of each step in that process.

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
- Transfer of client processes at different development stages from R&D scale to cGMP
- Small-scale experiments for production of research and non-clinical batches
- Small-scale run to certify quality of reagents
- Optimization studies to improve process
- Pilot run to set & define the production methods
- LPC & characterization studies
- Comparability studies
- Analytical development for potency & client specific assays
- Qualification of product specific analytical methods before final transfer to QC
- Implement & optimize automated assays

Upstream Process Development

- Flexible scale of production
  - Cell factories ≤ 48 L
  - Bioreactor ≤ 200 L
- Single-use technologies
- Extensive experience of developing in-house and optimizing client processes
- Production scale
  - Petri dishes
  - iCellis 500 system
  - Cell factory
  - iCellis Nano system

Downstream Process Development

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

Analytical Methods Development Performed In-House

- **Potency Assay**
  - Infectious Viral Titer
  - Infectivity
  - Physical Viral Titer
  - Transgene function
- **Identity & Chemical/Physical Characteristic**
  - Vector
  - 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
  - Cultural RCL
  - Sterility

cGMP Manufacturing & Quality Control

- In-house platform in cell factories ≤ 48L
- Release, IPC, characterization & stability testing
- Analytical method transfer
- Method validation in accordance with guidelines
- Stability studies management (scheduling, testing, documentation & statistical analysis)
- Characterization studies management
- Outsourcing testing management
- Raw materials release
- Fill & finish and in-house QC analytics

Quality Assurance

- Support with regards to regulatory submissions 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

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