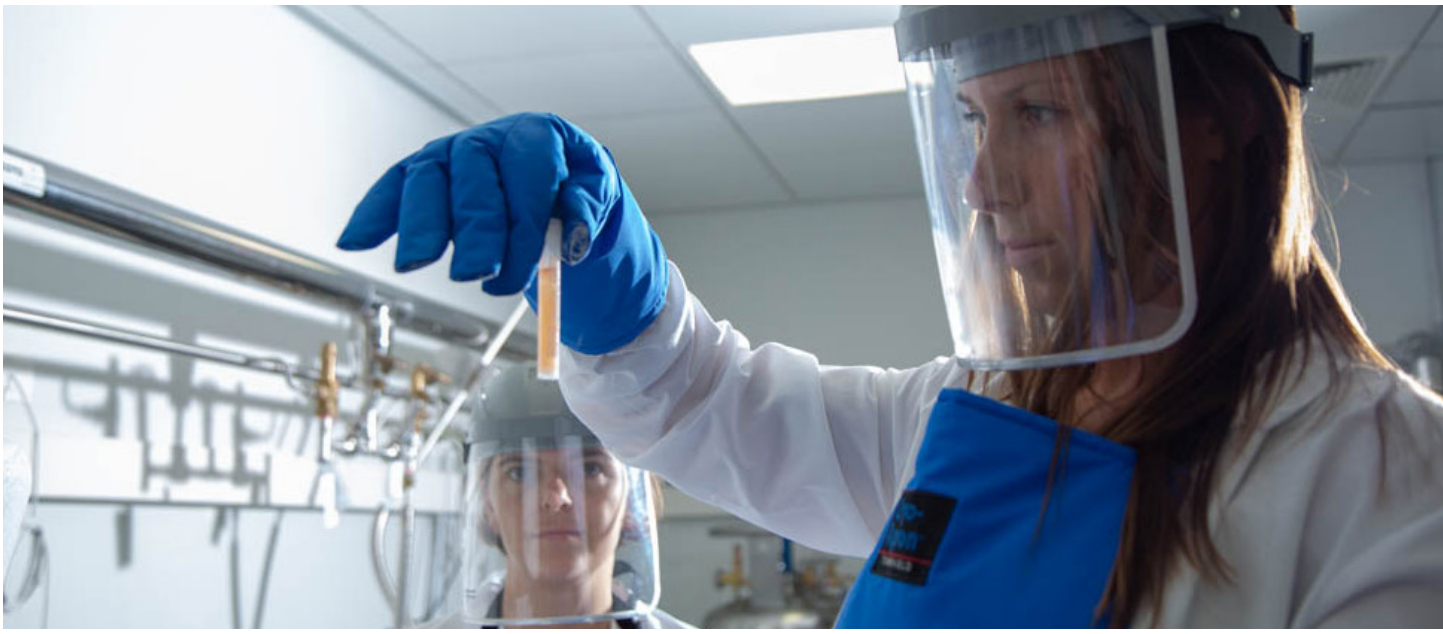
AGC Biologics



Cell Therapy Capabilities

AGC Biologics brings technical expertise to develop and optimize every aspect of cell 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 diverse cell therapies including CD34+ hematopoietic stem cells, **autologous and allogenic** T-cells, and NK cells. Our cell therapy capabilities cover numerous technologies, ranging from closed to open systems at different scales depending on client needs. Our quality systems, facility layout, as well as regulatory qualification, enables us to serve **both clinical and commercial demands**. We perform more than 160 analytical tests in-house to help bring your product to market as fast as possible. With experience manufacturing **4 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 & Development

- Knowledge transfer from client to AGC Biologics
- Feasibility studies for new processes with new reagents and materials
- Transfer of client process at different development stages from R&D scale to cGMP grade
- Optimization studies to improve process performance
- Verification studies to validate the production process
- Comparability studies
- Analytical development for potency and client specific assays
- Qualification of analytical methods before transfer into QC
- Implementation and optimization of automated assays

Analytical Methods Development
Performed In-house

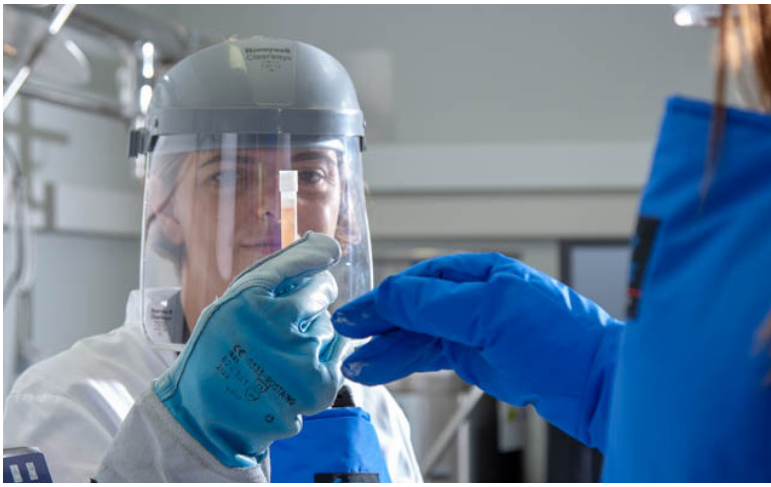
- **Drug Substance**
  - **Potency:** Viability
  - **Safety:** Mycoplasma PCR
  - **Identity:** Immunophenotype
- **Drug Product**
  - Potency:
    - Transgene functional assay
    - Viability
    - Immunophenotype
  - Safety:
    - Endotoxin
    - RCL Molecular assay
    - Microbiological control of cell suspension
  - Identity:
    - Vector identity/integrity

cGMP Manufacturing & Quality Control

- 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

Quality Assurance

- Raw materials release
- 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



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