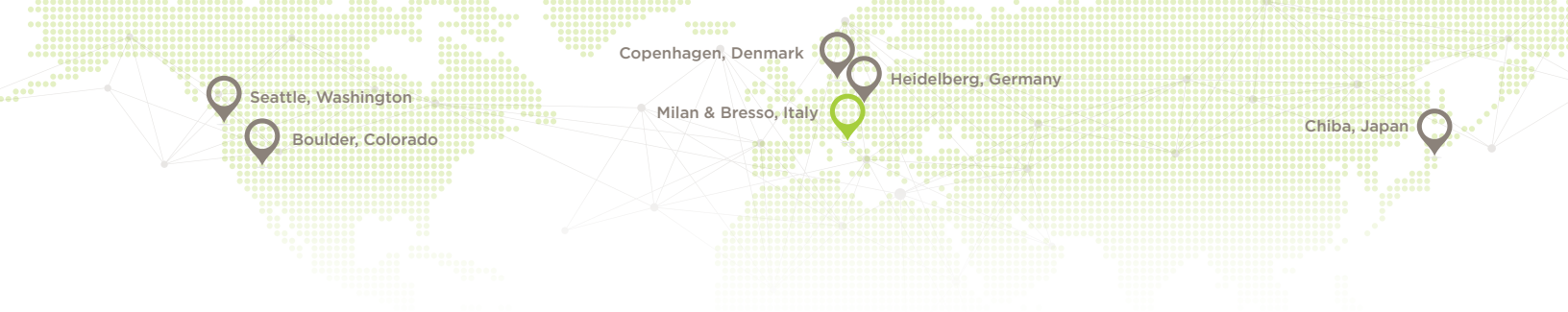
AGC Biologics
Right. On Time.

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. 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 cell and gene therapy CDMO, which has brought its own product to the market (Zalmoxis®).



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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