Modalities at this site: Cell Therapy | Viral Vector

AGC Biologics

MILAN FACILITY

Our Cell and Gene Center of Excellence

AGC Biologics Milan specializes in cell therapy and viral vector development and manufacturing. The site works with virtually any cell type and lentiviral, retroviral, and adeno-associated viral vectors.

The facility was the first cell and gene therapy site approved in Europe for GMP manufacturing of clinical and commercial supplies. The core scientific team has more than **25 years of expertise** in the field and unique knowledge you will not find anywhere else.

This site has more than 10,000 m^2 of technical space, 4,000 m^2 of office space, and nearly 300 experts and staff, including multiple QP's to release drug products.

The Milan team has developed **3 commercial products** including, before joining the AGC network, brought its own product to the market (Zalmoxis®). This experience means they understand the processes, procedures, and painstaking work involved in developing and bringing these treatments to market.

Cell Therapy Services

- Cell therapy services that can help from initial development to full commercial supply
- GMP manufacturing suite for cell therapy practice in one centralized location where all processes are managed
- Using both autologous and allogeneic systems; extensive experiencewith T cell, HSC / CD34, and NK cell products
- Industry-leading expertise in PD and internalizing client autologous and allogeneic processes
- Customization, development, qualification and validation activities for manufacturing and analytics
- Established experience working with MSC and EV capabilities
- 10 grade B/C suites of 20, 40 and 60sqm all with independent access and HVAC
- 550+ cell-therapy batches manufactured
- Commercial manufacturing experience with three cell therapy products

Viral Vector Services

- LVV / RVV / AAV offerings in adhesion (up to 750 L) and suspension (up to 2,000 L)
- New standardized platforms BravoAAV™ and ProntoLVV™ offering an innovative templated approach to AAV and LVV manufacturing
- Use of cell factories and fixed bed bioreactor for adherent protocols, and wave and stirrer bioreactors for suspension
- Prequalified scale-down models simplifying and accelerating the path to commercialization.
- 400+ cGMP viral vector batches manufactured
- Commercial manufacturing experience with three viral vector products, and 5 PPQ runs completed to support BLA filings
- Filler onsite with capabilities to address different type of vials (criovials, glass, polimer) at a range of volumes (2-8ml)

Analytics and Quality

- Quality management system in line with EU ATMP cGMP and FDA guidelines
- Dedicated quality control spaces for assays, and stability activities, including dedicated suites for microbiology biochemistry
- Over 160 analytical tests and 95% of release testing provided in-house including sterility, RCL and adventitious agents.
- Commercially approved since 2016
- Thorough documentation, policies, procedures
- Site-specific processes, specifications, and records
- Backed by a network of seven sites with decades of biologics expertise sharing best practices to meet clinical and commercial requirements

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