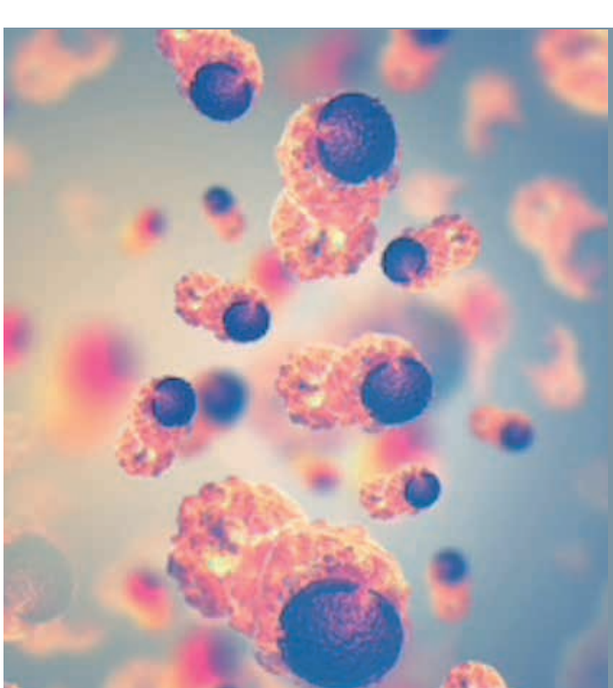
MOLMED

GMP Solutions for Cell & Gene therapies

# GMP CELL ENGINEERING

MolMed provides tailor-made services for Cell & Gene therapy projects, meeting Client's needs in terms of development and GMP manufacturing of retroviral and lentiviral vectors and genetically modified T-cells and Stem cells



**+ 250** Treated patients

**+ 20** Clinical trials

# Our Facilities

## DIBIT Facility (Milan)

- 1.500 SQM (16.000 SQF) areas of which 400 SQM are classified with Grade B/C suites and Grade C/D shared areas, dedicated to testing and production in accordance with the cGMP guidelines
- Authorized GMP manufacturing facility since 2003 for clinical programs and since 2015 for European commercial ATMP products

## OpenZone Facility (Bresso, Milan)

- 3.300 SQM (35.000 SQF) areas of which 1.500 SQM are classified with Grade B/C suites including BL3 classified containment area and Grade C/D shared areas, built in with flexible design and in accordance with the highest quality standards dedicated to production in accordance with the cGMP guidelines
- Authorized GMP manufacturing facility for clinical programs and for European commercial ATMP products since 2017

# GMP Engineering of genetically modified cells

MolMed offers its top level expertise for providing a panel of customized services including the tech transfer, development, scale up, automation and validation of RVV/LVV cell transduction processes, as well as DP filling and release, with the aim of making such processes suitable for clinical and commercial standard for ATMP. In parallel, MolMed offers the development, qualification and validation of analytical tests, both compendial and product specific. Over 100 analytical tests are performed in house for the release of the products.

MolMed can further assist its customers, offering proprietary processes for gene modification of HSC (CD34+) and T-cells.

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