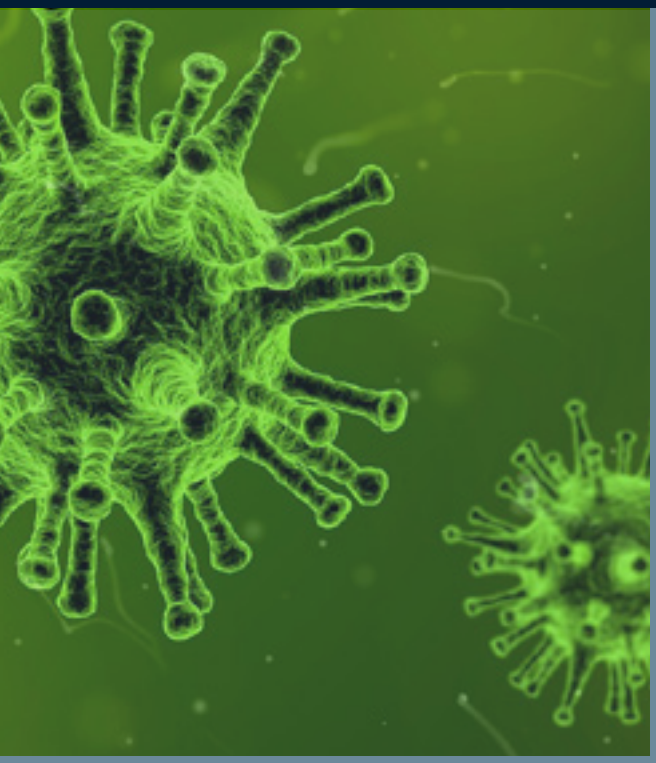
MOLMED

GMP Solutions for Cell & Gene therapies

# Solutions to bring your Cell & Gene therapy projects from bench to bedside

# MolMed provides a full range of tailor made services for your Cell & Gene therapy projects



## Up to 200 L
## Vector Manufacturing

Top player in the GMP production of retro and lentiviral vectors and genetically modified cells

## Excellent GMP capacity of
## 4.800 SQM (51.000 SQF)

authorized for clinical and commercial GMP manufacturing of ATMP into 2 facilities

# Viral vectors & Genetical modified cells

## Development

- Feasibility studies, tech transfer in and out and verification runs
- Process optimization, scale up and automations non-GMP manufacturing of viral vectors and genetically modified cells at different scales
- Development and qualification of analytical methods

## GMP Manufacturing

- Up to 200L Vector Manufacturing of retroviral and lentiviral vectors
- Drug product manufacturing of autologous and allogeneic cells (CD34+ and T-cells)
- Production of Master Working Cell Bank (MCB, WCB) of different cell pipes

## Quality Control

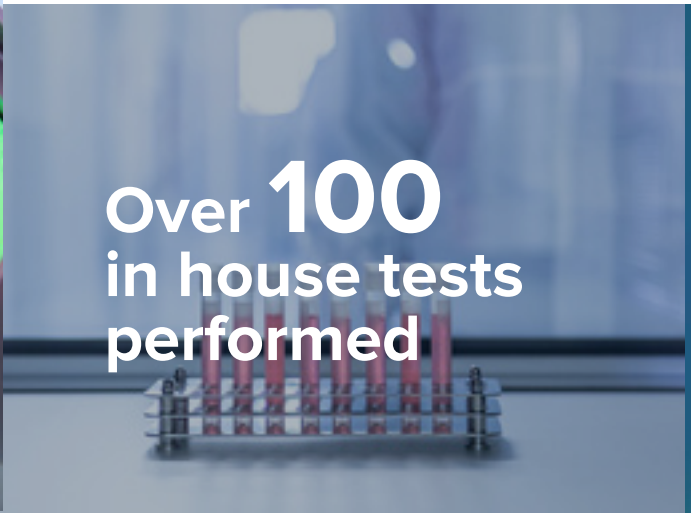
- Transfer and validation of process specific methods
- Safety, Identity, potency, purity testing on IPC and DS/DP
- Over 100 in house tests performed including rapid sterility assay, endotoxin, assays to detect product and process impurities, potency assay by flow cytometry or by qPCR, RCL by cultural and qPCR methods

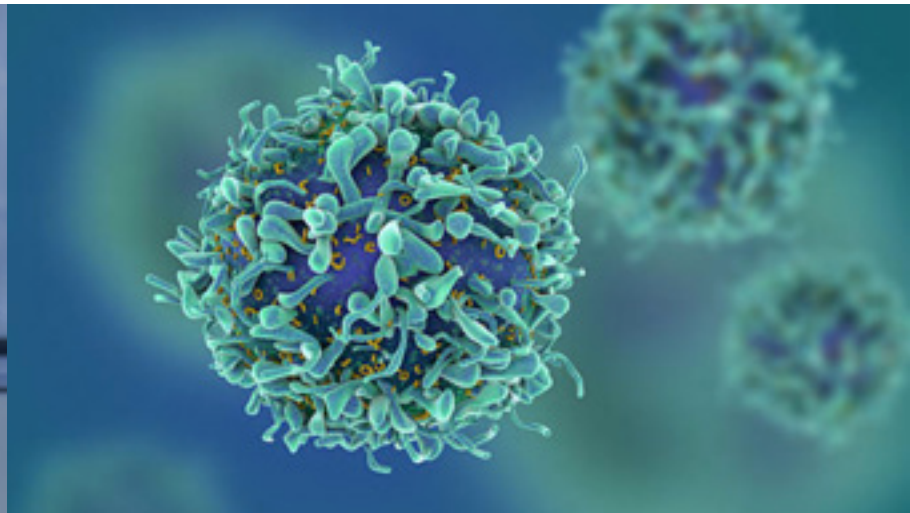
## Quality Assurance

- Quality management system in line with EU ATMP GMP guidelines and Food and Drug Administation (FDA)
- Guidelines
- Facilities are approved by Italian Health Authorities for production of both clinical and commercial manufacturing

## Regulatory

- Assistance for Scientific Advice to national and international bodies
- Documentation for Pre-IND, IND, IMPD and trial specific procedures
- Designation application (e.g. Orphan drug)
- Filing for Marketing Authorization and equivalent



**MolMed is able to satisfy the needs in Cell & Gene therapies of both academia and biopharma industry GMP turnkey solutions from feasibility studies to the market authorization**

MolMed S.p.A. is an Italian biotechnology Cell & Gene company, focused on research, development, manufacturing and clinical validation of innovative therapies in oncology and rare diseases. MolMed built an original dual business model, based on R&D on proprietary products, and third parties GMP services. MolMed is currently the developer and manufacturer for worldwide leader clients in the field of gene therapy for rare diseases and allogenic CAR-T therapies supporting their clinical trials and commercial supply.

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