

Solutions
to bring
your cell & gene
therapy projects
from research
to patient



GMP
SOLUTIONS
for cell and gene therapy

MolMed's service area, GMP Solutions, provides tailor made services for your cell & gene therapy projects.

MolMed GMP Solutions offers top expertise to develop, conduct and validate custom studies, devising innovative testing procedures and addressing the unique test specifications required for novel therapeutics.

Customers' satisfaction for MolMed GMP Solutions is driven by the strictly compliance with the current guidelines issued by all the relevant international regulatory authorities.



DEVELOPMENT

Feasibility Studies.

Development & Scale-up production processes, purification, filtration and filling (viral vectors, antibodies, proteins).

Preparation and characterization of cell lines and clones.

Development of Analytical Methods.

PRE-GMP MATERIALS

High quality materials, sterile and with low endotoxin content.

Cell line stocks.

Retroviral and lentiviral vectors.

Stocks of primary cells.

Genetically modified primary cells.

Monoclonal antibodies.

Recombinant proteins from mammalian cells.

GMP PRODUCTION

Cell Therapy: human cell production, in small and large scale.

Gene Therapy: retroviral and lentiviral vectors production and purification; human cell transduction.

Production and characterization of cell banks.

Filling and storage of final product.

QUALITY CONTROL

Safety testing.

Identity, potency, purity testing.

ELISA assays in biological fluids.

Stability studies.

REGULATORY

Compiling regulatory application for submission in different countries.

Assistance with regulatory legislation and during all stages of product development.

QUALITY ASSURANCE

Processes, analytic methods, instrumentations and computer systems validation.

Internal and external audit activities.

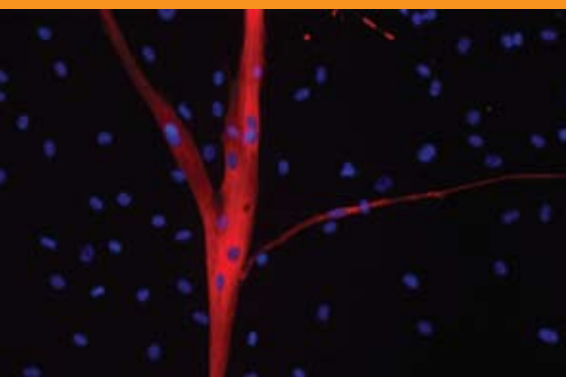
Medicinal Product for clinical use released by the Qualified Person.



MolMed S.p.A.

is a biotechnology company with a key expertise in cell & gene therapies.

The company in-house GMP facility, formally authorized by the Italian Pharmaceutical Agency (AIFA) in 2003, complies the requirements of current legislation for the manufacturing of patient-specific or genetically modified cells and active pharmaceutical ingredients for clinical use.



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