

## MolMed GMP Platform

Tailored solutions for your cell & gene therapy projects

MolMed S.p.A. (Milan, Italy) provides an integrated cGMP platform that offers tailor-made solutions for cell and gene therapy projects.

MolMed's modular organisation and top class track record guarantee a customised project design, that will drive your cell or gene therapy projects from preclinical to Phase III clinical trials with the highest of quality standards.

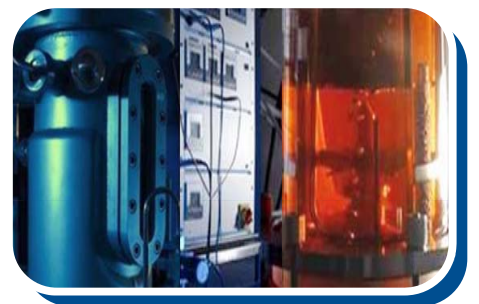
### CELL PRODUCTS



### GENE THERAPY



### VIRAL VECTORS



## PROCESS DEVELOPMENT & SCALE UP

- Development of robust and scalable process strategies
- Selection of adequate raw materials
- Selection, purification or depletion of cell populations
- Cell clone establishment
- Optimisation of culture conditions
- Optimisation of genetic modification
- Optimisation of parameters of expansion and harvest
- Process scale-up

## ANALYTICAL DEVELOPMENT & VALIDATION

- Cell biology (viability, functionality, proliferation, apoptosis, etc.)
- Immunocytochemistry (ELISA, FACS, etc.)
- Microbiology (sterility, mycoplasma, endotoxin)
- Molecular biology (Quantitative PCR, RT-PCR, Northern, Southern, etc.)
- FPLC analysis
- Virology (RCR, RCL, titration, etc.)
- Development of cell-based potency assays

## PRECLINICAL DEVELOPMENT

- Development and validation of *in vitro* assays

## GMP MANUFACTURING

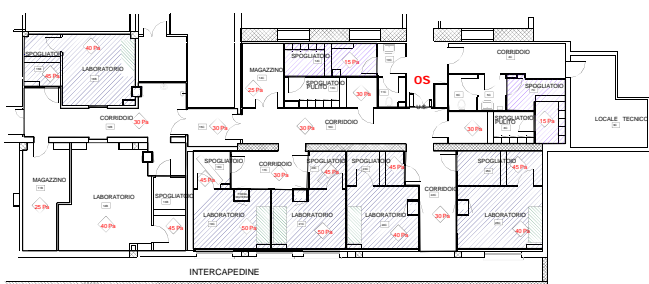
- Production of genetically modified human cells
- Production and expansion of genetically modified cells in different biological support
- Production of genetically modified cells in fully-closed system
- Establishment and characterisation of Master Cell Banks and Working Cell Banks
- Process validation
- Fill and finish

## GMP QUALITY CONTROL

- Safety assays
- Characterisation assays
- ELISA assays for dosage purpose in biological fluids
- Stability studies
- Validation of analytical methods according to ICH standards
- Lot release by Qualified Person

## QUALITY ASSURANCE & REGULATORY AFFAIRS

- Compliance to the European cGMP guidelines
- Authorised for manufacturing of Investigational Medicinal Products (IMPs) in 2003
- Support pre-IND and Scientific Advice meetings with Regulatory Authorities
- Support Orphan Drug Applications
- Support Clinical Trial Applications (IND & IMPD filing)
- Support Regulatory advice during all stages of product development activities



### FACILITY AREA

Process Development	188 sqm
Quality Control	160 sqm
Storage area (nitrogen)	121 sqm
Radioactive room	40 sqm
Clean Room area (class A/B)	135 sqm
Clean Room area (class C)	184 sqm
Clean Room area (Class D)	18 sqm
Total Laboratories	846 sqm
Total Facility Area	1675 sqm

## CONTACTS

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