

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.

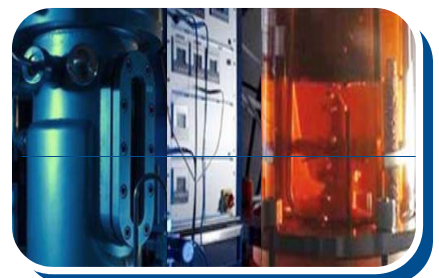
CELL PRODUCTS



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

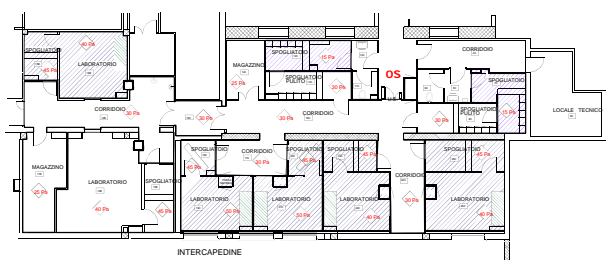
- Production of genetically modified human cells
- Production and expansion of genetically modified cells in different biological support
- Production of genetically modified cells in fully-closed system
- Establishment and characterisation of Master Cell Banks and Working Cell Banks
- Process validation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