# Millipore<sub>®</sub>

Expert Pharm/BioPharm Products & CTDMO Services





### Mammalian Biologics CDMO Services to bring your program to the next stage

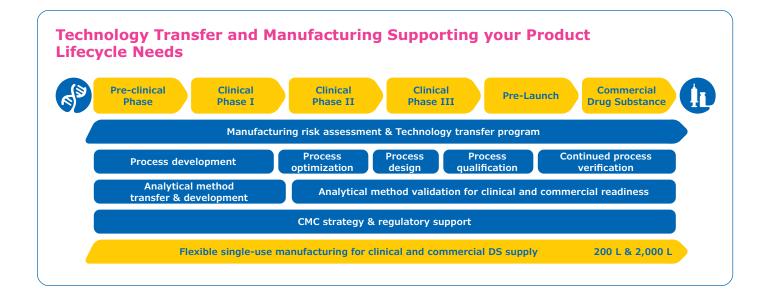
#### **Deep Expertise and Strong Partnerships**

With 35+ years of experience, we provide deep expertise and flexible solutions across clinical phases and commercialization for monoclonal antibodies, bi-specific antibodies, fusion proteins, or antibody fragments. We work with our clients to balance risk, optimize speed, and support all aspects of regulatory compliance on the journey to market.

- 25+ years of experience in GMP manufacturing
- 10+ years of experience in single-use technology
- CMC regulatory expertise across 280+ projects

## Discover our Mammalian Biologics Center of Excellence

Our Martillac site was established in 1987 and has grown to an integrated site that offers process development and pilot production of up to 200L and GMP clinical and commercial production of 200L and 2,000L. Our 2,700m² manufacturing facility is equipped with 100% single-use technology which simplifies and accelerates tech transfer and PPQ readiness for commercialization.



### Mammalian Biologics CDMO Services Aligned with Your Needs

Where ever you join us, our experts ensure flawless tech transfer and robust, scalable processes for your large-scale manufacturing needs.



#### Manufacturing risk assessment

Early gap assessment for process fit, materials, equipment, analytical methods & CMC strategy.



#### **Small-scale process optimization**

Scale-down model and troubleshooting to gain process efficiency prior to commercial.



#### Tech transfer at every stage

Phase appropriate tech transfer from preclinical to 2nd source commercial supply.



#### Strong analytical expertise

Platform and custom analytical methods development, optimization and validation.



#### Flexible process development

Building on your existing cell line and existing process.



#### **Process validation expertise**

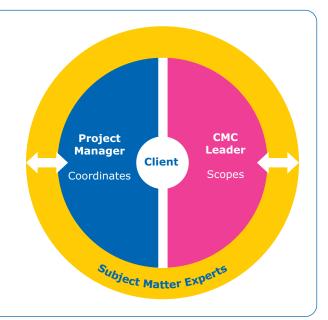
Process design, process qualification and continued process verification.

### A multi-disciplinary project team:

2 key roles assigned to each project to ensure transparent communication and collaboration

The **Project Manager** is in charge of leading, planning, coordinating and tracking the project.

The **CMC Leader** is in charge of leading the global technical scope and strategy for clinical and commercial projects.



Discover more about our Mammalian Biologics CTDMO services and contact us at: SigmaAldrich.com/services/contract-manufacturing/mab-manufacturing

MilliporeSigma 400 Summit Drive Burlington, MA 01803

