

RECOMBINANT PROTEIN CONTRACT MANUFACTURING

Meridian Life Science, Inc. (MLS) is an industry leader in the commercial production of critical raw materials for the diagnostic market. MLS has a proven track record in cell culture, viral propagation, and protein purification with specific expertise in developing and purifying recombinant proteins at research (mg) to commercial (g) scale.



OVERVIEW OF SERVICES

- Sub-cloning into new expression vector
- Transient expression and evaluation
- Stable cell line development
- Virus generation (insect only)
- Process Development - Upstream and downstream
- Yield optimization
- Pilot studies
- Master and working cell banks
- Dual site storage
- Validation lots
- Commercial scale manufacturing
- Formulation fill and finish



EXPRESSION SYSTEMS

- E. coli*
- Yeast
- Insect
- Mammalian

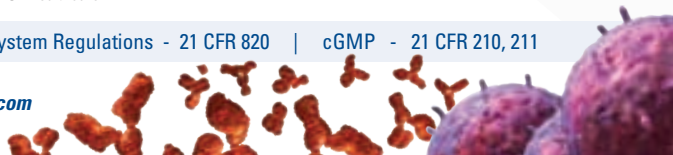


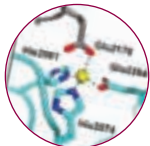
PRODUCTION SYSTEMS

- Tissue culture flasks
- Spinner flasks
- Roller bottles (smooth and ribbed)
- Cell factories
- WAVE Bioreactors™

WAVE Bioreactors™ is a trademark of GE Healthcare.

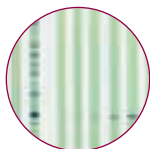
ISO 9001:2008 | Quality System Regulations - 21 CFR 820 | cGMP - 21 CFR 210, 211





PURIFICATION METHODS

SEC, IEC, HIC, HyAP
Affinity columns
Ultrafiltration, Dia-filtration, Tangential Flow Filtration
Centrifugation/ultracentrifugation



ANALYTICAL TESTING

Protein concentration (UV/Vis, BCA)
SDS-PAGE
Silver staining
HPLC
Western blot
Cell density/viability
Sterility
Mycoplasma
ELISA
Custom assay development and testing



WHY PARTNER WITH MLS?

- Unparalleled experience and proven track record (25+ yrs)
- Core expertise in cell culture, ascites, protein production and purification
- Flexibility in scale and production systems
- Complete R&D and Process Development service
- Dedicated project management
- All manufacturing conducted under ISO 9001:2008 and cGMP
- Complete confidentiality