

CONTRACT MANUFACTURING OF ANTIGENS AND ANTIBODIES

Meridian Life Science, Inc. is an industry leader in the commercial production of critical raw materials for the diagnostic market. With a proven track record in cell culture, ascites, viral propagation, and protein purification, we invite you to leverage our experience to design and develop manufacturing processes that are the right fit for you.



PILOT TO COMMERCIAL MANUFACTURING

In Vitro and *In Vivo* production to gram scale

Clone development services

Upstream and downstream process development

Scale-up, optimization and pilot studies

Fast turnaround time

Lot-to-lot consistency

Competitive bulk pricing

25+ years manufacturing regulated diagnostic raw materials



ANTIGEN SERVICES

Sub-cloning into new expression vector
Transient expression and evaluation
Stable cell line development
Virus generation
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

ANTIBODY SERVICES

Immunization and hybridoma fusion
Cell line rescue and subcloning
Master and working cell banks
Dual site storage
Conversion from ascites to cell culture
Fixed-fee pilot studies
Scale-up optimization
Yield optimization
Purification by Protein A/G, SEC, IEC, HIC,
and other chromatography techniques
Validation lots
Commercial scale manufacturing
Formulation fill and finish

OVERVIEW OF CAPABILITIES



PRODUCTION SYSTEMS

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



PURIFICATION METHODS

Protein A/G
SEC, IEC, HIC, HyAP
Affinity columns
Ultrafiltration
Dia-filtration
TFF (plate or hollow fiber)
Centrifugation/ultracentrifugation



IN VIVO / ASCITES CAPABILITIES

Dedicated facility with 55,000 mice capacity
Up to 5,000 mice per lot
Multiple strains available



QUALITY CONTROL AND ANALYTICAL TESTING

ISO 9001 accredited design and production quality assurance system
Follow Quality Systems Regulation: 21 CFR 820

In-house testing:

Protein concentration (UV/Vis, BCA)
SDS-PAGE
Silver staining
HPLC
Western blot

Cell density/viability
Sterility
ELISA
Custom assay development and testing

Customer audits welcome

WAVE Bioreactors™ is a trademark of GE Healthcare.

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