Contract Manufacturing

WE MAKE OUTSOURCING EASY

ISO CERTIFIED 13485:2016

Native antigens | Recombinant proteins | Monoclonal antibodies | Cell and viral banking | Virus production

meridian BIOSCIENCE ™
LIFE DISCOVERED. LIFE DIAGNOSED.

www.MeridianLifeScience.com
With over 40 years of experience in recombinant protein, antigen and antibody manufacturing, Meridian has earned the reputation as one of the most reliable and qualified contract manufacturers in the diagnostic industry.

**Services**

- Recombinant protein production at any scale from your plasmid or construct
- Monoclonal antibody production from your clone or hybridoma in cell culture or ascites
- Tech transfer of your fermentation process into our facility to increase your capacity
- Improvements to your protein purification process to increase yields
- Production of cell and viral bank with on-site storage options
- All manufacturing under a strict quality system to meet FDA regulatory requirements
Meridian offers a full suite of process development and manufacturing capabilities for upstream and downstream processes. Projects can start as a pilot or feasibility study and progress to commercial scale production with the option of scale-up and validation runs. Meridian employs highly trained and experienced scientists with advanced degrees in biochemistry, immunology and microbiology, with expertise in cell culture, virology, protein expression, protein purification and characterization.

### Upstream

**PRODUCTION SYSTEMS**
- Tissue Culture & Spinner Flasks
- Roller Bottles (smooth & ribbed)
- Cell Factories
- WAVE Bioreactors™
- Egg-based Virus Production
- 55,000 mice capacity

**EXPRESSION SYSTEMS**
- Mammalian (CHO, Vero, NS0, etc.)
- Bacterial (*E. coli*)
- Yeast (*P. pastoris, S. cerevisiae, H. polymorpha*)
- Baculovirus in Sf9
- Egg-based Virus Production
- Vaccinia & Adeno

### Downstream

- Protein A/G
- Ultrafiltration
- Diafiltration
- TFF (plate or hollow fiber)
- Centrifugation/ultracentrifugation
- ÄKTA FPLC for SEC, Affinity, Ion exchange, HIC
- Dialysis, tangential flow
- Chromatography, Monolith, membrane and resin based columns
- Microfluidization, freeze/thaw, chemical lysis
Recombinant Proteins

EXPRESSION SYSTEMS

- Mammalian
- Bacterial
- Yeast
- Baculovirus
- Eggs

PROTEIN PURIFICATION

- Equipment room with 20+ ultracentrifuges which process over 2000L per year
- ÅKTA systems with capacities of 10mL-8L per minute used to purify 400+ proteins

Experience

- *E. coli*, *P. pastoris*, *S. cerevisiae*, Baculovirus in Sf9, Eggs
- 200+ customized rec-Antigens in commercial in vitro diagnostic assays
- 25% of projects using *E. coli* and yeast; 75% are mammalian
- 200+ large scale fermentation runs using *E. coli*
- 100+ large scale Egg-based virus production (Flu A & B)
- 45+ projects using eggs and mammalian cell lines to produce challenge stocks (Rhinovirus, RSV, Influenza)
Meridian offers *in vitro* cell culture and *in vivo* ascites production of monoclonal antibodies following ISO Quality Systems. Meridian’s flexible production systems accommodate milligram to kilogram projects.

**In vivo**
- Dedicated facility - 55,000 mice capacity
- Up to 5,000 mice per lot
- Multiple strains available
- Ascites fluid or purified MAb service
- High lot-to-lot consistency
- Customized options (viability monitoring, mouse strain, yield optimization)

**In vitro**

**PRODUCTION SYSTEMS**
- Tissue Culture & Spinner Flasks
- Roller Bottles (smooth & ribbed)
- WAVE Bioreactors™

**CAPACITY**
- Up to gram quantities of pure MAb
- Conversion from ascites to cell culture
- Adaption to serum free media
- Pilot studies through to validation lots
- Yield and scale-up optimization
- Cell-line rescue and sub-cloning

**PURIFICATION**
- Protein A/G
- SEC
- Protein A/G
- IEC
- SEC
- HIC

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Quality Systems

ISO Certified 13485:2016
USDA - 9 CFR
EC 1069 - exportation of animal byproducts
Quality System Regulations - 21 CFR 820 for Medical Devices

Testing
- Assay development and test validation
- Purity by Western Blot or Silver Stain PAGE
- Total Protein (BCA)
- Isoenzyme Analysis
- HPLC Profiling
- ELISA (direct or capture)
- Sterility (USP)
- pH, appearance, conductivity

Contract Manufacturing
Global Manufacturing

**NORTH AMERICA**

**MEMPHIS, TN**
- Viral Antigens
- Recombinant Proteins
- *In Vitro* Antibodies
- PCR Reagents

**BILLERICA, MA**
- Magellan, Leadcare

**BOCA RATON, FL**
- *In Vivo* Antibodies

**QUEBEC, CANADA**
- GenePOC, Molecular Diagnostics

**EUROPE**

**LONDON, UK**
- PCR Manufacturing & Sales
- PCR /qPCR Molecular Reagents

**LUCKENWALDE, GERMANY**
- Large Scale Nucleotides
- PCR Enzymes
- Manufacturing

**PARIS, FRANCE**
- EU Diagnostics Sales & Admin

**WATERLOO, BELGIUM**
- EU Diagnostics Sales & Admin

**MILAN, ITALY**
- EU Diagnostics Sales & Admin

**ASIA PACIFIC**

**SYDNEY, AUSTRALIA**
- Warehouse & Sales

**BEIJING, CHINA**
- Wholly Owned Subsidiary

****MERIDIAN BIOSCIENCE, Inc.****

Parent Company | Founded in 1977 | Nasdaq: VIVO
Headquartered in Cincinnati, OH | 750+ Employees
Presence in 70+ Countries.