



Meridian
Life Science,® Inc.

INNOVATIVE SOLUTIONS. TRUSTED PARTNER.®

CAPABILITIES STATEMENT

**Contract R&D and
Biopharmaceutical
Manufacturing**

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1. Meridian Life Science Capabilities and Facilities

1.1. MLS Business Description and History

Meridian Life Science,® Inc. (MLS) is a premier provider of contract R&D, process development, and clinical cGMP biomanufacturing for vaccines, viral challenge materials, virus-like particles, vectored gene therapies, and recombinant proteins. MLS is also involved in the manufacture and distribution of bulk antigens, antibodies, proteins, and critical immunoassay reagents used by researchers, diagnostic, and biopharmaceutical companies.

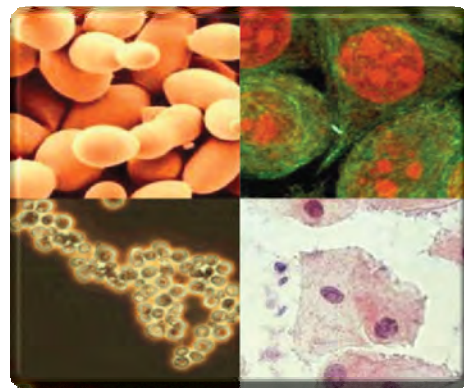
Notable Facts About MLS: We were awarded a \$12.2M, five year contract to manufacture up to ten experimental vaccines per year for the NIAID and have completed manufacture of a Phase I Dengue vaccine and a Phase I RSV vaccine under this contract with 4 to 6 additional vaccines in the queue for 2009. We have been selected to manufacture a live Rotavirus Vaccine for the Murdoch Children's Research Institute and PATH. We have manufactured a clinical RSV challenge virus that has successfully been used in human clinical studies; and we have manufactured a recombinant VLP vaccine to prevent parvovirus B19 infections in humans.



1.2. MLS Case Studies and Experience

Current Projects:

- Live Oral Rotavirus Vaccine for Phase I Clinical Trials (PATH). [Exceeded titer spec by ~80%], contracted to make second lot.
- Manufactured cGMP Phase I Divalent VLP vaccine in BEVS.
- R&D contract to manufacture a lentiviral vector for preclinical tox. studies.
- Completed Phase I Dengue Vaccine for NIAID.
- Completed Phase I RSV Vaccine for NIAID.
- Completed Phase I r-RSV.
- Completed r-PIV3/RSV Vaccine NIAID.
- Completed 2nd r-Dengue Phase I Vaccine, NIAID.
- Contract for H1N1 influenza grown in eggs.
- Contract for RSV NS1 and RSV A1 Phase I Vaccines, NIAID.
- R&D contract to optimize cell culture and downstream processing of a Hepatitis A vaccine.



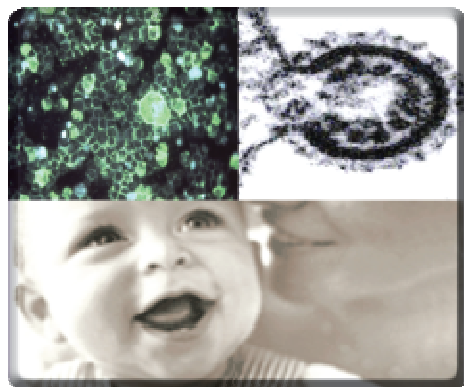
NIAID Experimental Vaccines Contract: MLS was awarded a contract by the National Institute of Allergy and Infectious Diseases (NIAID) Laboratory for production of 8 phase I clinical cGMP grade experimental vaccines. The contract requires production and safety testing of experimental non-Influenza, Influenza virus vaccines, and other vaccine-related products for use in humans. Specific activities include: 1) Manufacture of viruses shown to be promising candidates for use in vaccination of humans; 2) Preparation of wild type viruses needed for challenge studies to evaluate effectiveness of immunoprophylaxis or in pathogenesis studies; and 3) Manufacture and qualification of Master Cell Lines for production of these viruses or other uses as directed by NIAID.



Parvovirus B19 Vaccine: MLS has manufactured, and subsequently licensed, a recombinant Parvovirus B19 vaccine under a contract from the National Heart Lung and Blood Institute of the National Institutes of Health. The vaccine was manufactured according to cGMP in Meridian's fully qualified Spodoptera Frugiperda (Sf9) insect cell line and is now in Phase I/II safety/efficacy trials. The vaccine consists of two viral proteins (VP1 and VP2) in separate baculovirus vectors that are co-infected at the correct multiplicity of infections (MOI's) into Sf9 cells and that, upon expression; self assemble into immunogenic virus-like particles. MLS has a validated cGMP vialing line for this product of up to 2,500 vials.



RSV Clinical Challenge Stock: MLS has manufactured a cGMP Respiratory Syncytial Virus Clinical Challenge Stock (RSV-CS) from an original pediatric clinical isolate. The RSV-CS consists of an RSV high titer accession stock produced in characterized Vero cells infected with an RSV virus strain isolated from an original pediatric clinical sample. The RSV-CS enables precisely controlled clinical vaccine efficacy studies to demonstrate actual protection (vs. implied protection via neutralizing Ab response). For Anti-viral therapeutics, the RSV-CS also allows for precisely controlled clinical studies to show therapeutic efficacy in eliminating or mitigating the effects of the disease in patients who have developed a controlled RSV infection as compared to control.



2. Meridian Life Science Full Capabilities Statement

MERIDIAN LIFE SCIENCE, INC. CONTRACT R&D AND MANUFACTURING CAPABILITIES	
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Technical Contact	Vic Van Cleave, Ph.D., Vice President, Research and Development
Year Established	1982 Viral Antigens; 2006 Meridian Biologics
Private/Public	Public (NASDAQ – VIVO)
# of Employees	75
# of Mfg Employees	Operations – 34, QA/QC - 11
cGMP Facility	Memphis, TN: ~4,000 sq. ft. Dual Campaign Facility: <ul style="list-style-type: none"> • Two Eukaryotic Suites; • Class 10,000 Support Areas; • Class 10,000 Purification Area; • Class 100 Downdraft Hood; • Dedicated ÄKTAPilot, Centrifuges, Microfluidizer; • Dedicated HVAC Systems and WFI System; and • Dedicated Storage at -70°C, -20°C, 4°C and Room Temperature.
Manufacturing Sq. Ft.	Non-cGMP = 30,000; cGMP = 3,500.
# of Clean Rooms	<ul style="list-style-type: none"> • Two Eukaryotic Suites.
Key Products	Over 75 products for human and veterinary biotechnology industry including purified viral antigens, monoclonal Antibodies, recombinant therapeutic proteins, viral vectored gene therapies and contract manufacturing services.
# of Products Manufactured Since Company Began	<p>9 cGMP products:</p> <ul style="list-style-type: none"> • Parvovirus B19 VLP vaccine made in BEVs; in Phase I clinicals. • Manufacture of Qualified Clinical Vero MCB. • Phase I Dengue Virus Vaccine for NIAID. • Phase I recombinant RSV vaccine for NIAID. • Phase I recombinant PIV3/RSV vaccine for NIAID • RSV Viral Challenge stock for Alnylam Therapeutics, Inc. • RSV Viral Challenge stock as commercially available stock. Currently in use with several biopharma companies. • Phase I Oral Rotavirus Vaccine for Murdoch/PATH <p>R&D projects of various types (representative projects below):</p> <ul style="list-style-type: none"> • cGMP manufacture of a Phase I divalent VLP vaccine made in BEVS. • Chromatographic purification for 8 recombinant live influenza vaccine(s). • Cell culture and downstream processing of a Hepatitis A vaccine. • Hybridoma conversion to cell culture and Ab production (> 40). • BEVs protein production (7). • Viral stocks for vaccine development (3). • Antibody purification from human serum. • Lentiviral Gene Therapy process optimization. • Recombinant protein production from <i>E. coli</i> (2 projects).

Special Material Handling	Experts in live virus handling, BSL2. Staff inoculated against many viruses including vaccinia.
Capabilities by Phase	Pilot, Preclinical, Phase I, and Phase II cGMP manufacturing. Phase III quantities possible for small market or orphan biotherapeutics.
Regulatory Status (Inspections: FDA/EMA)	USDA Inspected and Certified, QSR, ISO 9001, FDA-CDRH Audited, Customer Audited.
Key Customers Served	Clinical Diagnostics Companies, NIH (current projects for NHLBI and NIAID), Department of Defense, Biotechnology Companies, small to mid-size Pharmaceutical Companies, and Research Institutions.
Key Collaborators	NIH (Projects for the NHLBI and NIAID) and Department of Defense.
Regulatory Compliance History	No 483's issued. Over 50 Customer Audits (~10 Customer audits for cGMP services).
Unique Selling Points	<ul style="list-style-type: none"> • Expertise in Baculovirus/Insect Cell Expression system. • Experts in virology, live virus production. • Experts in production of Viral Vected Gene-Therapies • Experts in <i>in vitro</i> MAb production in cell culture. • Trusted partners for difficult expression and biomanufacturing.

SERVICES OFFERED

Manufacturing Services	cGMP	Size / Number of Bioreactors Total Capacity (L)	Types of Products Produced
Mammalian Cell Culture	Y	Total Capacity in L = 100 Wave Bioreactor® and 10 X 10 Stack Cell Factory*	Viral vaccines, viral challenge stocks, viral vectored gene therapy, and recombinant proteins.
Insect Cell Culture	Y	Total Capacity in L = 100 Wave Bioreactor and 10 X 10 Stack Cell Factory	Recombinant proteins including antigens and virus like particles for a vaccine.
Egg-Based Vaccine Production	Y	Small Scale Production to support Phase I/II Studies	Viral vaccines.

Support Services	Description
Process Development:	<p># Cell Lines Developed = > 30 non-clinical. Three cGMP cell lines developed. # Process Development Employees = 15.</p> <p>Process Development Services: We can start with your traceable cell line or even your DNA sequence and generate Master and Working Stocks for production of recombinant proteins in our dedicated Eukaryotic or Prokaryotic suites.</p> <ul style="list-style-type: none"> • Eukaryotic culture in roller bottles. • Eukaryotic culture in 1 to 4 Wave Bioreactors (25 liters each). Batch, Fed Batch, and Perfusion Culture Experience. • Conversion of hybridomas for production in cell culture. • Media optimization. • Centrifuges for cell pelleting. • Plaque assay, TCID50, and end point dilution for determination of viral titer. • New assays can be developed to fulfill any requirement.
Cell Line Development/ Expression Systems:	<ul style="list-style-type: none"> • Seamless tech transfer from development to clinical production. • Experience with cell culture optimization. • Experience with BEVS. • Selection of optimal clones and expression systems.

Viral Banks:	MLS has 24 years of live virus production: MLS has produced master viral banks for baculovirus, β Gal Vaccinia, Cytomegalovirus (CMV), Epstein-Barr (EBV), Hepatitis A - (HAV), Herpes Simplex (HSV) Type I and II, Measles (Rubeola), Mumps, Respiratory Syncytial (RSV), Rotavirus, Rubella (German Measles), and Varicella-Zoster Virus (VZV), and others.
Cell Banking:	<p>General Experience: MLS has a great deal of experience producing master and working cell banks. All of the cells used in the production of MLS' OEM antigens have had master and working cell banks created. Cell banks manufactured by MLS include:</p> <ul style="list-style-type: none"> • Mammalian: VERO, FrHK, Hela, and various hybridoma cell lines. • Insect: Master and Working Cell Banks of insect Sf9 cells for our work on the PVB19 vaccine for the NIH. <p>Facilities and Equipment for Cell Banking Includes:</p> <ul style="list-style-type: none"> • Multi-use facility can be configured to meet your needs; • Call-out systems; • Separate rooms for uninfected and infected cultures; • Controlled-rate freezer; and • Vapor phase liquid nitrogen storage system.
Cell Culture and Egg Incubation Equipment:	<ul style="list-style-type: none"> • Shaker flask (non-cGMP or cGMP). • Cell-line or culture flask (non-cGMP or cGMP). • Roller bottle (Smooth or ridged, non-cGMP or cGMP, up to 1,500 bottles are processed weekly for diagnostic antigen production). • Spinner flask (Up to 30 Liter Spinner flask, non-cGMP or cGMP). • Wave Bioreactor (Up to 100 Liters non-cGMP or cGMP). • Cell Factories: Up to 40 CF10 stacks. • Egg Incubator for up to ~300 eggs.
Incubators:	A variety of incubators are available including over 25 roller bottle cabinets for high volume/speed production of antigens. Humidity and temperature controlled rooms/incubators also available.
Analytical and Biosafety Testing Capabilities:	<p>Standard tests include:</p> <ul style="list-style-type: none"> • Purity Testing by Western Blot and Silver Stain; • Sterility; • Bacteriastasis and Fungistasis; • Intact Cell Assay; • Benzonase; • Isoenzyme Analysis; • HPLC profiling; • ELISA assay, direct or capture; • Bioburden; • Endotoxin testing; and • Qualified cGMP laboratories for identity testing (N-Terminal Analysis, AAA, etc.), adventitious agent testing, and General Safety Test.
Purification and Harvest:	<p>Purification capabilities include:</p> <ul style="list-style-type: none"> • Ion exchange, affinity, size exclusion, and, hydrophobic chromatography; • Expanded bed "attachment-based" chromatography for purification from microfluidized/unfiltered cell lysates/perfused media; • centrifugation and gradient centrifugation; • TFF and standard filtration; • chromatography and filtration under clean room conditions; • cGMP ÄKTApilot™ purification system with flow rates to 800ml/min*; • Microfluidization for processing of cells prior to purification.

* ÄKTApilot™ is a trademark of GE Healthcare Bioscience BioProcess Corporation.

Formulation:	MLS has experience in optimizing formulations for baculovirus produced vaccines, live and attenuated viral vaccines, gene therapy products and other biotherapeutics.
Fill and Finish:	MLS offers fully validated clinical fill and finish up to 2,500 vials. MLS offers non-clinical fill and finish up to 1ml fills at a scale of 5,000 vials.
Storage and Distribution:	<p>Storage: MLS maintains banks of 4°C, -20°C, and -70°C (vapor and liquid phase) ultracold freezers. All freezers are on call out systems. All freezers are backed up with 48 hours of emergency generator power. Additionally, some freezers are equipped with liquid nitrogen backup tanks to prevent damage by thawing.</p> <p>Distribution: Memphis is the world-wide headquarters for Federal Express, thus, final product can be delivered anywhere in the world via overnight express service. Additionally, MLS has the capability to store final product to be shipped according to the client's wishes.</p>
Materials Management:	<ul style="list-style-type: none"> • Manufacturing is managed and inventory is monitored using INFOR software, a state of the art ERP system. • All incoming raw materials and components are quarantined pending QC/QA inspection and release, as described in receiving documentation for each item. • Shipping personnel are IATA trained to ship dangerous goods by air. • Frozen and refrigerated customer shipments are packed in qualified polyurethane insulated containers with dry ice or refrigerant. Calibrated temperature monitors are included as required. • Temperature monitored Nitrogen Dry Shippers are used for transporting cell banks and seed stocks that require shipping at temperatures below -150°C.
Stability Testing:	Up to 36 month stability testing programs with a variety of analytical testing methods can be accommodated.
Regulatory Assistance and Experience:	<ul style="list-style-type: none"> • MLS' regulatory group maintains regulatory compliance under guidelines specified by the USDA, QSR, ISO 9001, FDA-CDRH, FDA-CBER and our customers. • MLS has experience maintaining and holding INDs along with drafting and maintaining CMC documentation. • Quality is our primary focus, with all management, administrative and production personnel involved in the process. This is re-enforced through procedures, training and supervision. MLS' quality policies and procedures are intended to assure that our products meet or exceed customer expectations. Quality improvement is continuous and subjects all policies and procedures to periodic review. • MLS has a strong commitment to quality and regulatory compliance. We are also flexible and know that clients may have additional requirements to be integrated into MLS' existing documentation.

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