

MLS a premier partner for contract R&D, process development, and clinical cGMP biomanufacturing for vaccines, viral challenge materials, virus-like particles, vectored gene therapies, and recombinant proteins. Services include: cell and viral banking, process development, scale-up, downstream processing, formulations/stability and fill and finish to support cGMP biologics production.

cGMP Biopharmaceutical Manufacturing:

Focus Areas:

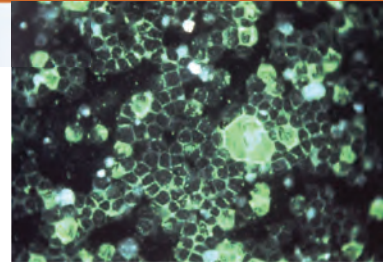
- Viral Vaccines:
 - Recombinant, live, and attenuated
 - Virus like particles
 - Oncolytic and therapeutic vaccines
- Viral challenge materials
- Gene therapies (viral vectored)
 - Adenovirus, AAV, HSV, vaccinia, lentivirus, etc.
- Recombinant proteins in BEVS

Expression System:

- Mammalian cell culture
- Insect cell/baculovirus system
- Egg-based virus production
- Plasmid transfection

cGMP Production:

- Master and working cell and viral banks
- Multiple cGMP clean rooms for Phase I/III clinical products
- Uninfected and infected eukaryotic cell culture suites
- Clinical fill and finish capacity



Process Development and Optimization:

• Upstream Process Development:

- Cell line development
- Production of cell and virus stocks
- Cell culture optimization (Media, MOI, Viability, Harvest)
- Flasks, spinner flasks, roller bottles, cell factories, and disposable bioreactor bags
- Analytical test method development and validation
- Viral quantitation and infectivity (Plaque, TCID50, FFA)

• Downstream Purification Development:

- Protein purification development
- Chromatography methods to maximize yield and minimize contaminants: SEC, IEC, HIC, affinity and expanded bed
- Filtration: Micro/ultra filtration, depth, CFF, and TFF
- Centrifugation and gradient centrifugation
- Formulations experience for VLP and viral vaccines
- Process validation



Photo courtesy of GE Healthcare



MLS has multiple cGMP production suites designed to meet FDA requirements for cGMP biopharmaceutical manufacturing. MLS has proven experience manufacturing viral based clinical products. With over 25 years of cell culture, virus production, protein purification, assay development, and regulatory compliance; MLS is your trusted partner for contract R&D, process development and Phase I/II cGMP biomanufacturing.

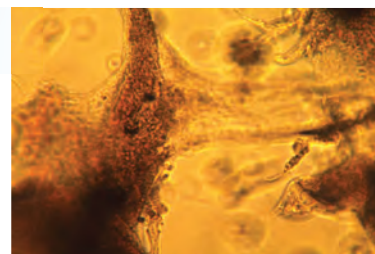
cGMP Clinical Production Facilities:

- Multiple clean-rooms for Phase I/II biopharmaceuticals
- Flasks, spinner flasks, roller bottles, cell factories, and disposable bioreactor bags
- SPF egg Incubators
- Class 10,000 support areas and class 10,000 purification area
- Class 100 downdraft hood
- Dedicated ÄKTApilot™, centrifuges, microfluidizer
- Dedicated HVAC systems
- Dedicated storage at -70°C, -20°C, 4°C and room temperature
- Validated facility
- Cleaning validation



Quality Assurance and Testing Services:

- Regulator compliance under USDA, QSR, ISO 9001, FDA-CDRH, and FDA-CBER
- Mature quality system with dedicated QA/QC and Regulatory Team
- In-house assays: purity testing by western blot and silver stain, sterility, bacteriastasis and fungistasis, intact cell assay, benzoylase, isoenzyme Analysis, HPLC profiling, ELISA (direct or capture), bioburden, endotoxin
- Assay development and validation
- Customized and standardized test procedures
- Viral quantitation and infectivity assays
- Complete document packages with continued Regulatory Support
- CMC regulatory support for your IND
- Materials management system, quarantine, storage, and shipping
- Validated document control system



Why Partner with MLS?

- Proven track record of clinical production
- Over 25 years experience in cell culture, virus production, protein purification, assay development, and regulatory compliance
- Dedicated team of Ph.D. Virologists, Cell Biologists, and Protein Chemists
- Trusted sole source supplier of critical raw materials
- Mature quality system
- Customization of processes to accommodate your needs
- Integration of special requirements and/or instrumentation
- Flexible scheduling
- All requests for services and products are considered confidential



ÄKTApilot is a Trademark of GE Healthcare Bioscience BioProcess Corp.