

Florida Biologix

cGMP Compliant Vector and Vaccine Production

The Florida Biologix team has extensive experience with viral vectors and vaccines and they participate on several national and international advisory committees in this field.



cGMP Master (MVB) and Working (WVB) Viral Banks

Florida Biologix can produce your MVB and/or WVB prior to vector clinical lot manufacturing in spatially segregated, campaign-dedicated ISO 7 cleanroom modules. After vialing, the banks are tested, characterized and stored in continuously monitored validated ultra-low temperature freezers. Offsite storage for added protection of these valuable materials is also available.

Upstream Cell Culture Processing

We can produce cGMP compliant cell culture supernatants or lysates containing viral vectors (in roller bottles, cell factories and/or Wave bioreactors) for downstream purification. We have the technology for producing vectors by transient transfection for recombinant adeno-associated viral vectors or lentiviral vectors, infection of cell substrates with adenoviral or herpesviral vectors, and producer cell line culturing of retroviral vectors.

Downstream Purification and Processing

We have the capability and experience to purify vectors using column chromatography, filtration and centrifugal methods. We use state-of-the-art equipment to purify and further process the target vector.

Cell lysis and clarification

Chromatographic purification

Diafiltration and other membrane filtration technologies

Ultracentrifugation

Formulation, fill, and finish

Clone Isolation and expansion

We can clone and expand viral seeds used in vector and vaccine manufacturing.

Plaque purification

Clone screening and lead clone identification

Lead clone expansion and viral seed banking

In-House QC Analytical Methods Development

Our QC group develops, qualifies, and performs in-process, release, and stability testing.

Infectious and vector genome titer determination

Transgene expression assays

Purity and identity testing

Facility for Vector and Vaccine Production

Our experienced and fully trained staff, using state-of-the-art disposable technologies, generate the highest quality bulk drug substance and finished product.

FACILITY

The Florida Biologix 16,000 sq. ft. manufacturing facility was designed and built to accommodate simultaneous production of multiple products. The facility has been

commissioned and fully calibrated with all systems and equipment validated. Preventive maintenance, calibration and revalidation programs are in place, as are validated cleaning and changeover procedures. Backup generators ensure all equipment is protected from power outages.

cGMP COMPLIANT VECTOR AND VACCINE PRODUCTION MODULES

The ISO 7 modules are capable of handling BSL-1 or BSL-2 gene transfer agents. The modules have dedicated gown-in and de-gown rooms allowing for unidirectional flow of material and personnel, and single pass air supply with HEPA filtration at 60 air changes per hour. Our facility design, rigorous cleaning procedures and procedurally controlled flow patterns ensure that there is no cross contamination of any material from one module to another.

VIRAL BANKING

Florida Biologix can also produce your MVB and/or WVB used in vector and vaccine manufacturing prior to vector manufacturing. These banks are manufactured in spatially segregated, campaign-dedicated ISO 7 cleanroom modules.

Non-GMP production services are available for your research and non-clinical toxicology studies

cGMP Master (MCB) and Working (WCB) Cell Banks

Florida Biologix can manufacture your MCB and/or WCB used in vector and vaccine manufacturing prior to cGMP clinical lot manufacturing in a dedicated cell banking module that houses two spatially segregated,

campaign-dedicated ISO 7 small-scale cell culture bays. Once developed, tested, grown and frozen in controlled rate freezers, the banks are stored in validated, continuously monitored liquid nitrogen freezers.

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