

## cGMP Bulk Substance Production & Purification

### cGMP BULK SUBSTANCE MODULES:

Our experienced staff and state-of-the-art equipment generate the highest quality bulk material.

There are three ISO 7 cell production modules, each with dedicated gown-in gown-out rooms.

Suites have unidirectional flow of material and personnel, single pass, 100% exhausted air supply with independent HEPA filtration.



**Process Development:** Prior to GMP manufacturing, Florida Biologix can conduct scientifically rigorous upstream and/or downstream process development to ensure that your process is cost-efficient, high-yielding and scalable.

**cGMP Upstream Cell Culture:** We can produce cell culture supernatants or lysates (from 10L-400L) containing the target biologic for downstream purification. The available production methods include a state-of-the-art 2 x 200L disposable stirred tank bioreactor, flat stock (cell factories or roller bottles) or small-scale Wave bioreactors. End of production cell banking and testing is also available.

**cGMP Downstream Processing and Purification:** We use state-of-the-art equipment to further process and purify the target biologic. We offer:

- Depth or other filtration methods, TFF concentration and buffer exchange
- Purification of the target biologic using chromatography (affinity, size exclusion, anion/cation exchange, mixed mode, HIC), centrifugal methods or other new technologies such as membrane absorbers, monoliths etc.
- Viral inactivation by various methods (filtration, low pH, surfactants etc.)

**IN-HOUSE QUALITY CONTROL AND QUALITY ASSURANCE:** QC conducts the facility environmental monitoring program and a full battery of analytical methods. QA provides audited Production Batch Records, product release, certificates of analysis and compliance oversight, and other appropriate regulatory documentation. Expert CMC support is also available.

**cGMP Master (MCB) and Working (WCB) Cell Banks:** Florida Biologix can produce your MCB and/or WCB prior to cGMP manufacturing. These banks are manufactured in one of two dedicated, spatially segregated, ISO 7 small scale cell culture bays. Once manufactured and frozen in controlled rate freezers, the banks are stored in validated, continuously monitored liquid nitrogen freezers until released and shipped to the client. All cell banks are manufactured and tested in compliance with cGMP regulations.

**FACILITY:** The Florida Biologix 16,000 sq. ft. state-of-the-art manufacturing facility in Alachua, FL was designed and built to accommodate the simultaneous production of multiple cGMP products. The facility has been commissioned and fully calibrated with all systems and equipment qualified.