
Non-Clinical Production and Process Development

The Florida Biologix 5,000 square foot fully equipped laboratories are located in a separate building adjacent to its cGMP manufacturing facility. The lab facility was designed and built to accommodate multiple simultaneous process development (PD) projects. Only trained Florida Biologix staff have laboratory access to ensure project security.

This facility houses the most technically advanced PD equipment that mirrors the equipment in the cGMP facility, including an AKTA Pilot Chromatography system and a Millipore Tangential Flow Filtration system.



The process development scientists have extensive expertise in the design and development of reproducible, robust and scaleable processes which can be transferred to cGMP manufacturing.

Process Development activities include:

- **Product batch record preparation for transfer to cGMP manufacturing**
- **Mammalian cell culture** - Optimize a cell line's culture conditions and growth parameters for optimal protein production. We can work with all major mammalian cell lines to:
 - Characterize and assess cell line productivity and stability
 - Develop batch, fed-batch and perfusion processes and cell feeding strategies using flasks, roller bottles, cell factories, disposable bioreactor systems
 - Clone and adapt cells to serum-free or protein-free media
 - Evaluate various cell culture and bioreactor systems
- **Purification** - Develop a new purification process or verify and scale-up a transferred process. We also troubleshoot and optimize column/filtration conditions (TFF, diafiltration).
 - Column chromatography - affinity, HIC, IEX, SEC etc.
- **Analytical Development** - Develop assay methods that are transferrable to the Quality Control department for qualification and validation for cGMP production
- **Troubleshooting, Product Formulation and Stability Studies**
 - Conduct formulation studies to develop the best buffers and reagents
 - Develop and execute stability studies to determine storage temperature and time that the product can be held without losing potency

cGMP MANUFACTURING FACILITY: *The Florida Biologix 16,000 sq. ft. state-of-the-art 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.*