

## Sterile Fill and Finish

**FILLING SUITE:** Our specifically-designed ISO 6 filling suite and our experienced fill team ensure that we produce the highest quality products



- Equipment, including the Gruenberg depyrogenation oven, is validated, calibrated or certified
- Flexicon FP50 automated filler with head gas capacity and automatic stoppering
- ISO 5 Terra Universal VLAFF workstations
- 120 air changes an hour
- Unidirectional material and personnel flow
- Epoxy walls and floor
- Single pass air supply with an independent HEPA filtration system
- Windows to allow client observation and facilitate compliance audits

**SERVICES:** We can formulate and aseptically fill (volumes of <0.125 mL to 3L) into a variety of final containers (glass vials, bags, cryovials, bottles, or tubes), then label, package and ship. In addition, we are manufacturing up to 1,000L batches of sterile buffer solutions and can fill various bag sizes (100 mL - 3L). Both stability studies and cGMP storage are available.

**AUTOMATED:** Our Flexicon FP50 is used to fill and stopper in an ISO5 vertical laminar flow Terra workstation. We have filled many drug products and can fill: **monoclonal antibodies, recombinant proteins, peptides, natural products, antigen vaccines, small molecules, oligonucleotides, plasmid DNA and buffers.** Our capacity is up to 5,000 vials per day. Head gas overlay is available.

**SEMI-AUTOMATED:** We can perform semi-automated or manual fills of the products above into a variety of final containers filling (up to 2,000 per day) of various other containers, such as bags, cryovials, bottles, tubes or syringes.

**IN-HOUSE QUALITY CONTROL AND QUALITY ASSURANCE:** QC provides facility environmental monitoring and a full battery of analytical methods. QA provides audited Production Batch Records, product release and other regulatory documentation.

**If you aren't sure of the best way to fill your product, we can also recommend strategies and systems that will result in a successful fill. Please talk to us about your parenteral filling and other cGMP or non-GMP manufacturing needs.**

**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.