

## CUSTOM GMP MANUFACTURING

### Exclusively Manufactured in the USA

BioSpectra offers a range of Custom GMP Contract Products & Services manufactured exclusively in our state-of-the-art, FDA registered and inspected GMP facility in Bangor PA, USA.



BioSpectra operates under a stringent Quality Program rigorously adhering to US GMP, IPEC and ICH Q7 guidelines for the manufacture of all custom products

### Custom GMP Categories

- Unique GMP Compounded Solvents & Solutions
- API Development & Manufacturing
- Small Molecule Custom Synthesis
- Full GMP Product Development
- Purification of Key Ingredients
- Drug Master File Submissions
- Pilot Scale Up
- Lab Services



## Custom GMP Manufacturing

- **SYNTHESIS:** APIs & other Key Ingredients / Organic and Inorganic molecules and salts / Corrosive molecules / Chlorides Chlorinations / Ionic Substitution / Small volume support with Scale 1-1000 kg lots / Solvent, Alcohol & Aqueous based
- **LIQUID CHEMISTRY: UNIQUE GMP COMPOUNDED SOLVENTS & SOLUTIONS:** Acid-Base/ Solvent & Alcohol Based/ pH, Zwitterionic Buffers / Hazardous Blends and Compounds / Various Concentration Ranges / 10 liter to 24,000 liter batch volumes
- **PURIFICATION:** Crystallization / Low Micron Filtration / Ion Removal / Trace Metal Reduction / Low Bioburden Low Endotoxin demands / Alcohol, Aqueous & Solvent base



- **CUSTOM TESTING, LABELING & PACKAGING:** Per Customer Request
- **SCALE-UP:** Bench to Bulk – We offer turnkey services for product and process development with the ability to scale-up from lab to pilot batches to bulk production all in one facility under one Quality & Regulatory system
- **PARTICLE CHARACTERISTICS:** Various milling and particle manipulation techniques to achieve consistent and defined crystal size according to customer requirements – Jet Milling / Blending / Rotary, Fluid Bed, Spray and Tray drying
- **GMP COMPLIANCE SUPPORT:** Up to and including DMF Type II and Type IV submissions

With manufacturing suites dedicated to synthesis, purification and full GMP product development our goal is to become a valued partner in your secure supply chain and the solution to any key ingredient issues you may have.