

**CRITICAL INGREDIENT ISSUES?**

**Purity?**

**Security?**

**Source?**

**Scale?**

**Synthesis?**

**Specifications?**

**Compliance Standard?**



**BioSpectra Provides a Complete Solution with:**

**Premium Pharmaceutical Ingredients Exclusively Manufactured in the USA**

**Full GMP Product Development**

**Contract Synthesis**

**Purification of all Ingredients**

**Custom Specifications**

**Full Regulatory Compliance Support**

**True Quality Based GMP Manufacturing**

**100% reliable traceability of all raw materials**

**Qualified Equipment / Validated Processes**

**Complete finished product testing**

**ICH Q7, IPEC and US GMP Compliance**

**FDA Registration**



## Typical Problems

### Critical Manufacturing & Ingredient Issues

- Inconsistencies from lot to lot
- Insufficient purity levels
- Contamination
- Need for “real” GMP mfg.
- Non-dedicated facilities
- Incomplete lot testing
- Documentation deficiencies
- Absence of true traceability
- High Microbial and Endotoxin levels
- Recalled or scrap finished products
- Need for small-scale synthesis
- Need for custom specifications
- Need for higher levels of quality and compliance

### Supply Chain Security Issues

- Availability
- Reliability & trustworthiness
- Distance
- Safety stock
- Manufacturing interruptions
- Authentic chain of custody

### Regulatory Issues

- IPEC, ICH, GMP, FDA, EMA, other Compliance issues
- Need for global specifications
- Need for true validated manufacturing processes
- Requirement for a higher compliant, more suitable raw material



## BIOSPECTRA Your Complete Solution

For over 20 years, BioSpectra has manufactured exclusively in the USA, Premium, GMP Bulk Fine Chemicals for critical Life Science Applications answering many needs and challenges such as:

- Manufacturing Capabilities
- Chemical Synthetic Experience
- Purification Techniques
- Quality & Regulatory Expertise
- High-Touch management of your solution