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OUTSOURCING & CONSULTING SERVICES

# CORPORATE CAPABILITIES



## BioConvergence®

### Corporate description

BioConvergence offers parenteral product development, cGMP supply chain and materials management, and consulting services for the pharmaceutical and life sciences industries. We are a small, women-owned business and compliant with FDA and international regulatory standards. Our expert staff, robust business processes, and state-of-the-art facilities make BioConvergence the logical choice for clients that expect great service, value, and results from their outsourcing partner.

Why should you choose BioConvergence instead of our competition? Because you deserve higher quality service, performed with more reliability, responsiveness, speed, transparency, and innovation.

### Technical services

*Parenteral Product Development:* BioConvergence offers parenteral product development services covering all stages of the development cycle. We work with solutions, suspensions, emulsions, and lyophilized formulations, and on small & large molecules and cytotoxics. Our development services include:

- Preformulation studies
- Formulation & process development, including compatibility studies
- Lyophilization cycle development and optimization
- Analytical method development, validation,



- release and stability testing
- Pre-clinical and toxicology batch manufacture and packaging
- Technology transfer support to clinical and commercial manufacturing sites
- Counterfeit detection
- 2,500 SF cGMP analytical laboratory with: HPLC, FTIR, CE, DSC, XRPD, LS/MS, Bioanalyzer, Karl Fisher, Freeze-Dry Microscopy, and other equipment.

*cGMP Supply Chain & Materials Management:* BioConvergence

offers cGMP supply chain & materials management solutions for clinical/commercial products, including APIs, intermediates, raw materials, packaging components, delivery devices, and product. We provide:

- cGMP controlled temperature storage and distribution
- 51,000 SF of storage space available
- -80°C to 25°C redundant conditions
- Sampling and dispensing, labeling and packaging services
- Logistics: monitoring, packaging, S&H
- Supply chain design and management
- Analytical testing for incoming materials

*Consulting Resources:* BioConvergence is committed to addressing each client's unique requirements, and we can readily develop a custom consulting solution to meet your needs. Let us know how we can assist you with your project, large or small.

### Facilities

BioConvergence offers a 71,000 state-of-the-art cGMP facility with 51,000 SF of climate controlled storage. We have fully redundant systems, including temperature monitoring, IT, power, and security.

### Markets served

Biotech and pharmaceutical—we work with clients of all sizes, from virtual to large established firms.