BIOSPECTRA
Premium Pharmaceutical Ingredients

# GMP Support Package for all ICH-Q7 Level Products

## Analytical Support

- Analytical Method Validation
- Transfer of Analytical Methods
- Custom Analytical Methods and Specifications
- Bioburden and Endotoxin Testing
- Complete Impurity Profile
- Elemental Impurities
- Residual Solvents

## Development Support

- Stability Study
- Custom GMP Services as needed
- Custom Labeling and Packaging
- Manufacture of API Registration Batches
- Drug Master File submission
- Letter of Authorization
- Efficient Development Timeline
- High-touch management of your project

## Ongoing Support - Post FDA Approval

- Commercial Manufacturing of your API
- On Site Audits
- Annual Product Review
- Management of Change
- Post Submission Change Notification
- Full support through the life of your product

www.biospectra.us

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400