

# BIOSPECTRA

## CORPORATE OVERVIEW

JULY 2025

REVISION 11.5

# OUR VISION, MISSION & CORE VALUES

## VISION

BioSpectra is committed to being a leading manufacturer of cGMP fine chemicals that support the production of safe drugs and vaccines, delivering consistent, reliable therapeutic effects with every dose.



## MISSION

Our mission is to manufacture the safest, highest quality sustainable cGMP fine chemicals under the supervision of the most rigorous quality system while upholding the most stringent compliance standards.

## VALUES

✓Honesty   ✓Integrity   ✓Respect   ✓Safety   ✓Sustainability

BioSpectra rigorously upholds uncompromised standards because...  
People matter!



# CORPORATE PROFILE

## WHAT WE DO

BioSpectra manufactures a unique line of cGMP fine chemicals for use in pharmaceutical processes as well as finished drug products used by global BioPharma, Bio-CMOs and Biochemical companies. This includes cGMP bulk biological buffers, cGMP large volume bio-buffer solutions, cGMP process fine chemicals, cGMP chlorinated amino acids, highly purified parenteral grade carbohydrates and carbohydrate (Dextran) polymers, as well as other novel and compendial excipients.

## WHO WE ARE

- BioSpectra is an end-to-end producer of raw materials and manufacturer of the highest purity cGMP fine chemicals for biopharmaceutical applications.
- We control, own and operate the production and quality of over 95% of all chemical raw materials used to make our finished cGMP products.
- Our base of cGMP manufacturing is at our FDA registered, cGMP facilities in Bangor and Stroudsburg, PA, USA.
- We can offer long term fixed pricing to shield against tariff fluctuations
- We are absolutely the best at supporting new qualifications via documentation, samples and audits.



# FDA REGISTRATION STATEMENT

BioSpectra is registered with the US FDA at the following locations, with registration renewed on an annual basis.

Firm Name	Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
BioSpectra Inc.	3003380159	957030729	Analysis; Manufacture	1474 Rockdale Lane, Stroudsburg, Pennsylvania 18360, United States	12/31/2025
BioSpectra Inc.	3010476065	042724830	Analysis; API Manufacture	100 Majestic Way, Bangor, Pennsylvania 18013, United States	12/31/2025



Bulk cGMP Fine Chemical Manufacturer

## CRITICAL cGMP INGREDIENT NEEDS?

Synthesis | Purification | GMP Solutions



- Bulk Biological Buffers
- Functional Excipients
- Amino Acids / Sugars
- Critical Small Molecules
- Customer Buffer Solutions

# SUSTAINABILITY AND SUPPLY CHAIN

## SUSTAINABILITY

BioSpectra is committed to the ideals of sustainability. BSI is registered with Ecovadis, SBTi, M2030, and Carbon Disclosure Project (CDP). Our annual Corporate Sustainability Report (CSR) is made available on our website, [www.biospectra.us](http://www.biospectra.us).



## SUPPLY CHAIN SECURITY

BioSpectra is fundamentally committed to the ideals of supply chain security. We prosecute an aggressive raw material supplier qualification program, and we take the global supply-chain very seriously by assessing and reacting to threats with real solutions. BioSpectra continues it's long history of sourcing and qualifying raw materials, avoiding being sole-sourced on any key chemical that originates from only one country.



# COMMITMENT TO TRUE cGMP STANDARDS

BioSpectra does not simply test and package products under a “GMP system,” rather, we increase the quality and compliance levels through many steps of synthetic manufacturing and/or purification for all BioSpectra labeled products.

## STANDARDS & COMMITMENTS

- Authentic, secure supply chain utilizing 100% traceable raw materials from qualified sources
- Reliable, consistent, uniform, quality-based manufacturing of premium ingredients
- Fully validated GMP manufacturing systems and qualified equipment
- True GMP product claim, our products are always synthesized and/or purified, tested and packed under full cGMP standards.



# COMPREHENSIVE QUALITY & REGULATORY PROGRAM

## OUR SYSTEM

- FDA registered & inspected
- Full transparency in documentation
- Stringent quality program & controls
- Rigorous compliance to global standards
- State-of-the-art instrumentation & labs

## REGULATORY CONTROL & SUPPORT

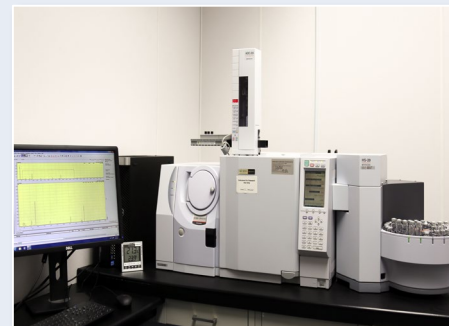
- Creation and submission of Drug Master Files for excipients
- Management of all external audits & certifications
- Creation & control of all critical documentation

## QUALITY CONTROL

- Fully staffed, on-site quality control labs
- Validation and verification of all test methods
- Qualification of all instrumentation

## QUALITY ASSURANCE

- Validation of all GMP manufacturing suites
- Thorough preventative maintenance program
- Qualification of all equipment
- Stringent cleaning protocols
- Change control processing
- Equipment IQ-OQ-PQ
- Document control



# WHAT WE DO

## SYNTHESIS

Dextran  
Derivatives

Small Molecule  
NCE's

Chlorinated  
Amino Acids

## PURIFICATION

Bulk Bio Buffers  
& Buffer  
Solutions

High Purity  
Carbohydrates

cGMP Pharma  
Process Fine  
Chemicals

## GMP SOLUTIONS

Custom  
Specifications

Parenteral  
Ingredients

Multi-  
Compendial  
Excipients

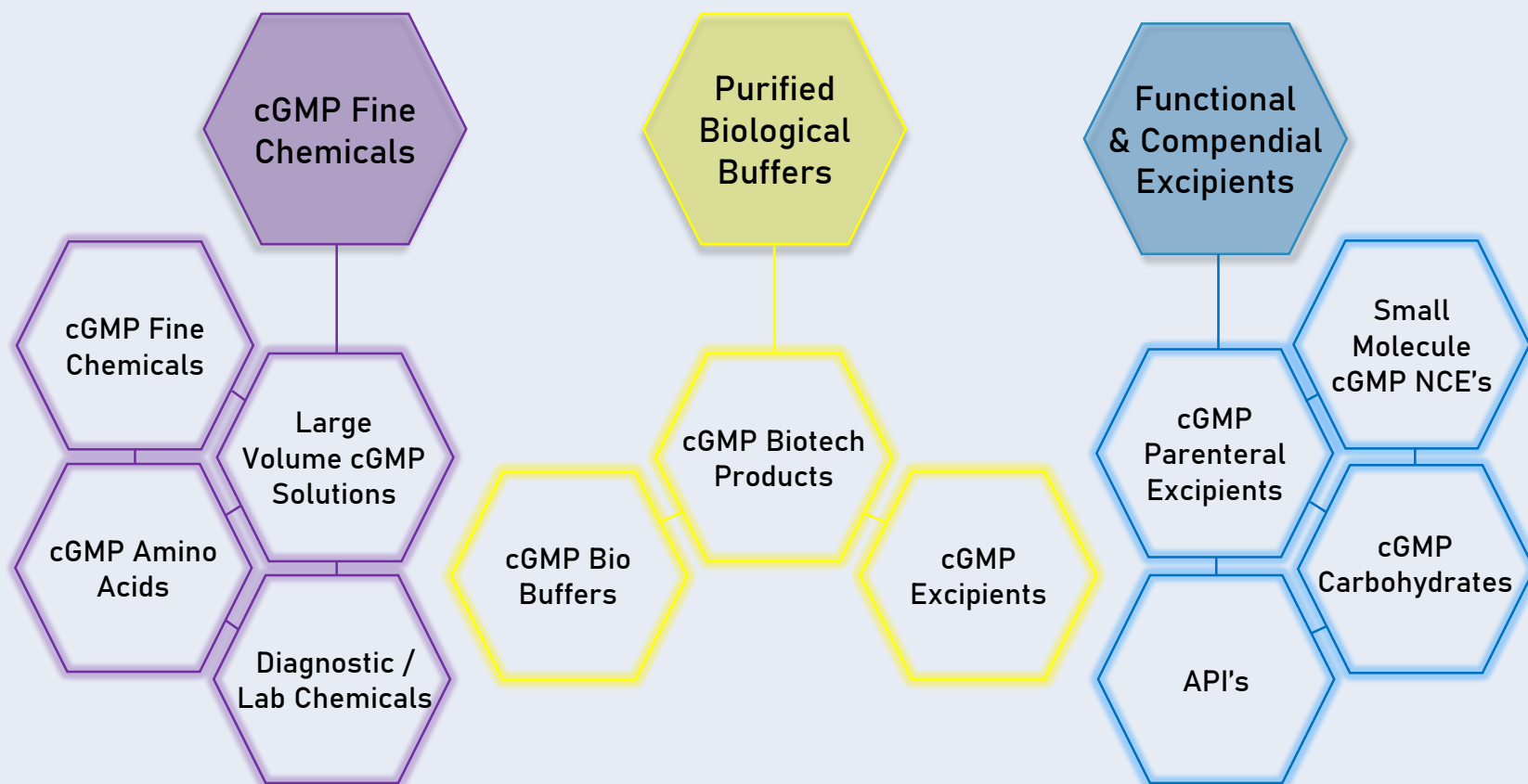
BSI is focused on the specific cGMP product needs of our key accounts, driving the synthesis, purification, testing and packaging of an expanding portfolio of products under full cGMP conditions. All of our manufacturing processes are fully validated. Each product is produced under quality managed cGMP systems with various levels of regulatory compliance based on the needs and use of each specific product; This includes ISO, IPEC, US-FDA and ICH-Q7 guidance. Testing of all raw materials and finished products are performed onsite by BSI staff, in the USA, by our own analytical lab personnel with the exception of Bioburden testing which is performed by a qualified, audited third party.

Our commitment is to quality, compliance and cGMP manufacturing with unparalleled regulatory and technical support, operating under the most rigorous quality system while holding to the most stringent regulatory demands.

Our goal is to be a valued partner in your secure supply chain for key cGMP fine chemicals and the solution to key ingredient issues you may have.



# WHAT WE OFFER



# BSI PRODUCT GRADES

BioSpectra manufactures products in the following grades, with LBLE\* versions available.

\*LBLE = Low bioburden, low endotoxin

## BIO EXCIPIENT GRADE

- Intended for use in pharma manufacturing requiring ICH-Q7 excipient grade quality and regulatory compliance.

## BIO PHARMA GRADE

- Intended for use in pharmaceutical and biopharmaceutical cGMP processes, applications and products.

## BIO TECH GRADE

- Intended for use in biopharmaceutical and biotechnological applications and products

## BIO ULTRA GRADE

- Intended for use in commercial life science manufacturing, diagnostic and lab applications

## COMPLIANCE

cGMP (US-GMP)

IPEC (International GMP)

FDA Registered & Inspected

ICH Q7 & other applicable CFR & ICH standards

# BIO SPECTRA FACILITY PROFILE

Overall, BioSpectra facilities consist of approximately 343,000 square feet and 52+ acres of land.

## MAJESTIC PHARMACEUTICAL INGREDIENT MANUFACTURING



100 Majestic Way, Bangor, PA 18013  
Approx. 150,000 square feet

## COMSTOCK BioSPECTRA CANADA D.B.A. DEXTRAN PRODUCTS



421 Comstock Road, Scarborough,  
ON M1L2H5, Canada  
Approx. 25,000 square feet

## ROCKDALE BIOLOGICAL BUFFER MANUFACTURING



1474 Rockdale Lane, Stroudsburg, PA 18360  
Approx. 35,000 square feet

## MCCONNELL SUPPLY CHAIN CENTER



51 N 3<sup>rd</sup> Street, Stroudsburg, PA 18360  
Approx. 60,000 square feet

## FULMER BioBUFFER SOLUTIONS LAB & WAREHOUSE



51 N 3<sup>rd</sup> Street, Stroudsburg, PA 18360  
Approx. 80,000 square feet

## JACOBSBURG CORPORATE SERVICES CENTER



1349 Jacobsburg Road, Wind Gap, PA 18091  
Approx. 25,000 square feet

## FACILITIES & EQUIPMENT

- Quality control labs containing industry-leading instrumentation
- Over 30 glass, 316-stainless steel and composite reactors
- Reactors:
  - Solvent & alcohol
  - Corrosive resistant glass lined
  - Stainless steel
- Drying systems:
  - Spray
  - Fluid bed
  - Rotary
  - Tray



# MANUFACTURING SCALE & KEY EQUIPMENT

## CAPACITY & SCALE

- Reactor scale:
  - 20L to 6,000L
- Dry batch scale:
  - 1kg to 20,000kg
- Solutions batch scale:
  - 800L to 14,000L
- Overall annual capacity:
  - Thousands of Metric Tons



## MANUFACTURING CAPABILITIES

- Synthesis, purification and compounding
- Environmentally controlled packaging rooms
- More than 24 cGMP manufacturing suites with compliance levels ranging from IPEC to ICH Q7



# CONCLUSION

If your company is...

- Focused on customer needs
- Committed to sustainable solutions
- Seeking increased security of supply
- Seeking flexibility, transparency and responsiveness from suppliers
- Working to support future commercial demands due to a strong growth model
- Seeking a manufacturer with a proven commitment to the pharmaceutical industry
- In need of higher-purity, higher-compliance pharma ingredients or cGMP fine chemicals
- Facing critical ingredient issues that fall within our scope of chemistry, capabilities and capacity

Then considering BioSpectra as your supplier could be your solution!

