BIOSPECTRA

Bulk cGMP Fine Chemical Manufacturer

Corporate Overview

Revision 11.3
02/04/2025

Corporate Vision, Mission, Values

People Matter

Vision

Committed to be a leading manufacturer of cGMP Fine Chemicals that support the production of safe drugs and vaccines that deliver consistent, reliable therapeutic effect with every dose

Mission

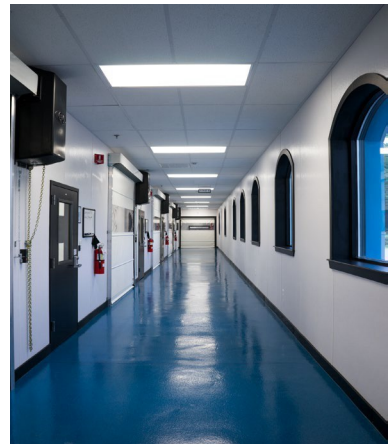
To manufacture the highest quality, safest and sustainable cGMP Fine Chemicals under the supervision of the most rigorous quality system while upholding the most stringent compliance standards

Values

Honesty / Integrity / Respect / Safety / Sustainability

BioSpectra rigorously upholds uncompromised standards because… "people matter"

Corporate Profile



BioSpectra™ is a manufacturer of cGMP Fine Chemicals, located in Stroudsburg, Bangor and Wind Gap, PA, USA. We own and operate seven facilities in the USA: two cGMP manufacturing sites, our cGMP warehouse and Supply Chain Center (SCC), and other Lab, Storage and Support facilities. In addition, BioSpectra oversees key raw material production and R&D operations in Canada, India and China – all under stringent quality oversight with full traceability and transparency of all raw material sources.

BioSpectra manufactures a unique line of cGMP Fine Chemicals for use in pharmaceutical processes and finished drug products used by global BioPharma, Bio Contract Manufacturers a.k.a. Bio-CMOs (for APIs and Finished Drug Products), and Biochemical Companies. This includes bulk Biological cGMP Buffers, large volume cGMP 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.

FDA Registration

BIOSPECTRA
Bulk cGMP Fine Chemical Manufacturer

October 9th, 2024
Revision 3

US FDA Registration Statement

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

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
BioSpectra Inc.	3003380159	957030729	ANALYSIS; MANUFACTURE	1474 Rockdale Lane, Stroudsburg, Pennsylvania (PA) 18360, United States (USA)	12/31/2025
BioSpectra Inc.	3010476065	042724830	ANALYSIS; API MANUFACTURE;	100 Majestic Way, Bangor, Pennsylvania (PA) 18013, United States (USA)	12/31/2025

For further information, please contact info@biospectra.us

BIOSPECTRA HISTORY

From its humble beginning, BioSpectra remains a pioneer in the development and manufacture of fully validated GMP versions of Biological Buffers and other fine chemicals for a constantly evolving Pharmaceutical industry.
Launched in the foothills of the Poconos and rooted in Eastern Pennsylvania work ethic and culture, BioSpectra has expanded to become a regional, multi-plant manufacturer of High Purity Pharmaceutical Ingredients, serving the leading Pharmaceutical Companies around the World.
Come visit with us as we journey through our history of growth… https://www.biospectra.us/about-us/history

1993-1995 - The BioSpectra Organization was created On December 26, 1993 operating from offices near Shawnee on the Delaware. BioSpectra, Inc. (BSI) was first incorporated in Pennsylvania, USA, on September 15, 1995.

2019-2020 – In 2019 and 2020 we acquired several other local properties to house external services (such as our Fleet of cars and trucks, building and ground equipment and non- controlled storage)

2001 – In 2001, BSI opened the Stroudsburg, Rockdale Lane facility and creating the first fully dedicated manufacturing facility for the production of the repurified GMP Biological Buffers that changed the scale of available cGMP Biological buffers to the BioPharma Industry.

2006 – In 2006, BSI created BioBuffer Solutions Brand to support the need for upstream materials to our critical customers. That brand will undergo further expansion at a new facility in 2024/2025.

BioBUFFER SOLUTIONS

2011 – In 2011, BSI acquired the much larger, Bangor, PA facility to expand manufacturing and expand our portfolio of GMP Pharmaceutical Process Fine Chemicals, Excipients and API's

1996 – The Original BioSpectra operated from a site in Sciota, PA., manufacturing reagent grade buffers and laboratory chemicals.

2021 – In April of 2021 BSI opened our Corporate Services Center in Wind Gap, PA.

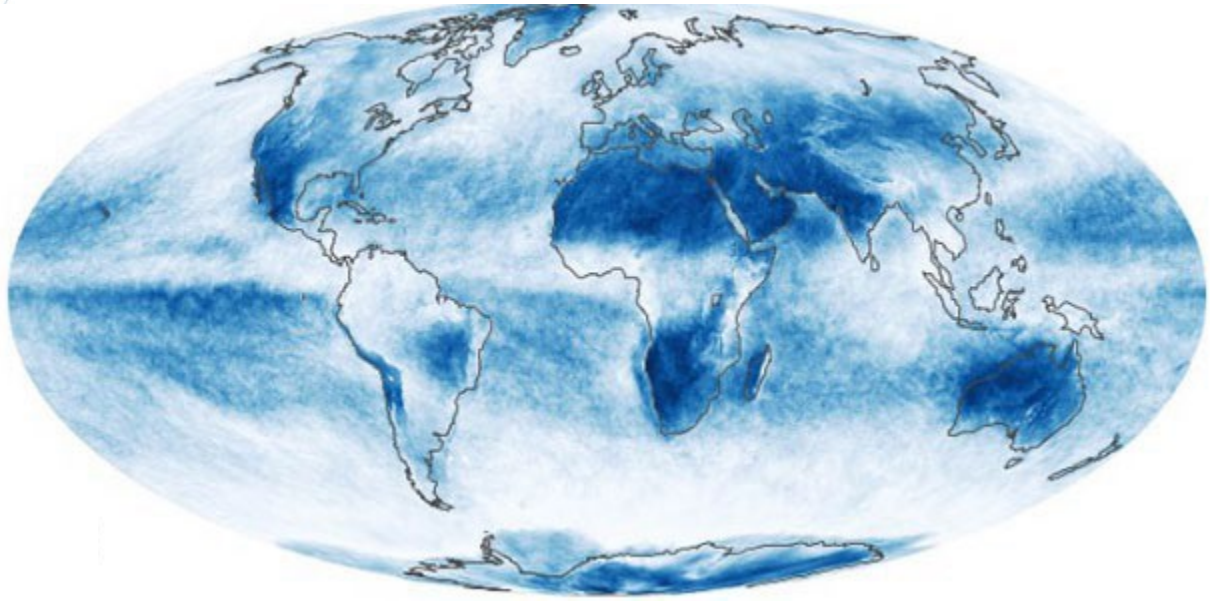
2023 –More recently in January 2023 we opened our 60,000 square foot GMP storage facility on 3rd street in Stroudsburg, PA.

The Future of BSI –And we are not done! We are busy working to expand our manufacturing footprint overseas as well and in 2024/2025 we plan to open another 80,000 square foot facility adjacent to our GMP Storage facility to house our expanding analytical services and automated packaging operations.

Sustainability and Supply Chain Security

Sustainability

BioSpectra is committed to the ideals of Sustainability and has launched a five-year multi-million dollar capital investment program to help achieve these goals. We are registered with ECOVADIS, SBTi, M2030, and Emitwise.



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 very seriously the global supply-chain situation assessing and reacting to threats with real solutions. BioSpectra continues it's long history of sourcing and qualifying raw materials so as not to be sole sourced on any key chemical that originates from only one country.

cGMP Manufactured Premium Fine Chemicals

Corporate Commitment to True cGMP Products

- Authentic, Secure Supply Chain – 100% Traceable Raw Materials from Qualified Sources
- Reliable, Consistent, Uniform, Quality-Based Manufacturing of Premium Ingredients
- Fully Validated GMP Manufacturing Systems & Qualified Equipment
- True GMP Product Claim – Always Synthesized and/or Purified, Tested and packed under full cGMP

Comprehensive Quality & Regulatory System

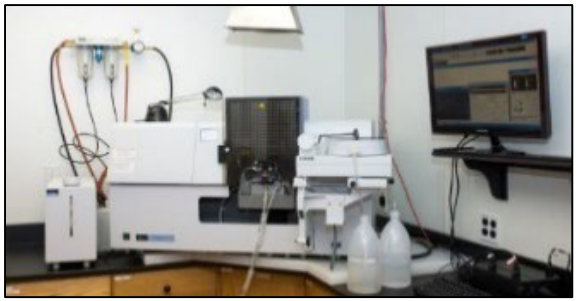
- FDA Registered & Inspected
- Full Transparency in Documentation
- Stringent Quality Program & Controls
- Rigorous compliance to Global Standards
- State-of-the-art Instrumentation & Laboratories

TRUE GMP

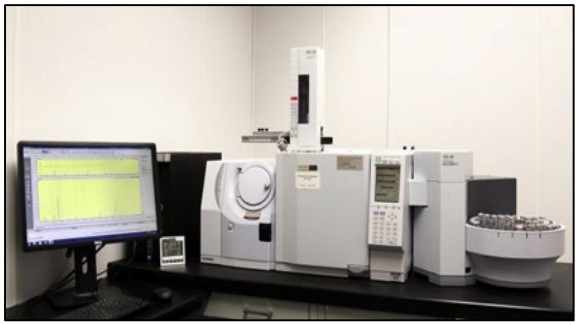
BSI does not simply test and package under a "GMP system"; rather, we always increase the quality and compliance levels through multiple steps of synthetic manufacturing and/or purification for all BioSpectra labeled products.

Comprehensive Quality & Regulatory Program

Quality Assurance



- Validation of all GMP Manufacturing Systems
- Rigorous Preventive Maintenance Program
- Qualification of all Equipment
- Stringent Cleaning Protocols
- Environmental Monitoring
- Change Control Process
- Equipment IQ-OQ-PQ
- Document Control



Regulatory Control & Support

- Creation and Submission of Drug Master Files for excipients
- Creation and Control of all Critical Documentation
- Management of all External Audits and Certifications

Quality Control

- Fully staffed, on-site Quality Control Laboratories
- Validation and Verification of all Test Methods
- Qualification of all Instrumentation including ICP-MS, GC-MS, HPLC, UV/Vis, TOC, Ion Chromatographer, Conductivity Meter, Microcount UATR, Polarimeter, Karl-Fisher Titrator & more

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 Product Specifications

Parenteral Ingredients

Multi-compendial Excipients

Our focus is on 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 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 that product. This includes ISO, IPEC, US-FDA and ICH-Q7 Guidance. Testing of all raw materials and finished products are performed on site by BSI staff, in the USA, by our own analytical lab personnel with the exception of Bioburden which is performed by a qualified, audited third party.

Our commitment is to quality, compliance and cGMP manufacturing with unparalleled regulatory & 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 Do


When You
Absolutely Need
FULL cGMP!
BIOSPECTRA
Bulk cGMP Fine Chemical Manufacturer
• Full cGMP Development
• Synthesis & Purification
• Small & Large Volumes
• Amino Acids / Sugars
• Critical Small Molecules
• Custom Buffer Solutions
• Functional Excipients
Exclusively Manufactured in the USA
www.biospectra.us
100 Majestic Way, Bangor, PA 18013

Product Grades & Compliance Levels

Premium Pharmaceutical Ingredients

Bio Ultra & Bio Ultra w/ BET (LBLE)*
Bio Pharma & Bio Pharma w/ BET (LBLE)*
Bio Excipient & Bio Excipient w/ BET (LBLE)*

***Note: LBLE** = Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

- **cGMP (US-GMP)**
- **IPEC (International GMP)**
- **FDA Registration / Inspection**
- **Internal Controls and Systems**
- **ICH Q7 & other applicable USP & ICH standards**

Visit our website www.biospectra.us to view our complete list of products.

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BIOSPECTRA

Bulk cGMP Fine Chemical Manufactuer

ICH Q7 PARENTERAL INGREDIENTS

LOW BIOBURDEN | LOW ENDOTOXIN | HIGH PURITY

Rigorous Quality System

State-of-the-art Facilities

Validated GMP Process

- Carbohydrates
- Small Molecule
- Amino Acids
- Excipients
- Buffers

STRINGENT QUALITY PROGRAM

FDA Registered and Inspected / US GMP / IPEC / ICH Q7 Guidelines

www.biospectra.us
610-599-3400

100 Majestic Way
Bangor PA, 18013

Visit our website www.biospectra.us to view our complete list of products.

BIOSPECTRA
Bulk cGMP Fine Chemical Mfg.

PURIFIED cGMP FINE CHEMICALS

CARBOHYDRATES | AMINO ACIDS | BIO-BUFFERS

d-Galactose,
Trehalose Dihydrate

L-Arginine-HCl, 2-MEA,
L-Cystine Dihydrochloride, L-Glutamine,
L-Histidine Monohydrochloride Monohydrate

Bis-Tris, Guanidie HCl, HEPES,
MES, MOPS, Tris HCl, Tromethamine

LOW BIOBURDEN | MULTI-COMPENDIAL GRADES | LOW ENDOTOXIN



www.biospectra.us

100 Majestic Way, Bangor, PA, USA 18013

BIOSPECTRA
Bulk cGMP Fine Chemical Manufactuer

PURIFIED cGMP BIOLOGICAL BUFFERS

Exclusively Manufactured in the USA

TROMETHAMINE, TRIS HCL,

GUANIDINE HCL, HEPES,

MES, MOPS, BIS-TRIS

- Low Bioburden / Endotoxin
- Pharma GMP Process
- Multi-Compendial
- Excipient Grades
- Bulk Solutions

STRINGENT QUALITY PROGRAM
FDA Registered and Inspected / US GMP / IPEC / ICH Q7 Guidelines

www.biospectra.us
610-599-3400

100 Majestic Way
Bangor PA, 18013

Facility Profile

Overall
Facilities: 343,000 sq. ft. 52+ Acres
5 Campuses
Staff: 250+ Employees
More Info: www.biospectra.us

"Majestic"

Pharmaceutical Ingredient Manufacturing
Bulk Manufacturing Facility & Head Corporate Offices: Administration, Regulatory Affairs, Quality Assurance & Control
Address: 100 Majestic Way, Bangor, PA 18013
Staff: 125+ Employees | Site: 150,000+sq. ft. on 37+ Acres

"Rockdale"

Biological Buffer Manufacturing
Bulk Manufacturing Facility, Quality Assurance & Control
Address: 1474 Rockdale Lane, Stroudsburg, PA 18360
Staff: 50+ Employees | Site: 25,000+sq. ft. on 3+ Acres

"Comstock"

Biospectra Canada d.b.a → Dextran Products
Address: 421 Comstock Rd, Scarborough, ON M1L 2H5, Canada

"McConnell"

Supply Chain Center
Shipping and Receiving & Security HQ
Address: 51 N 3rd Street, Stroudsburg, PA 18360
Staff: 20+ Employees | Site: 60,000+sq. ft. on 2+ Acres

"Jacobsburg"

Corporate Services Center
Commercial, IT, HR, Finance & Training Center
Address: 1349 Jacobsburg Road, Wind Gap, PA 18091
Staff: 30+ Employees | Site: 25,000+sq. ft. on 2+ Acres

"Fulmer"

BioBuffer Solutions
Wet Chemistry Labs / Raw Material Warehousing
Address: 51 N 3rd Street, Stroudsburg, PA 18360
Completed Date - 2025

Key Equipment & Manufacturing Scale

Premium Pharmaceutical Ingredients

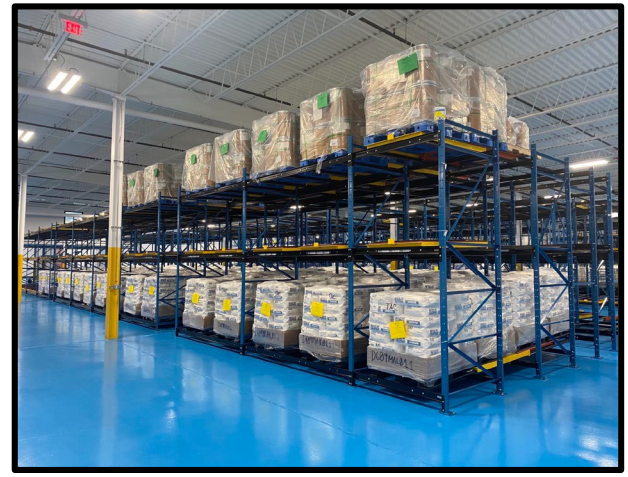
- **More than 24 GMP Manufacturing Suites** with compliance levels ranging from IPEC to ICH Q7
- **More than 30 Glass, 316-Stainless Steel and Composite Reactors**
- **Environmentally controlled Packaging Rooms**
- **Quality Control Labs** with industry leading instrumentation
- **Manufacturing Capabilities**: Synthesis / Purification / Compounding
- **Drying Systems**: Spray / Fluid Bed / Rotary / Tray

Scale & Capacity

- **Reactors:** Solvent & Alcohol / Corrosive Resistant Glass Lined / Stainless Steel
- **Reactor Scale:** 20L to 6,000L
- **Solutions Batch Scale**: 800L to 14,000L
- **Dry Batch Scale**: 1kg to 20,000 kg
- **Overall Operational Capacity**: Thousands of Metric Tons per Year

cGMP Warehouse Complex

51 North 3rd Street Stroudsburg, PA 18360



Final Word

We Seek to Service…

Customers who are seeing:

- Increased security of supply
- A company with a strong growth model to support future commercial demands
- A company with a proven track record of commitment to the Pharmaceutical Industry
- A company focused on customer needs
- A flexible, transparent and responsive supplier
- A company committed to Sustainable Solutions

Customers who:

- Have critical ingredient issues that fall within our scope of chemistry, capabilities and capacity
- Need higher-purity, higher-compliance Pharma ingredients or cGMP process fine chemicals Ingredients
- Value full cGMP synthesized and/or purified products