

# BIOSPECTRA

Premium Pharmaceutical Ingredients

**Organizational Excellence**

**Quality Excellence**

**Manufacturing Excellence**

**Operational Excellence**

**Environmental Excellence**

**Sustainability Excellence**

Organizational Strategic Plan for February 1, 2023 through September 30, 2025

## Pharmaceutical Ingredient Manufacturing

100 Majestic Way, Bangor, PA

## Biological Buffer Manufacturing

1474 Rockdale Lane, Stroudsburg, PA

## Corporate Services Center

1349 Jacobsburg Road, Wind Gap, PA

## Quality Services Center

53 North 3<sup>rd</sup> Street, Stroudsburg, PA

## Bio Development, Inc.

11 University Place, Rensselaer, NY

## Supply Chain Center

51 North 3<sup>rd</sup> Street, Stroudsburg, PA

## Fleet Services

Murray Street, Bangor, PA

# BIOSPECTRA

Manufacturers of Critical Life Science Ingredients.

*Founded: December 26, 1993  
Operational: February 15, 1994  
Incorporated: September 15, 1995  
Manufacturing: March 1, 1996  
30<sup>th</sup> Anniversary September 15, 2025*

**The BioSpectra Organization is a group of companies committed to manufacturing and supplying the most Sustainable chemicals, of Exceptional Quality and Regulatory Compliance, to the Global BioPharmaceutical Industry.**

## **MISSION**

BioSpectra provides safest, most sustainable and highest-quality materials for drug and vaccine manufacturers.

## **VISION**

BioSpectra will be a leading member of the pharmaceutical community committed to providing ingredients supporting safe and consistently therapeutically effective drugs and vaccines for every person.

## **VALUES**

**HONESTY:** in everything we say and do

**INTEGRITY:** in our systems and work

**SUSTAINABILITY:** in our business and decisions

**COMPLIANCE:** to the true meaning of our standards and commitments

**RESPECT:** for people, communities and the environment



The BioSpectra Organization operates 343,000 sq. ft. of space on 52 acres of land in 6 Municipalities of Pennsylvania and New York. BioSpectra owns over 97% of the land, facilities and space it occupies.

The BioSpectra Organization owns and operates an FDA Registered, Bulk Chemical, Premium Pharmaceutical Ingredient manufacturing facility in Bangor, PA, an FDA Registered, Bulk Chemical, Biological Buffer manufacturing facility in Stroudsburg, PA and a cGMP Kilo-Scale manufacturing facility in Rensselaer, NY. The Organization also owns and operates a Corporate Center facility in Wind Gap, PA, a Supply Chain facility in Stroudsburg, PA, and a Fleet Management facility in Bangor, PA. The Organization employs approximately 300 people.

While the BioSpectra Organization was created on December 26, 1993, BioSpectra, Inc. was first incorporated in Pennsylvania, USA, on September 15, 1995 (BioSpectra 1.0). The Original BioSpectra operated from a site in Sciota, PA. In 2001, we committed to opening the Stroudsburg facility and changing the scale of available cGMP Biological Buffers to our Industry (BioSpectra 2.0). In 2006, we created BioBuffer Solutions to support the need for upstream materials to our critical customers (BioSpectra 3.0). In 2011, we acquired our Bangor, PA facility to launch into specialty materials and API's (BioSpectra 4.0). In 2018, we started the process of restructuring the organization into its current Divisional form (BioSpectra 5.0). Using the September 15, 1995 incorporation date, we will celebrate our thirtieth Anniversary in Q4 2025. This Strategic Plan will launch the BioSpectra 6.0 phase.

This Strategic Plan will be based on our expectations and goals for our thirtieth anniversary and define primary measurables for the 32-month period starting February 1, 2023 and ending September 30, 2025.

The period of time from October 1, 2025 through November 30, 2025, "the Landing Period" will be dedicated to formulating BioSpectra's next five year plan. This 60-day period will include the Executive Leadership Team meeting extensively with the Leadership Team and other key stakeholders to formulate the growth plan for the BioSpectra Organization as it relates to chemistry, technology, facilities and product lines for the following five-year span of time (BioSpectra 7.0). The 2025-2030 Strategic Plan will be approved, published and shared with all relevant stakeholders before December 31, 2025.

#### The Goal of this Strategic Plan:

***Entering the Landing Period, BioSpectra 6.0, as an organization, will ensure all properties owned by BioSpectra are "Sustainably Renewed" in six critical areas, with twenty-four key deliverables, and ready to launch BioSpectra 7.0.***

## I: Organizational Excellence

- **Business Continuity Plan**

BioSpectra's Leadership Team will undertake an in-depth review of our business systems and Business Continuity Plan (BCP). The review of this plan will evaluate the key areas necessary for the successful continuity of all critical business functions and will focus on Crisis Management, Disaster Recovery and Uninterrupted Business Continuation. The enhanced BCP will provide a guide to ensure that BioSpectra's Critical Business Functions continue during a time of crisis, emergency, or disaster. There will be one printed version of this plan stored with the BioSpectra Book of Books in our Corporate center and a digital copy will be maintained on our file server to be made available to members of the Leadership Team. This plan will be reviewed annually.

- **Succession Plan**

Vice Presidents are the operational backbone of the BioSpectra Organization and the President is the driving force of the Organization. There must be a documented plan outlining how the business model and facilities operate in the event the President or a Vice President is no longer able to serve in that capacity including death. The plan must outline roles and responsibilities for each member of the Senior Leadership Team and provide enough information that, when used in conjunction with the Book of Books and the Business Continuity Plan, there will be no disruption to the operation of the Organization. This plan, when completed, must be reviewed annually by the Senior Leadership Team to ensure preparedness.

- **100% Validated and Implemented ERP/MRP**

All aspects of order entry and fulfillment, Material Requirements Planning (MRP), Inventory, production scheduling, and financial systems will be operating using a validated Enterprise Resource Planning System (ERP). We will continue to enhance the SAGE ERP system acquired and implemented during the BioSpectra Digital 2022 Capital Project. Inventory tracking will be controlled by our Supply Chain Division on a unified platform (SAGE) across the Organization for movement, tracking and verification of materials. Together, these systems will combine to provide the scalable and secure digital platform required to enable the continued growth of the Organization.

- **Human Development Plan**

We will commit to maintaining our proactive Compensation and Benefit management program including fully documenting the program and adding key aspects to the Organizational Leadership Calendar. By the time of the Landing Period, 100% of the roles at BioSpectra will be defined for clarity and accuracy. This is not an enhancement to Job Descriptions, but rather a fully integrated and detailed list, chart and searchable program capable of defining all key responsibilities in the Organization including which team members are able to perform those functions.

## II: Quality Excellence

- **100% Validated and implemented Digital QMS**

The BioSpectra Organizational Quality Management System (QMS) will function entirely in electronic format before the Landing Period. The Document Management System (DMS), which has already been implemented electronically, will support the implementation of fully electronic Training Records, Standard Operating Procedures (SOP's), Work Instructions, Forms, and the electronic documentation of cGMP activity performed by BioSpectra. Training for the implementation of the remaining portions of the Quality Management System to be fully electronic will be administered to all impacted teams during the electronic format implementation.

- **100% Validated and Implemented LIMS**

All BioSpectra Laboratory locations will be operating using a unified Laboratory Information Management System (LIMS). The LIMS system will be the main application used to store laboratory testing results. LIMS will utilize a validated sample workflow that provides full traceability of laboratory data with robust data reporting capabilities. All Test Methods, Analytical Procedures, Specifications, Standard Operating Procedures, and related document links will be set up and available for reference while using the Laboratory Information Management System. A training program will be developed to ensure that all BioSpectra employees with access to the Laboratory Information Management System, have the documented skill set to navigate the systems required to ensure compliance with Organizational Quality System standards.

- **Expansion of Data Integrity and Quality Programs**

BioSpectra's quality culture provides the assurance of compliance in our work and documentation. Data Integrity is vital to BioSpectra's Quality Culture. The expanded Data Integrity and Quality Programs will ensure the complete, consistent and accurate recording of data and ensure data is retained in a secure and compliant manner. The Data Integrity and Quality Programs will be enhanced to convert all paper copies to true electronic copies and will ensure that records are easily retrieved and retained for the required period of time. BioSpectra will continue to enforce all regulatory data integrity requirements and BioSpectra's Quality Program in all areas of the organization.

- **Buildout of new Laboratory**

A critical need, necessarily tied to many projects and initiatives, is the addition of a new testing facility at our Quality Services Center. This will become our primary, and largest, testing facility which will drive innovation in our Laboratory environment and allow for the creation of an Advanced Technology Laboratory in the Bangor facility. This facility will also need to be integrated with the QMS, LIMS and ERP Systems.

### III: Manufacturing Excellence

- **100% Validated and implemented EBR's**

Every Batch Record, for every product at every location, will be converted to an electronic format. This will allow for the execution, approval and record retention of batch records to be completely electronic. A training program specific to each batch record will continue to be delivered to all impacted personnel. The Training Program will ensure every chemical operator, and any person with access to Electronic Batch Records (EBR's), has proven and documented skills to navigate the system required to ensure compliance with Organizational Quality System standards. All Standard Operating Procedures and Work Instructions required for all batch records will be linked to the converted batch records to ensure each are made available while using the Electronic Batch Record System.

- **30 Days Critical Product Inventory**

BioSpectra will expand its capacity and capabilities to ensure that every supply chain backed legacy product is available, from inventory, with at least 30 days of forward stock (by volume) on hand in our Supply Chain Center at any time. This material may be in finished packages, or as available bulk finished goods needing only to be converted to final packaging.

- **100% Qualified Equipment and Validated Systems**

BioSpectra develops and designs manufacturing suites for the compliant manufacturing of high-quality ingredients. BioSpectra's Process Validation Program will ensure all processes deliver high quality ingredients that consistently meet critical process parameters and quality attributes. The suitability and qualification of the equipment and systems is critical in the successful manufacturing of all BioSpectra products. BioSpectra will enhance the development, design, installation and qualification of all equipment and utilities used in process suites. BioSpectra's qualification and validation program enhancement will also bring forth robust and effective manufacturing, cleaning and preventative maintenance programs.

- **Spray Drying Technology Expansion**

By the time of the Landing Period, BioSpectra will have installed, qualified and validated commercial products from all five of the Polar Dry Spray dryers at our facilities, making our organization the largest nitrogen spray dryer in the pharmaceutical industry. These dryers will be manufactured of 316SS and C22 Hastelloy. This will give us the ability to spray dry internally chlorinated products and temperature sensitive materials.



#### IV: Operational Excellence

- **100% Sustainably Renewed Buildings**

Every BioSpectra owned facility, which is every facility we occupy other than our Rensselaer, NY facility, will have a new energy efficient, safe, environmentally sound, easily repairable and beautiful roof not more than five years old and with at least ten years of warranty against failure. Every window in every BioSpectra facility will be industrial, high energy efficiency, bronze framed, copper mirrored panels for energy conservation. All floors will be finished with Epoxy, Acrylic or another suitable, cleanable material. This upgrade will ensure uninterrupted opportunity for growth through the next multiple Strategic Plans.

- **100% of workspace will be compliant to our four levels of classification**

BioSpectra will establish Standards of Air Quality and Air Flow for the following generalized areas: 1. Bulk Operational Space (i.e., warehouses, maintenance shops, etc.), 2. Administrative Space (i.e., Offices, conference rooms, etc.), 3. Laboratory Space, and 4. Basic Manufacturing Space. The standards will be tied to an Internationally recognized system and will be tested annually for compliance. Specialized Manufacturing and Testing Environments will be classified individually for use, inside the new standardized spaces.

- **100% Uniform and standardized workspaces, break areas and offices**

BioSpectra will complete the renovation of all existing office, conference and break spaces to conform to our new organizational standard of equity, form and function. Every desk, flooring material, wall, chair, computer, etc., will be standardized to ensure everyone enjoys the same elevated work experience. All break areas will be fitted with Organization-subsidized fresh food and beverage vending systems to be available 24/7/365.

- **Property beautification at every facility completed**

As part of our commitment to the environment, we will use the next 32 months to secure and beautify every piece of land we own and occupy. We will remove any non-beneficial fallen trees/plant life. We will collaborate to ensure the removal of any invasive species of plant life, increase the amount of sustainable plant life and ensure that all land and water is protected, clean and readily available for the personal enjoyment of our staff to ensure its sustained wellbeing.

V: Environmental Excellence

- **Dust Collection/Cyclone Upgrade Program**

After more than ten years evaluating the benefit of adding dust collection cyclones to our dust collection systems in various manufacturing lines, we will standardize our manufacturing platform to include dust collection cyclones for every process using a dust collector. The immediate benefit is the massive reduction on load and life of the actual duct collectors, but this will also allow us to evaluate the overall number of dust collector systems in use at any one site for energy conservation and emergency redundancy planning. Further, collection of material from the product dedicated cyclones will allow for removal of that material from our waste stream.

- **Commercial Recycling program implemented**

As a large consumer of packaging to meet the needs of our customers. BioSpectra will launch an organization-wide effort to recycle as much of our incoming packaging materials as possible. We will evaluate new methods of reusing plastic drums, and safe methods of separating the metal portions from the paper portions of our fiber drums. We will start this program by quantifying the impact we make currently in our existing format and then offer evidence of significant improvements to our partners and stakeholders during audits and business visits.

- **Solid Waste Reduction program implemented**

The BioSpectra Organization will establish a three-year history of solid waste volumes, to the best degree of accuracy available, to form a plan to reduce all solid waste wherever possible. While the actual mass volume of solid waste attributed to paper may not be significant in relation to overall solid waste volume, we will also have transitioned to a paperless quality and business platform during this same period. We will develop metrics to indicate the amount of solid waste by headcount and by units of materials produced.

- **Liquid Waste Reduction Program implemented**

The BioSpectra Organization will establish a three-year history of liquid waste volumes, to the best degree of accuracy available, to form a plan to reduce all liquid waste wherever possible. We will separate our Liquid Waste into High-Risk waste and Low-Risk waste categories. We will develop metrics to indicate the amount of liquid waste by headcount and by units of materials produced. We will build a program to better utilize our Mother Liquor reclaiming system to reduce both solid waste and liquid waste. The net benefit of this program will be tracked and monitored.

## VI: Sustainability Excellence

- **Vertically Integrated HCl Gas/Liquid supply**

To ensure that an event like the HCl Gas crisis of 2022 never impacts our organization again, and to ensure availability of Chlorinated Buffers, Salts and Aminos from truly secure supply chains, BioSpectra will become the first fully vertically integrated manufacturer of Chlorinated Life Science materials by building and qualifying redundant HCl Gas Generator systems and qualifying the first ever, cGMP HCl gas for pharmaceutical production. We will also launch a cGMP version of exceptionally pure HCl liquid to support other initiatives.

- **100% Energy-efficient HVAC Systems**

Recognizing the need for clean air, BioSpectra will build out, design, purchase and install 100% new HVAC air handling systems for every site in the Organization by the Landing Period. Systems of the highest efficiency, environmental rating for sustainability, and ability to provide safe, clean, compliant and comfortable working conditions will be installed. We will track the benefits in energy consumption and sustainability throughout the process for reporting to key stakeholders at future business meetings.

- **Unified and expandable Utilities at each site**

Responsible and urgently-flexible manufacturing for our industry requires access to qualified utilities. Historically, to provide time sensitive new products or scale-ups, this meant the addition of new utility systems for core processing needs. BioSpectra will rebuild its current heating, chilling and steam systems that supply the manufacturing lines in our two bulk manufacturing facilities with state of the art, environmentally agreeable, sustainable and secure systems including fully qualified redundant back-ups for each system by the Landing Period. This massive investment in Sustainability and efficiency will allow immediate growth at any time without installing additional systems. We will build each system with significant excess available capacity and additional physically engineered space for add-on modules for the primary and secondary to expand well past the ability of either site to consume such utilities. These two systems will replace, when completed, over 20 significant systems, each requiring independent Preventative Maintenance programs, utilities, spare parts and risk management programs.

- **Inter-site Supply Chain Management Program**

As we prepare to open our new Supply Chain Center in Stroudsburg, PA, our newly formed Supply Chain Division will build a system and program that supplies, readily available, approved raw materials, components and critical supply items within hours to any site while simultaneously significantly reducing the number of trucks and vehicles required to supply the sites. By centralizing all incoming regulated shipments and building scheduled deliveries, customizable by the sites real-time, we will reduce traffic, expand manufacturing space and better secure all raw materials and finished goods to better serve our customers and reach exceptional sustainability levels. Our Supply Chain team will document the effectiveness of this program starting at the beginning of the Strategic plan.

- *At no time during the span of this Strategic Plan will BioSpectra reject the need to advance product lines and product offerings or restrict the need to increase capacities, but it may temporarily limit certain activities related to land/facility addition as well as activity related to acquisition of other manufacturing platforms to ensure our successful Landing Period during Q4 2025.*
- *Further, to clarify the scope of this Strategic Plan, this plan does not address the other Project Management Office projects underway, of which there are nearly 100, representing over \$60MM in investment to increase capacities, implement new technologies and provide additional workplace safety to maintain our global leadership position in business model growth. This plan, while incorporating key projects from our PMO, is fully separate and necessary to build our platform into a business model that will comply with the needs of our Global Pharma customer base in the coming years.*
- *This plan will be monitored by our PMO Project Management team who will organizationally report to the PMO, but who will spend significant time working with and reporting results to the President to ensure daily, weekly and monthly compliance to these growth and sustainability goals. The PMO team will also assist in reporting results against nationally and internationally recognized standards and objectives for Sustainability and Reduction of Carbon Footprint.*

The Proposed timeline to complete the 24 Initiatives is shown on the following two Roadmap time-charts. These charts are based on balancing these objectives within the full scope of all the Projects scheduled in our Organizational Business calendar.