

BIOBUFFER SOLUTIONS

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

BIOBUFFER SOLUTIONS QUALITY MANAGEMENT SYSTEM REGULATORY PACKET



Signature/Date:

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TABLE OF CONTENTS

1.	MATERIAL HANDLING, RELEASE SITE, AND SUPPLIER INFORMATION:.....	3
1.1.	FACILITY OVERVIEW:.....	3
1.1.1.	MATERIALS HANDLING	3
1.1.2.	CUSTOMER AUDIT POLICY:	3
1.1.3.	SITE DETAILS:.....	4
1.1.4.	MATERIAL RELEASE:	5
1.1.5.	SUPPLIER INFORMATION:	5
1.2.	COMPLIANCE DETAILS:.....	5
2.	CONTACT INFORMATION:	5

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1. MATERIAL HANDLING, RELEASE SITE, AND SUPPLIER INFORMATION:

1.1. Facility Overview:

1.1.1. Materials Handling

1.1.1.1. BioSpectra Facilities handle materials from BioSpectra’s Approved Suppliers and Manufacturers once received at a BioSpectra facility in accordance with the respective elements of the Quality Management System pertaining to Material Handling, Release, and Supplier Information.

Table 1. BioSpectra Facilities

Name	Address	Activity
Jacobsburg	1349 Jacobsburg Road Wind Gap, PA 18091	Commercial, IT, HR, & Finance Offices, Training Center, and Small Warehouse for applicable materials
Majestic	100 Majestic Way Bangor, PA 18013	Packaging and Release of Bio Pharma Grade for BioBuffer Solutions Product Line, Bio Qualified Grade, and Bio Ultra Grade Materials. Corporate Offices: Administration, Regulatory Affairs, Quality Assurance & Quality Control ¹
Rockdale	1474 Rockdale Lane Stroudsburg, PA 18360	Packaging and Release of Bio Ultra Grade and Bio Pharma Grade for BioBuffer Solutions Product Line Materials. Quality Control and Assurance ¹
McConnell	51 North 3 rd Street Stroudsburg, PA 18360	Shipping and Receiving & Security Headquarters
¹ BioSpectra additionally manufactures higher compliance grade materials at this site. Reference the BioSpectra Quality Management System Regulatory Packet DCN: BSI-RPT-1355 for further details.		

1.1.2. Customer Audit Policy:

1.1.2.1. BioSpectra welcomes auditors and visitors. Our customers and business partners are assured access to our facilities based on purchased product grade attributes and/or Supply/Quality Agreements. BioSpectra allows scheduled audits to maintain assurance of current information related to the systems, equipment, utilities and operations at each site. Potential customers and potential business partners may be provided with appropriate access while establishing business relationships. Audits may be restricted in the absence of a current commercial relationship.

1.1.2.2. To request an audit, please complete the Audit Request Form:

1.1.2.2.1. <https://biospectra.us/audit-request-form/>

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1.1.3. Site Details:

1.1.3.1. General Site Information

1.1.3.1.1. BioSpectra was founded in 1994 and was officially incorporated in the State of Pennsylvania in 1995. The first BioSpectra manufacturing facility was opened in Sciota, PA in March of 1996. This facility was created for the cGMP manufacturing of Biological Buffers. BioSpectra opened the Stroudsburg, PA facility (Rockdale) in December of 2000. Between 2000 and 2003, BioSpectra moved its processes from the Sciota, PA facility to its Stroudsburg, PA facility. This site is registered with the US Food and Drug Administration. The processes were initially validated in the Stroudsburg facility throughout 2000 and 2003 and revalidated in accordance with BioSpectra's approved Manufacturing Process Validation Master Plan. The manufacturing operations at this site operate 24 hours per day 7 days per week.

1.1.3.1.2. BioSpectra purchased the Bangor, PA facility (Majestic) in December of 2012. This facility develops new processes, conducts research and development, and manufactures Active Pharmaceutical Ingredients, Excipients, and Life Science Intermediates, as well as Custom Buffers and Blends. This site is registered with the US Food and Drug Administration. The manufacturing operations at this site operate 24 hours per day 7 days per week.

1.1.3.1.3. In April of 2021 BioSpectra opened the Wind Gap Corporate Center (Jacobsburg), which houses office and warehousing space. The warehouse consists of multiple push-back racking systems and additional pallet positions designated on the warehouse floor. This facility is the Corporate Center with office locations for Commercial, IT, Human Resources, and Finance. Additionally, this facility is the training center. There are no products currently manufactured at this site.

1.1.3.1.4. In 2023, BioSpectra opened the Supply Chain Center (McConnell) in Stroudsburg, PA, which houses offices, security headquarters and warehousing space for sampling and storage of raw materials and components as well as storage, release, and shipment of finished goods in accordance with cGMP guidelines. There are no products manufactured at this site.

1.1.3.2. Facility Size and Composition

1.1.3.2.1. The BioSpectra Majestic facility is approximately 150,000 square feet in size and is comprised of various Zones. Each Zone represents a particular geographical portion of the facility. Any one zone may include multiple operational areas, which include manufacturing, packaging, storage, or further processing areas. The map of the facility contains details of each zone. Detailed site information is available in DCN: BSI-SOP-0218.

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- 1.1.3.2.2. There are multiple processing rooms, packaging rooms, and drying rooms within BioSpectra's 25,000 square foot Rockdale facility, as well as a warehouse with a push-back racking system, and a Quality Control Laboratory. Detailed site information is available in DCN: BSI-SOP-0078.
 - 1.1.3.2.3. The BioSpectra Jacobsburg facility is 25,000 square feet. Detailed site information is available in DCN: BSI-SOP-0425.
 - 1.1.3.2.4. The BioSpectra McConnell Facility is approximately 52,000 square feet. Detailed site information is available in DCN: BSI-SOP-0557.
 - 1.1.3.3. Site Activities Conducted
 - 1.1.3.3.1. The activities conducted at BioSpectra for Bio Pharma Grade for BioBuffer Solutions Line, Bio Qualified Grade and Bio Ultra Grade materials include the following:
 - 1.1.3.3.1.1. Supplier and Manufacturer Qualification
 - 1.1.3.3.1.2. Quality System Management of materials at BioSpectra
 - 1.1.3.3.1.3. Quality Control Analysis, as applicable
 - 1.1.4. Material Release:
 - 1.1.4.1. Bio Pharma Grade for BioBuffer Solutions Product line, Bio Qualified Grade, and Bio Ultra Grade materials are manufactured by BioSpectra's Approved Suppliers and Manufacturers. Testing may be transcribed by BioSpectra or analyzed by BioSpectra's Quality Control Laboratory, as applicable, for the respective material. BioSpectra's Quality Assurance Department reviews available documentation in order to issue the Certificate of Analysis in accordance with the Certificate of Analysis Issuance Procedure.
 - 1.1.5. Supplier Information:
 - 1.1.5.1. BioSpectra has several approved suppliers and manufacturers managed in accordance with the Supplier, Manufacturer, and Service Provider Qualification Master Plan.
 - 1.2. **Compliance Details:**
 - 1.2.1. BioSpectra is committed to the quality, safety, identity, and purity of each of our products. BioSpectra provides the intended end use statements for each grade of material with every certificate of analysis issued. The intended end use statements for the Bio Pharma Grade for BioBuffer Solutions Product line, Bio Qualified Grade, and Bio Ultra Grade materials are available in the respective Certificate of Analysis for the applicable product.
- 2. CONTACT INFORMATION:**
- 2.1. <https://www.biospectra.us/about-us/commercial-marketing-team>