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BioBuffer Solutions Quality Management System Regulatory Packet

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

1.1. Facility Overview:

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 Facility Names and Addresses

Name	Address	Activity
Jacobsburg Road	1349 Jacobsburg Road Wind Gap, PA 18091	Commercial, IT, HR, & Finance Offices, Training Center, and Small Warehouse for applicable materials
Majestic Way	100 Majestic Way Bangor, PA 18013	Packaging and Release of Bio Ultra Grade and Bio Pharma Grade for BioBuffer Solutions Product Line Materials. Head Corporate Offices: Administration, Regulatory Affairs, Quality Assurance & Quality Control[1]
Rockdale Lane	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]
Supply Chain Center	51 North 3rd 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 allows for customer audits as required by the customer and as appropriate for the scope of materials purchased. Access to the raw material supply chain is also available. Each customer audit provides a general overview of processing information and facility operations.

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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 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 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 which houses office and warehousing space. The warehouse consists of multiple push-back racking systems with a total of 252 rack positions and additional pallet positions designated on the warehouse floor. This facility is the Corporate Center with office locations for Commercial, IT, Human Development, and Finance. Additionally, this facility is the training center and Security Headquarters. The Corporate Center also includes warehousing space for storage of raw materials, components, manufacturing equipment (in storage), and facilities supplies in accordance with cGMP guidelines. There are no products currently manufactured at this site.

1.1.3.1.4. In 2023, BioSpectra opened the Supply Chain Center in Stroudsburg PA, which houses office 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.

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1.1.3.2. Facility Size and Composition

1.1.3.2.1. The BioSpectra Majestic Way 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 the BioSpectra Bangor Site Quality Overview DCN: BSI-SOP-0218.

1.1.3.2.2. There are multiple processing rooms, packaging rooms, and drying rooms within BioSpectra's Rockdale Lane 25,000 square foot facility, as well as a warehouse with a push-back racking system, and a Quality Control Laboratory. Detailed site information is available in the BioSpectra Stroudsburg Site Quality Overview DCN: BSI-SOP-0078.

1.1.3.2.3. The BioSpectra Jacobsburg Road facility is 25,000 square feet. Detailed site information is available in the BioSpectra Wind Gap Site Quality Overview DCN: BSI-SOP-0425.

1.1.3.2.4. The BioSpectra 3rd Street Supply Chain Center is approximately 52,000 square feet. Detailed site information is available in the BioSpectra Supply Chain Center Stroudsburg Site Quality Overview 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 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 Ultra Grade and Bio Pharma Grade for BioBuffer Solutions Product line 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.

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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, and Bio Ultra Grade materials are stated below.

1.2.1.1. Bio Pharma Grade for BioBuffer Solutions Product line

1.2.1.1.1. Bio Pharma Grade for BioBuffer Solutions Product Line is suitable for use as a process chemical. It is GMP manufactured by the approved supplier in accordance with the approved supplier's Declared guidance or Standard stated by the supplier and accepted by BioSpectra as the certified management system. The Bio Pharma Grade for BioBuffer Solutions Product Line material is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

1.2.1.2. Bio Ultra Grade

1.2.1.2.1. Bio Ultra Grade Material is suitable for use as a process chemical. Bio Ultra Grade material is not suitable to be used as an Excipient, Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

2. CONTACT INFORMATION:

2.1. https://www.biospectra.us/about-us/commercial-marketing-team