



# BIOSPECTRA

## BioSpectra

Presentation for:

### KSE Scientific

November 10<sup>th</sup> 2022

Bangor, PA

Virtual cGMP Audit



# Pre-Audit Agenda

BioSpectra Mission Statement

Stroudsburg, PA Facility Diagram

Bangor, PA Facility Diagram

Wind gap, PA Facility Diagram

Facility Registration

BioSpectra Regulatory Inspection History

BioSpectra Quality Management

BioSpectra Regulatory Support



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# BioSpectra Mission and Vision

## Mission

To manufacture the **highest quality** Pharmaceutical ingredients under the supervision of the **most rigorous** quality system while upholding the **most stringent** compliance standards

## Vision

A world with safe & effective drugs that deliver consistent, reliable therapeutic effect with every dose

## Values

Quality / Integrity / Respect

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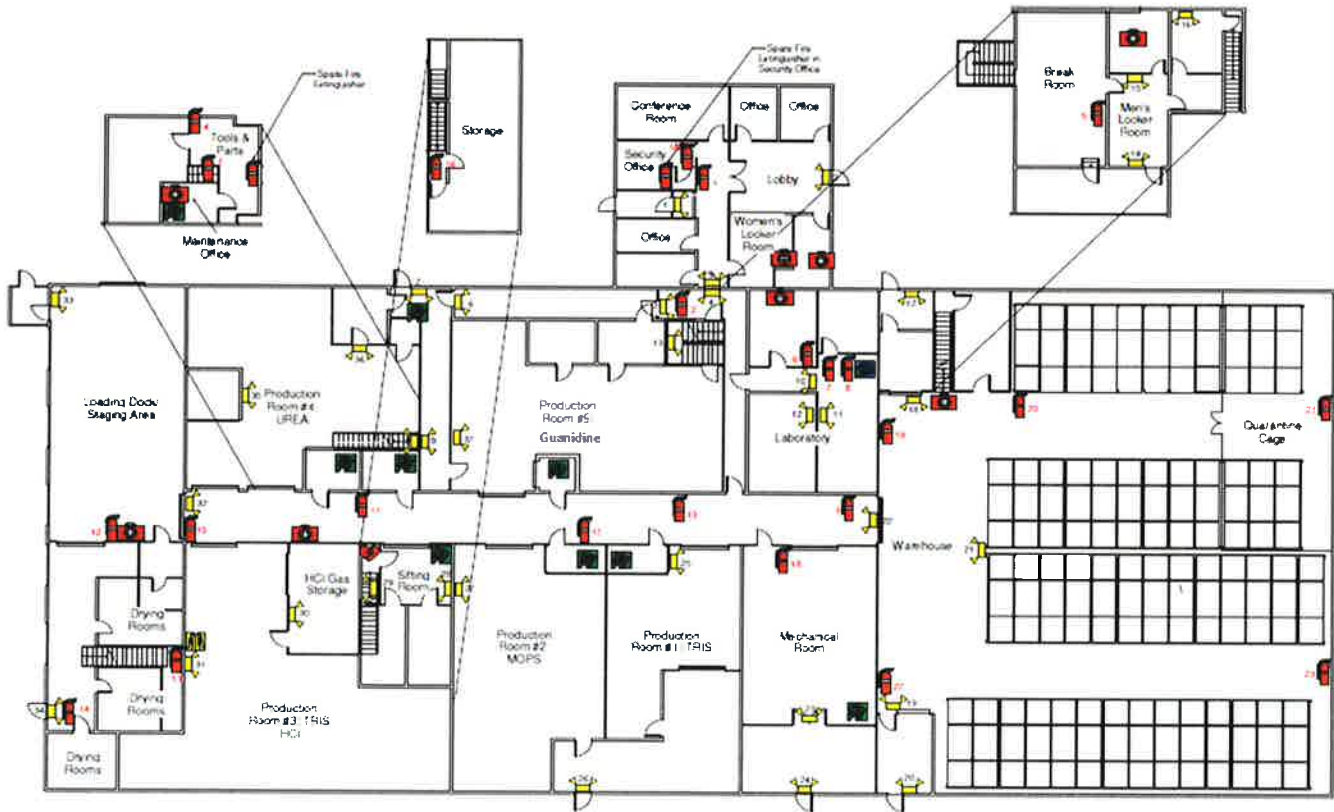
# Stroudsburg Facility



Stroudsburg, PA / 25,000 Sq. Ft.  
Life Science Intermediates & Excipients

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# Stroudsburg, PA Facility Layout





# Bangor, PA Facility



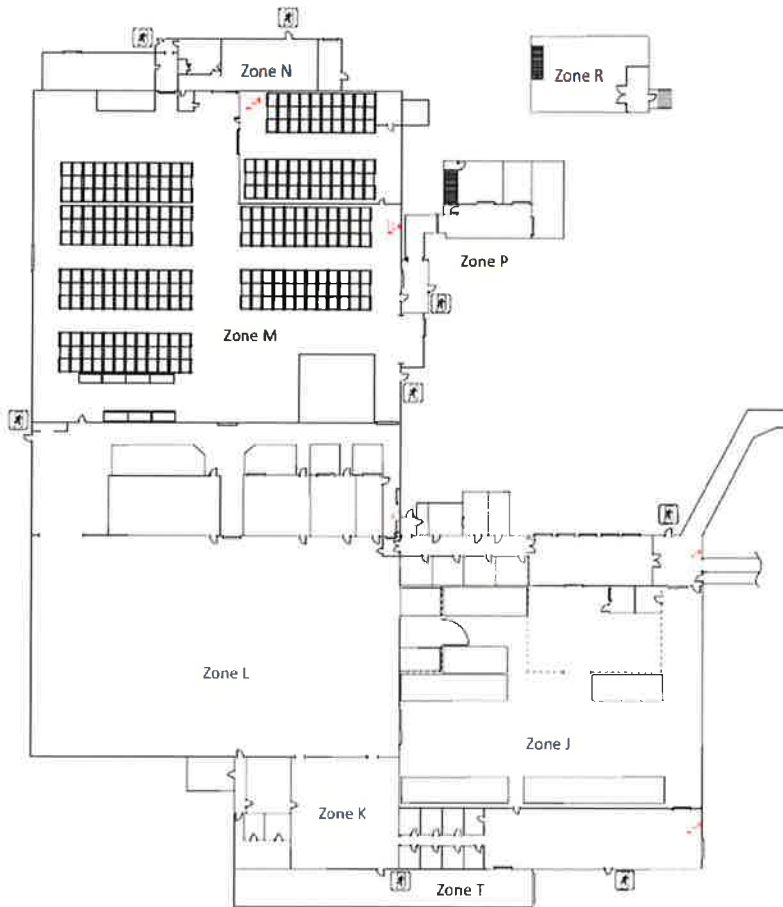
Bangor, PA / 150,000 Sq. Ft.

Pharmaceutical Excipients

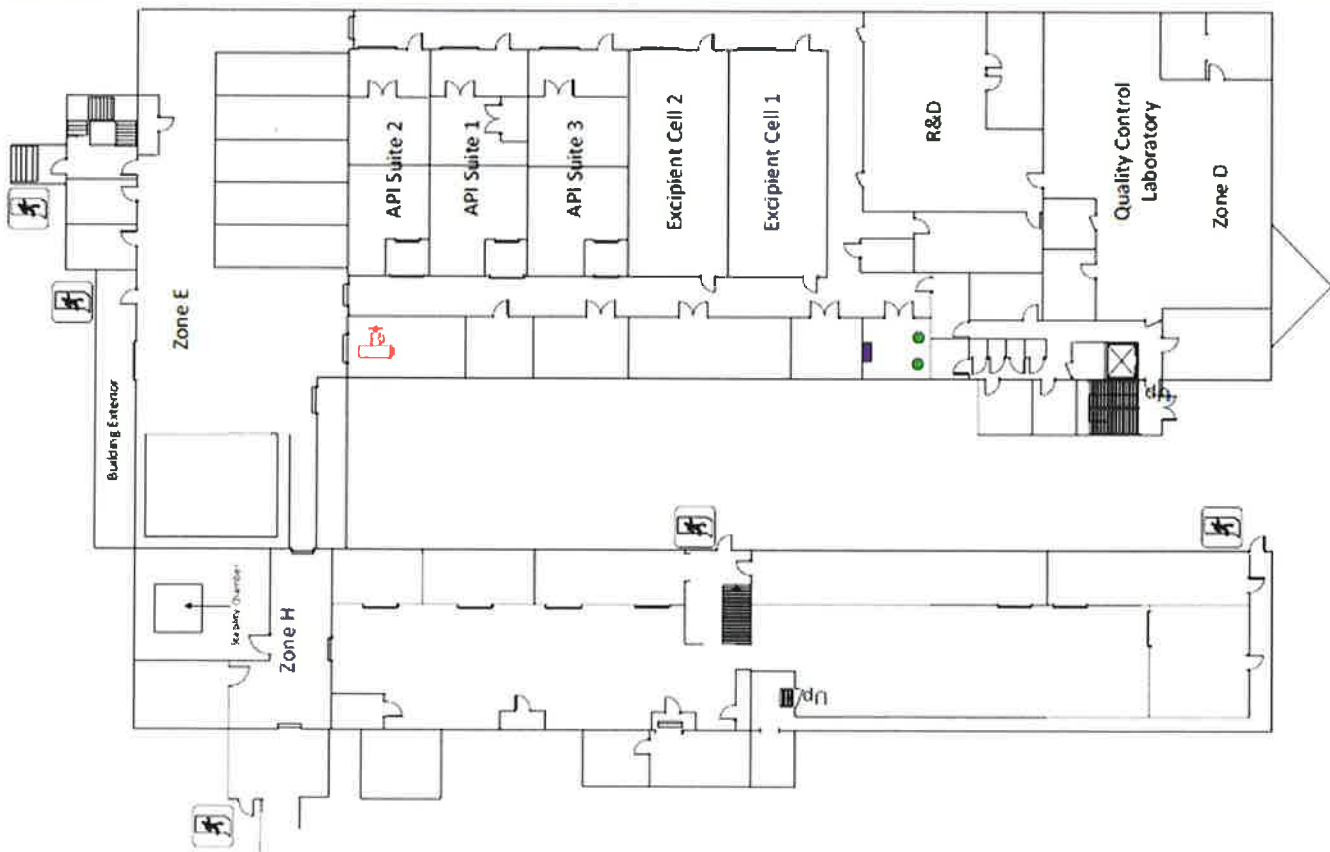
Active Pharmaceutical Ingredients and Custom Manufacturing

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# Bangor, PA Facility Layout



# Bangor, PA Facility Layout





# Wind Gap Facility



Wind Gap, PA / 25,000 Sq. Ft.  
Offices and Warehouse Area

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# Wind Gap, PA Facility Layout



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# Facility Registration

- ❖ BioSpectra's Stroudsburg and Bangor, PA Facilities are registered with the US FDA
- ❖ There are no third-party GMP Certifications at this time
  - ❖ <https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm>

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
BioSpectra	3010476065	042724830	ANALYSIS; API MANUFACTURE;	100 Majestic Way, Bangor, Pennsylvania (PA) 18013, United States (USA)	12/31/2022
BioSpectra Inc.	3003380159	957030729	ANALYSIS; MANUFACTURE;	1474 Rockdale Lane, Stroudsburg, Pennsylvania (PA) 18360, United States (USA)	12/31/2022

<https://www.biospectra.us/about-us/company-profile>

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# Regulatory Inspection History

**FDA**

**U.S. FOOD & DRUG  
ADMINISTRATION**

BioSpectra's Bangor, PA facility

January 2016, August 2017, April 2021, and May 2021 with no 483

BioSpectra's Stroudsburg, PA Facility

August 2010 with no 483

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# BioSpectra Quality Overview

Developed and continues to evolve using the guidance documents from ICH

- Key Components and Systems
  - Quality Manual
  - Personnel Qualification
  - Facility/Systems Management
  - Data Integrity
  - Document Management
  - Validated Manufacturing Systems
  - Qualified Equipment and Utilities
  - Analytical Method Validation or Verification
  - Stability Testing Program
  - Change Control
  - Non-Conformance Management



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# BioSpectra Regulatory Program

## cGMP Product Support

- ✓ Global Regulatory Compliance
- ✓ Drug Master File/Veterinary Master File
- ✓ Active Substance Master File
- ✓ Certificate of Pharmaceutical Product
- ✓ Drug Establishment Registration
- ✓ Drug Listing
- ✓ REACH Registration
- ✓ BioSpectra Product Statements
- ✓ Regulatory Packets
- ✓ Questionnaires
- ✓ Audit/Inspection Hosting
- ✓ Additional Support Materials

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# BioSpectra: Your Partner for Purity, Regulatory Compliance and GMP Product Development

US Manufactured Premium, Bulk, GMP Fine Chemicals



*We look forward to your upcoming audit*



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