BIOSPECTRA

Premium Pharmaceutical Ingredients

Corporate Overview

Bulk cGMP Fine Chemical Manufacturers for Pharmaceutical Processes

Revision 9.9
03/18/2024

Corporate Vision, Mission, Values

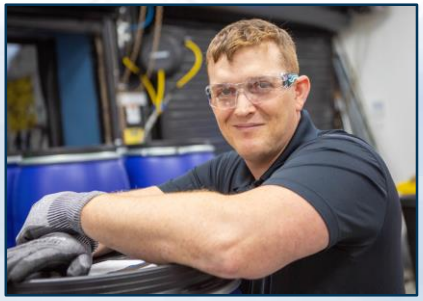
People Matter

Vision

Committed to be a **leading manufacturer** of pharmaceutical ingredients that support **safe** drugs and vaccines that deliver **consistent, reliable therapeutic effect** with every dose

Mission

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



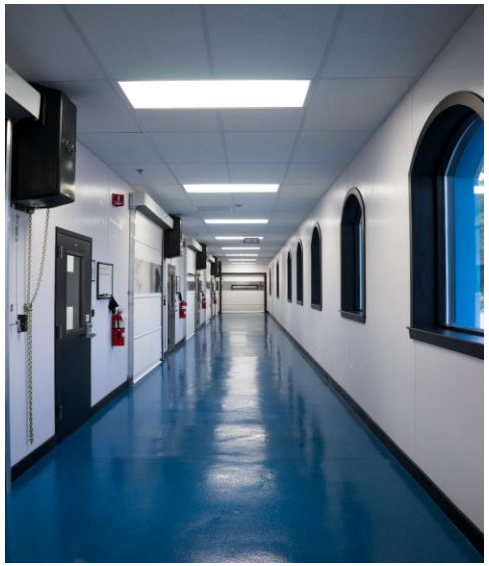
Values

Honesty / Integrity / Respect / Safety / Sustainability

BioSpectra rigorously upholds uncompromised standards because… **"people matter"**

Corporate Profile

BIOSPECTRA™ is a family of companies under common (private) ownership that incudes Dextran Products (Ontario, Canada), BioDevelopment Inc. (Rensselaer, NY) and BioSpectra Inc., located in Stroudsburg, Bangor and Wind Gap, PA, USA.



In addition to these seven manufacturing and storage facilities in North America, BioSpectra Inc. oversees contract R&D facilities in Mumbai, India and a cGMP manufacturing plant in Sarigam, India as well as several manufacturing sites in China for chemical raw materials. All Finished Products are fully tested and packaged under cGMP conditions if not purified and/or synthesized in the US.

As a true, global organization with US based manufacturing, packaging and testing of all its products, BioSpectra Inc. offers a unique range of products to the Pharmaceutical industry that includes Actives, Excipients, GMP Process Chemicals & Bulk GMP Buffers and Solutions

Our focus is small molecule synthesis and true, phase change multistep purification for both traditional and bio-pharmaceutical applications, coupled with robust Supply Chain Security and Sustainability programs.

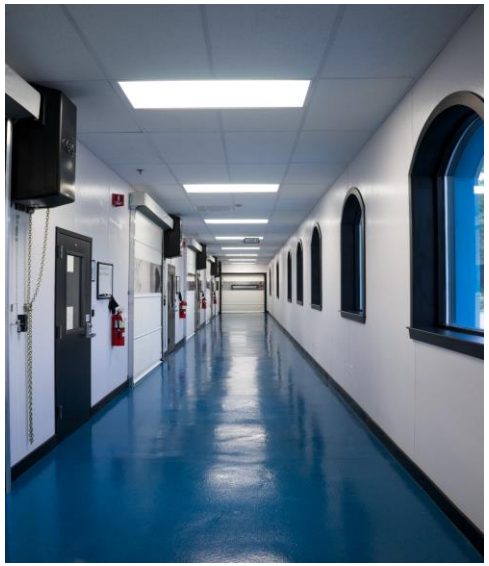
Corporate Profile

Our services include Contract GMP product development coupled with ongoing commercial manufacturing and regulatory support up to and including DMF submissions.

All our manufacturing processes are fully validated. Our cGMP Quality System & regulatory support package complies with USFDA, IPEC & ICHQ7 guidelines. Our onsite analytical testing capabilities include multi-compendial and custom specifications with full traceability and transparency of all raw materials and sources.

Our commitment is to quality, compliance and true, cGMP manufacturing with unparalleled regulatory & technical support, operating under the most rigorous quality system while holding to the most stringent regulatory demands.

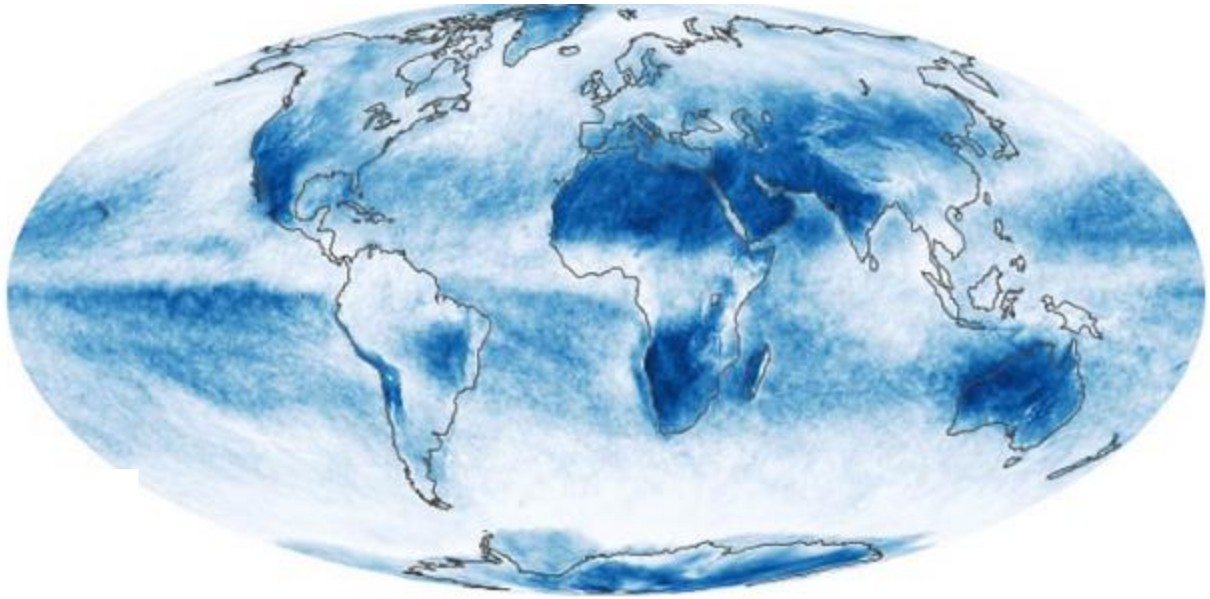
Our goal is to be a valued partner in the secure supply chain and the solution to key ingredient issues our customers may have.



Sustainability and Supply Chain Security

Sustainability

BioSpectra is committed to the ideals of Sustainability and has launched a three-year thirty million dollar capital investment program to help achieve these goals. We are currently working on an external program that is available on our website. We are registered with ECOVADIS, currently achieving Bronze Status.



Supply Chain Security

BioSpectra is fundamentally committed to the ideals of Supply Chain Security. We prosecute an aggressive raw material supplier qualification program. Our Quality Program is posted and available on our website. We take very seriously the global supply-chain situation assessing and reacting to threats with real solutions. BioSpectra Inc, continues it's long history of sourcing and qualifying raw material so as not to be sole sourced on any key chemical that originates from only one country.

Corporate Commitment to True GMP 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
- Manufactured Exclusively in the USA

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.

PREMIUM PHARMACEUTICAL INGREDIENTS

MANUFACTURED EXCLUSIVELY IN THE USA

GMP Product Categories

- GMP Process Chemicals
- Bulk Custom Solutions
- Bulk Biological Buffers
- Functional Excipients
- Active Ingredients

GMP Custom Services

- GMP Product Development
- Small Molecule Synthesis
- Purification of Excipients
- Scale-Up, Bench to Bulk
- Regulatory (product) Support

Corporate Values & Commitments

- True GMP Product Claim-Always Synthesized and/or Purified, and not simply tested and repackaged
- Reliable, Consistent, Uniform, Quality-Based
- Authentic, Secure Supply Chains - 100% Traceable Raw Materials from Qualified Sources
- Fully Validated GMP Mfg. Systems & Qualified Equipment

Comprehensive Quality & Regulatory System

- FDA Registered & Inspected
- Full Transparency in Documentation
- Stringent Quality Program & Controls
- Document Support- DMF Submissions
- Rigorous compliance to Global Standards
- FDA & ICH Q7 Guidance for Drug Substances
- State-of-the-art Instrumentation & Laboratories
- Culture of Embracing Evolving Regulatory Demands





Comprehensive Quality & Regulatory Program

Operating a Stringent Quality & Regulatory Program

- Upholding Global Regulatory Requirements
- Testing to the Highest Quality Standards
- Applying Rigorous Oversight & Controls

- **Global GMP Standards** Meeting US-FDA, ICH Q7 & IPEC Guidelines
- **Comprehensive Internal Auditing** of all Manufacturing Processes
- **Regulatory Services** including Drug Master File Submissions
- **FDA Process Validation** for all GMP Manufacturing Systems
- **Complete Testing** of all Finished Manufactured Lots
- **On-site Quality Control Labs** Operating 24/7
- **Robust Preventive Maintenance Program**
- **State-of-the-art Instrumentation**
- **FDA Registered & Inspected**
- **Raw Materials:**
  - Qualified and Inspected Sources
  - 100% Authentic Traceability
  - Complete Testing

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 APIs and 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

GMP Support Package

GMP Support Package for all ICH-Q7 Level Products

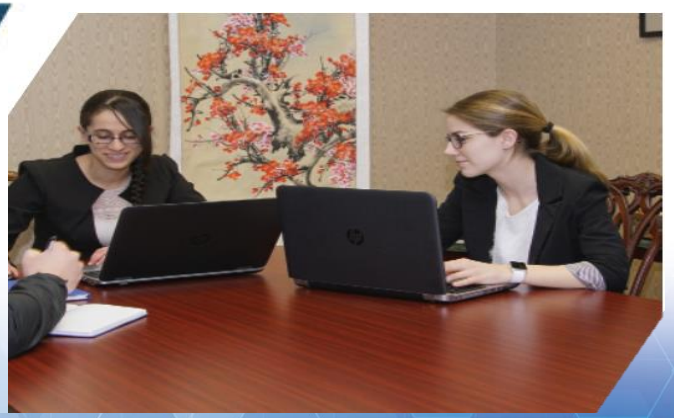
Analytical Support

- Analytical Method Validation
- Transfer of Analytical Methods
- Custom Analytical Methods and Specifications
- Bioburden and Endotoxin Testing
- Complete Impurity Profile
- Elemental Impurities
- Residual Solvents

Development Support

- Stability Study
- Custom GMP Services as needed
- Custom Labeling and Packaging
- Manufacture of API Registration Batches
- Drug Master File submission
- Letter of Authorization
- Efficient Development Timeline
- High-touch management of your project

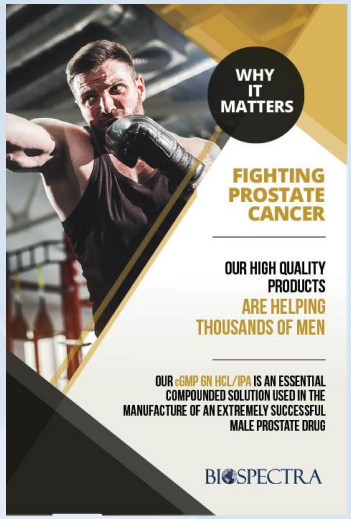
Ongoing Support - Post FDA Approval

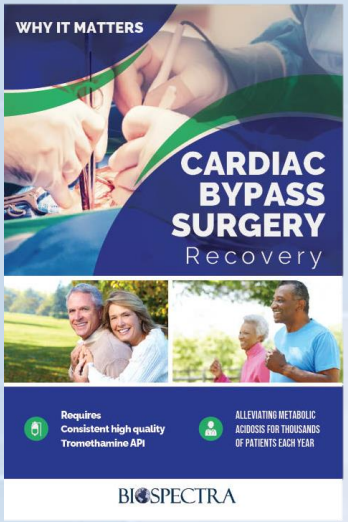


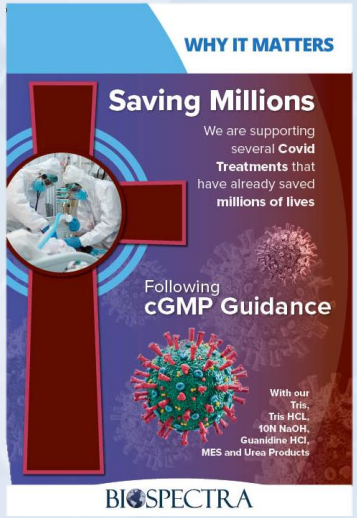
- Commercial Manufacturing of your API
- On Site Audits
- Annual Product Review
- Management of Change
- Post Submission Change Notification
- Full support through the life of your product

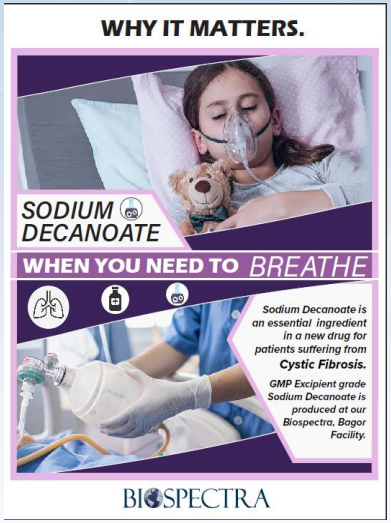
WHY IT MATTERS

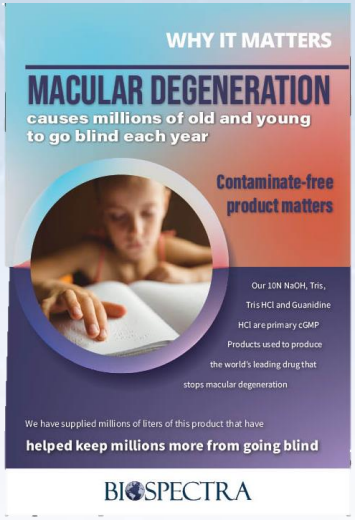
Our Internal Marketing Campaign

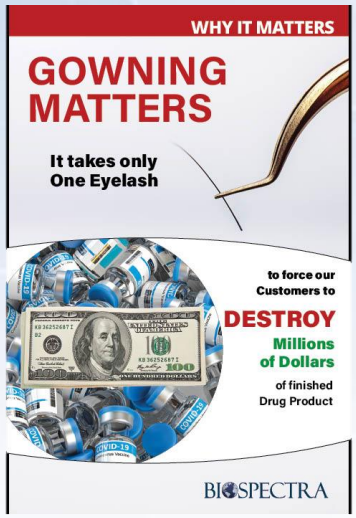


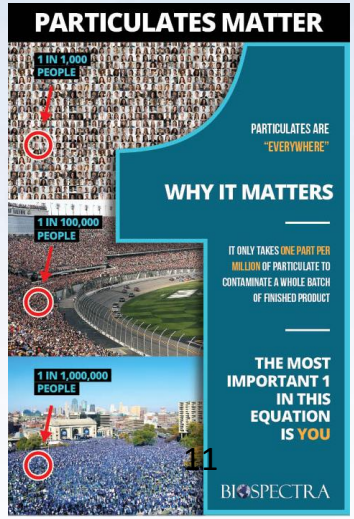












Our Focus

Premium Pharmaceutical Ingredients

1. Solving Key Ingredient Needs

a) Launching New Commercial Products
b) Full cGMP Product Development
c) Synthesis, Purification & Technical Support

2. Upgrading Your Supply Chain

Facilitating the move to higher levels of:

a) Quality
b) Security
c) Regulatory Compliance

3. Commercial Volumes

a) Scalable
b) Sustainable
c) Supported through your Product Lifecycle

CRITICAL INGREDIENT ISSUES?

Purity?

Security?

Source?

Scale?

Synthesis?

Specifications?

Compliance Standard?

Critical Manufacturing & Ingredient Issues:

Inconsistencies from lot to lot / Insufficient purity levels / Contamination / Need for "real" GMP mfg. / Non-dedicated facilities / Incomplete testing & Documentation deficiencies / Absence of true traceability / High Microbial & Endotoxin levels / Recalled or scrap product / Need for custom specifications / Need for higher levels of quality and compliance

Supply Chain Security Issues:

Availability / Reliability & trustworthiness / Distance / Safety stock / Manufacturing interruptions / Authentic chain of custody

Regulatory Issues:

IPEC, ICH, GMP, FDA, EMA Compliance issues / Need for global specifications / Need for true validated manufacturing processes / Requirement for a higher compliant raw material

Mitigation Experts

Premium Pharmaceutical Ingredients

SOLUTION

- **True GMP Process**
- **Actual Purification**
- **Dedicated Facilities**
- **Base Synthesis of raw materials**
- **US Manufactured GMP Products**
- **True Quality-Based Manufacturing**
- **Total Quality Program: QC / QA / Regulatory**
- **100% Reliable Traceability of all raw materials**
- **Proven record of adherence to GMP, IPEC, ICH Guidelines**

BioSpectra represents consistent high quality, uniformly manufactured pharmaceutical ingredients.

Always synthesized, purified or compounded under true GMP standards.

Always manufactured at the appropriate specifications and compliance levels for the intended use in the final drug product.

Business Model

Exclusive to Bio Pharma and Traditional Pharma

Stroudsburg PA

GMP Buffers

Large Commercial Volumes

EXAMPLE

TRIS, TRIS HCl, MOPS, Guanidine HCl

Bangor PA

GMP EXCIPIENTS & PROCESS CHEMICALS

Mid-Large Comm. Volumes

EXAMPLE

Trehalose Dihydrate, Galactose, Na- Decanoate, Uridine, MES, HEPES, 10N NaOH, Buffer Solutions

Rensselaer NY

SMALL MOLECULE, GMP API's & EXCIPIENTS

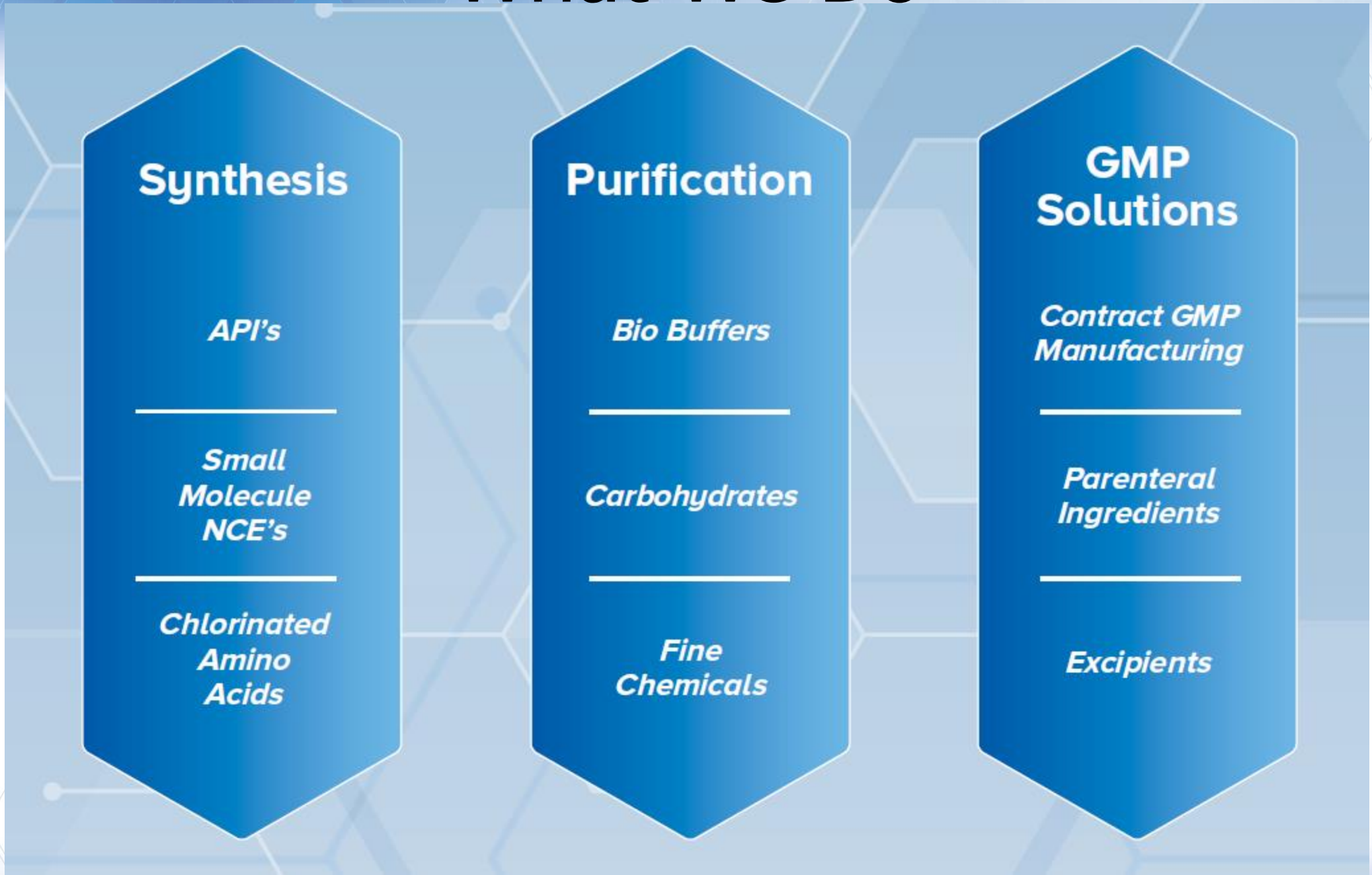
Small Commercial Volumes

EXAMPLE

Uracil, Dextran Sulfate 8000, L-Hist., Mono-Mono, Hydrolyzed PVA API's: Uridine & Cytidine

BioSpectra sells buffers, denaturants and other products into large molecule BioPharma, but also manufactures GMP process chemicals, Excipients and API products for traditional, synthetically derived, small molecule, Pharma.

What We Do


Synthesis
API's
Small Molecule NCE's
Chlorinated Amino Acids
Purification
Bio Buffers
Carbohydrates
Fine Chemicals
GMP Solutions
Contract GMP Manufacturing
Parenteral Ingredients
Excipients

What We Do


When You Absolutely Need FULL cGMP!
BIOSPECTRA
Premium Pharmaceutical Ingredients
• Full cGMP Development
• Synthesis & Purification
• Small & Large Volumes
• APIs / NCEs
• 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)*
Bio Active & Bio Active 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**

Facility Profile

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

Overall

Facilities: 343,000 sq. ft. 52+ Acres
5 Campuses in PA and NY
Staff: 300+ Employees
More Info: www.biospectra.us

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

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

Bio Development Inc
R&D Kilo-Scale GMP Manufacturing
Address: 11 University Place, Rensselaer, NY 1214
Staff: Growing| Site: 10,000+sq. ft.

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

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**: 1 kg to 20,000 kg
- **Overall Operational Capacity**: Thousands of Metric Tons per Year

cGMP Warehouse Complex

51 North 3rd Street Stroudsburg, PA 18360

BIOSPECTRA

Premium Pharmaceutical Ingredients

PURIFIED - cGMP
BIOLOGICAL BUFFERS

Exclusively Manufactured in the USA

Made in the USA

TROMETHAMINE, TRIS HCl,

GUANIDINE HCl, UREA,

HEPES, MES, MOPS

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

STRINGENT QUALITY PROGRAM

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

BIOSPECTRA
Premium Pharmaceutical Ingredients

GMP BULK SOLUTIONS

Exclusively Manufactured in the USA

Made in the USA

NaOH 10N, 5N, 2N, 1N & 0.1N
Custom Buffer Blends
Guanidine HCl 6M
IPA/HCl 6M
NaCl 5M
Urea 6M

- Made w/ WFI
- Sterile Filtered
- Class 7 Mfg. Suites
- Sterile Single-use Pkg
- Custom Compendial Specs

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

BIOSPECTRA

Premium Pharmaceutical Ingredients

CONTRACT cGMP MANUFACTURING

ACTIVES | EXCIPIENTS | PROCESS CHEMICALS

Made in the USA

Synthesis
Compounding
Purification

Aqueous
Solvent
Alcohol

- Small Molecules
- Custom Solutions
- Functional Excipients
- Scale Up - Bench to Bulk
- Small & Large Commercial Qty's

STRINGENT QUALITY PROGRAM

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

BIOSPECTRA

Premium Pharmaceutical Ingredients

ICH Q7 PARENTERAL INGREDIENTS

LOW BIOBURDEN – LOW ENDOTOXIN – HIGH PURITY

Rigorous Quality System

Validated GMP Process

State-of-the-art facility

- APIs
- BUFFERS
- EXCIPIENTS
- AMINO ACIDS
- CARBOHYDRATES
- SMALL MOLECULES

STRINGENT QUALITY PROGRAM

FDA Registered and Inspected / US GMP / ICH Q7

BIOSPECTRA

Premium Pharmaceutical Ingredients

Functional Small Molecules

Kilo-Scale / cGMP

Located In Rensselaer NY & Bangor PA, USA

Eight Multipurpose Suites

Wide Range of Synthesis

5-15 Kg Batch Sizes

- Orphan Drug Support
- Functional Small Molecules
- Parenteral / Transdermal / Oral Application

STRINGENT QUALITY PROGRAM

FDA Registered and Inspected / US GMP / ICH Q7

Summary List of Products

2MEA (Cysteamine Hydrochloride) - GMP, Excipient Grade-Low Bioburden, Low Endotoxin (LBLE)

BIS-TRIS - GMP, LBLE, Bio Excipient Grade

L-Cystine Dihydrochloride - GMP, Pharma Process Grade

Cysteamine Hydrochloride - API Grade

Dextran Sulfate Sodium 8000 MW - GMP, Pharma Process Grade

Galactose - GMP Excipient Grade - Low Bioburden, Low, Endotoxin (LBLE), Low Elemental Impuritites (LEI), Multicompendial

Guanidine HCl - GMP, Pharma Process, and Excipient Grades

Guanidine HCl, 6M Solution - GMP, Pharma Process, and Excipient Grades

Guanidine Thiocyanate - GMP, Pharma Process Grade

HEPES Free Acid - GMP, Pharma Process, and Excipient Grades

HCl in IPA (6N) - GMP, Pharma Process Grade

MES Monohydrate - GMP, Pharma Process, and Excipient Grades

MOPS Free Acid - GMP, Pharma Process, and Excipient Grades

Potassium Bromide (KBr) - GMP, API Grade

Sodium Chloride 5N - GMP, Sterile Filtered, made with WFI, BPC, Excipient Grade

Sodium Decanoate - GMP, Functional Excipient for Parenteral Applications

Sodium Hydroxide 10N - GMP <5 ppm Cl, made with WFI, BET Tested

Sodium Hydroxide, 25%, 5N, 2N, 1N, 0.5N, 0.1N - GMP, made with WFI, Low Chloride

Trehalose Dihydrate - GMP, Excipient Grade - Low Bioburder, Low Endotoxin (LBLE), Low Elemental Impurites (LEI) - Multicompendial

Tris HCl - GMP, Pharma Process, Excipient, and LBLE Grades

Tris / Tromethamine - GMP, Pharam Process, Excipient, LBLE and API Grades - Multicompendial

Uracil - GMP, Pharma Process Grade

Urea, 6M Solution - GMP, Bio Excipient Grade - made with WFI

Uridine - GMP, Bio Excipient Grade

Water for Injection (WFI) - GMP, Multicompendial, USP, EP, JP

Product Overview

Current & Future Programs and Projects

Nitrogen Based Electron Pulse Spray Dry Technology

- ✓ Expanding Spray Dry Technology for various buffers and other Chlorinated products
- ✓ Offers efficiency in production
- ✓ Lowers exposure during drying process
- ✓ Reduced human “touch points”
- ✓ Creates less dense, more free-flowing material

Current & Future Programs and Projects Continued

1. **Small Molecule R&D and Synthetic Capabilities:**
   a. **Rensselaer NY**
   b. **Mumbai India**

2. **Expanded Advanced Instrumental Capabilities: Elemental Analysis (ICP-MS and ICP-OES) and Particle Identification (Electron Microscopy)**

3. **Expanded GMP Carbohydrate Polymer Line (Dextrans)**

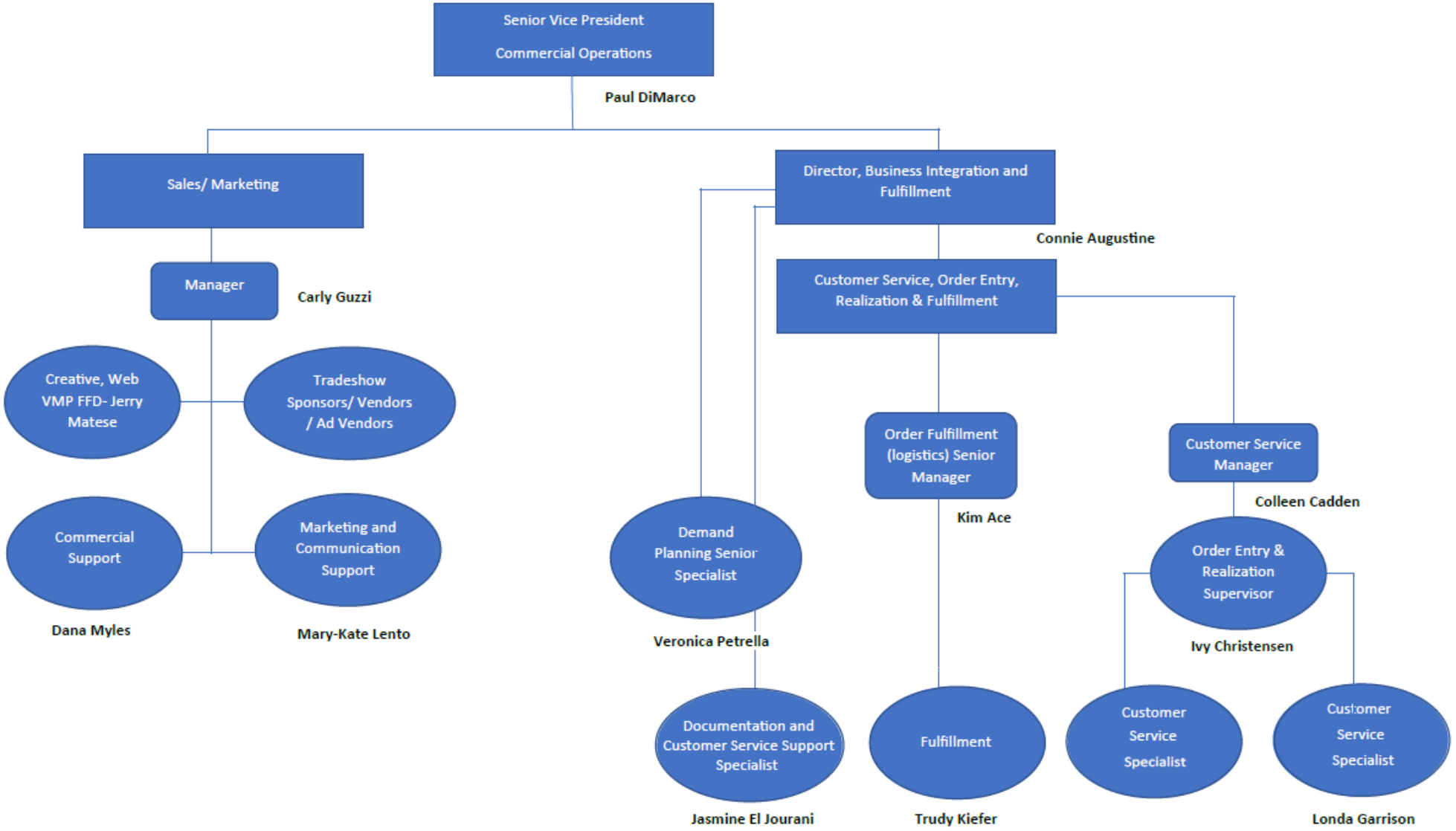
4. **Supply Chain Security: Raw material synthetic platform expansion for pilot and commercial scale (Sarigam, Gujarat, India)**

5. **Expanded automated packaging facility and wet labs (Monroe Plaza Complex, Stroudsburg PA)**

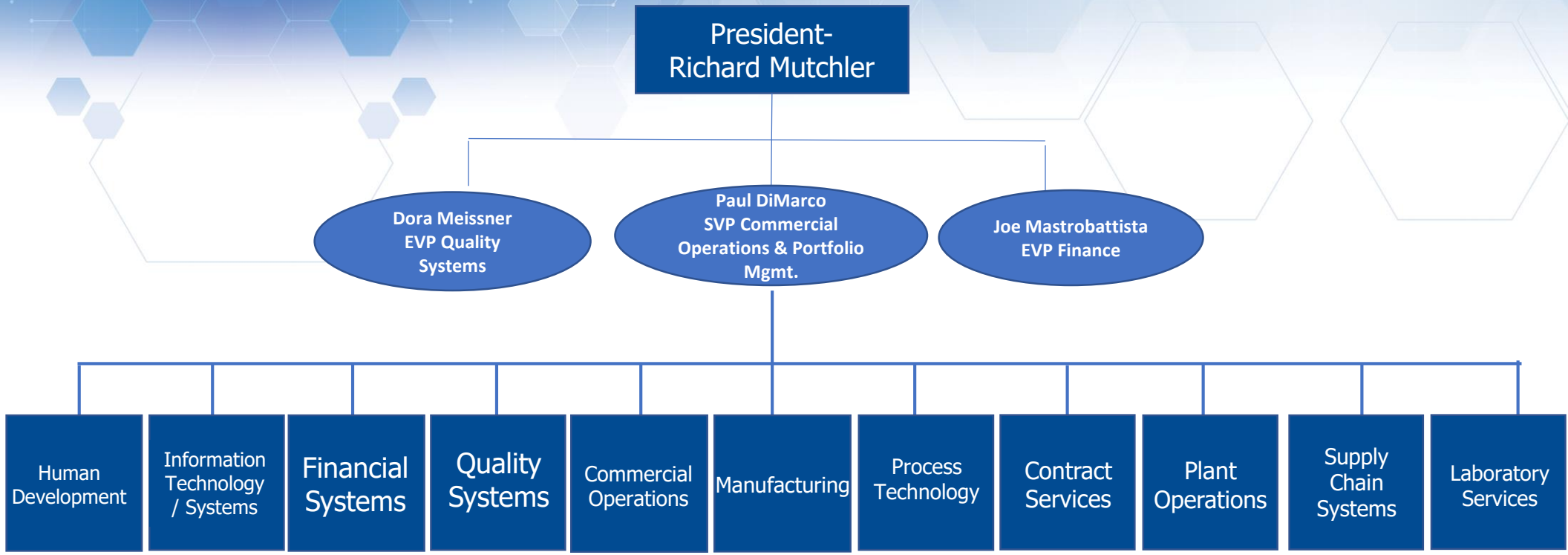
6. **Sustainability Program – three year program to address key sustainability issues**

7. **Virtual Market Place and future e-commerce site**

Commercial Operations



Corporate Organizational Chart



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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
- A company investing in future technology

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