

# BIOSPECTRA

US Manufactured Premium Pharmaceutical Ingredients

Reshoring and Onshoring  
**Premium Pharmaceutical Ingredients**  
for over 25 years

Rev 5.91 08.22.2020

# Onshoring and Reshoring US Based Drug Manufacturing

## US Manufactured Premium Pharmaceutical Ingredients



- **Reshoring:** bring manufacturing back to the USA
- **Onshoring:** bring manufacturing to the USA that is only being done overseas.
- **Creates** secure Supply Chains for critical drugs.
- **Reduces** dependency on foreign manufacturers at risk.
- **Providing** sustainable US economic expansion.

# Secure Drug Supply Chains - Insights and Perspective

## US Manufactured Premium Pharmaceutical Ingredients

- With **80-90%** of all **drug ingredients** being imported today, the crisis for critical drug supply is **far greater** than most people realize. **Solving** that problem, however, will have a **tremendously positive economic impact!**
- More than **100 site visits** with foreign chemical manufacturers has **provided** BioSpectra with a **unique understanding** of the **risks** and the **delicate balance** in the supply of offshore chemicals – many of which are only made overseas.
- Consequently, the **BioSpectra model** presents the **best path** to provide **secure and sustainable supply chains** for all US drugs and drug ingredient manufacturing.



**BIO SPECTRA**  
Premium Pharmaceutical Ingredients

### ACTIVE PHARMCEUTICAL INGREDIENTS

Exclusively Manufactured in the USA

- Parenteral / Transdermal / Oral Applications
- Full Development & Compliance Support
- Orphan Drug Substance Quantities
- FDA Registered & Inspected
- Generic and Novel APIs

- Small Molecule
- Small Volume Support
- Chlorinations / Chloride Compounds
- Inorganic & Boutique Organic Synthesis
- Low Endotoxin - Low Bioburden Demands

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



**BIO SPECTRA**  
Premium Pharmaceutical Ingredients

### PREMIUM PHARMA INGREDIENTS

Exclusively Manufactured in the USA


COMMERCIAL PRODUCT CATEGORIES

- Bulk, GMP Processed Buffers & Disintegrants
- GMP Process Chemicals and Solutions
- Excipients and Key Ingredients
- GMP Custom Products
- Active Substances

CUSTOM PRODUCTS & SERVICES

- Complete GMP Product Development
- Purification of Key Ingredients
- Small Molecule Synthesis
- API Development and Mfg
- GMP Solutions & Solvents

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



**BIO SPECTRA**  
Premium Pharmaceutical Ingredients

### CONTRACT GMP MANUFACTURING

ACTIVES | EXCIPIENTS | PROCESS CHEMICALS

Synthesis  
Compounding  
Purification

Aqueous  
Solvents  
Alcohol

- Purification
- GMP Buffer Solutions
- Scale from Bench to Bulk
- Full GMP Product Development
- Small Molecule Organic Synthesis
- Custom Testing, Labeling & Packaging
- Unique Component Solvents & Solutions

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



**BIO SPECTRA**  
Premium Pharmaceutical Ingredients

### PARENTERAL DRUG INGREDIENTS

LOW BIOBURDEN - LOW ENDOTOXIN - HIGH PURITY

- Stringent Environmental Controls
- Validated GMP Processes
- Rigorous Quality System
- State-of-the-art Facility
- Made in the USA

- Buffers
- Carbohydrates
- Excipients & Active Grades
- Full GMP Product Development
- Contract Synthesis and Purification

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



**BIO SPECTRA**  
Premium Pharmaceutical Ingredients

### GMP BIOLOGICAL BUFFERS

Exclusively Manufactured in the USA

- GMP Process, Excipient and API Grades
- Multi-Component Specifications
- Multi-Level Purification
- Free Flowing Grades

- Low BET Grades
- Custom GMP Solutions
- USFDA Registered Facilities
- US GMP, IPEC & ICH Q7 Compliant

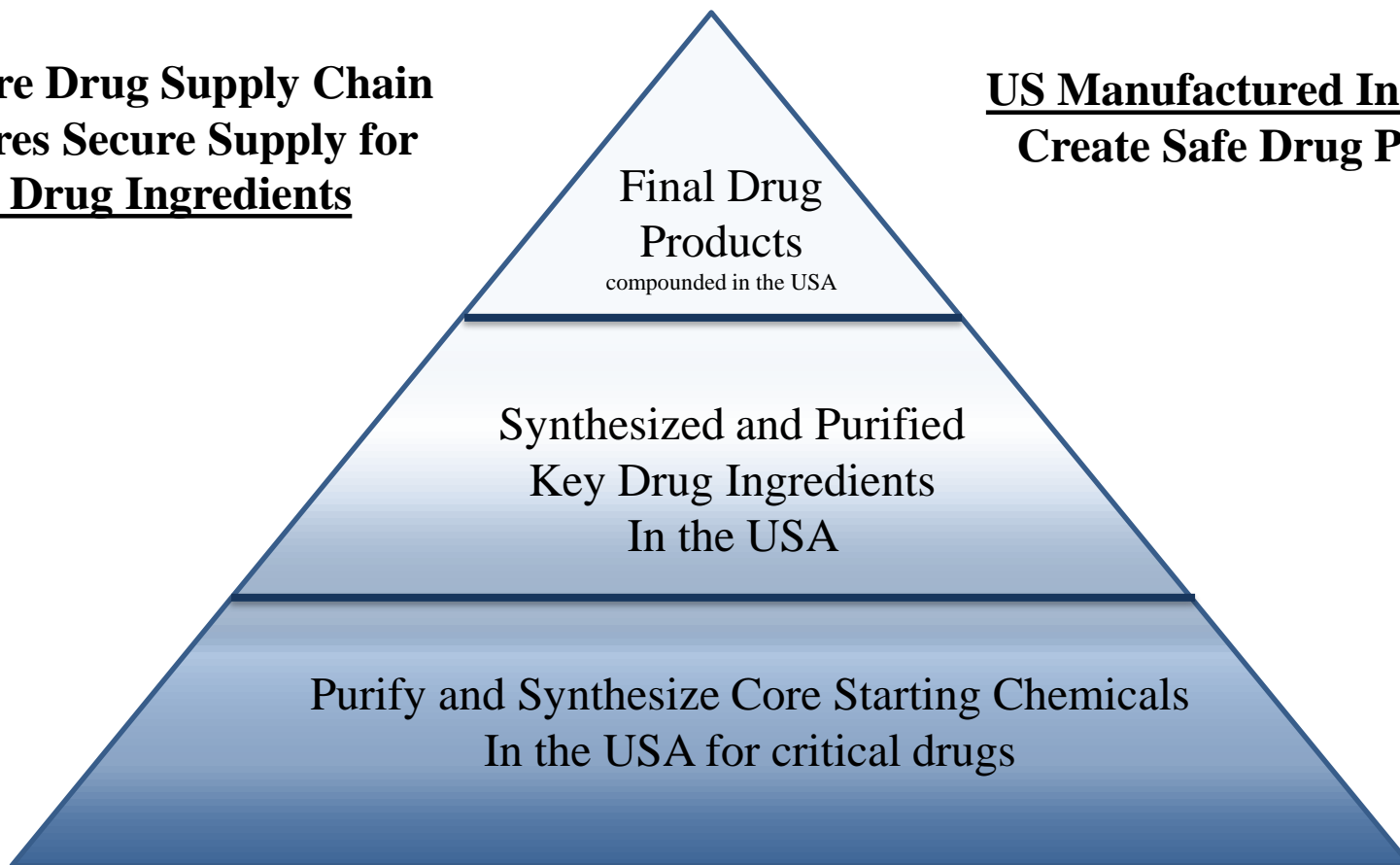
STRINGENT QUALITY PROGRAM  
FDA Registered and Inspected / US GMP / IPEC / ICH Q7 Guidelines

# Vertically Integrated US Based Drug Manufacturing For Critical Drug Products

US Manufactured Premium Pharmaceutical Ingredients

**A Secure Drug Supply Chain  
Requires Secure Supply for  
All Drug Ingredients**

**US Manufactured Ingredients  
Create Safe Drug Products**



# Benefits to Onshoring/ Reshoring Drug Supply Chains

## US Manufactured Premium Pharmaceutical Ingredients

- **Significant, Direct Economic Impact:**
  - Economic expansion in manufacturing of over **\$500bn** per year.
  - Job Creation: estimated at 800,000 – direct, industry-related fulltime jobs.
- **Significant, Indirect Economic Impact:**
  - Manufacturing supplies and raw materials.
  - Manufacturing equipment and instrumentation.
  - Consumption of vast amounts of resources for employees.



# Further Benefits of Onshoring/ Reshoring

## US Manufactured Premium Pharmaceutical Ingredients



- **Supports key federal initiatives for secure supply** of critical drugs while **reducing dependency** on high-risk foreign companies.
- **Ensures quality** of drug products and **patient safety**.
- **Drives advancements in technology and innovation** that will **keep America first** in drug development and manufacturing.

# Twenty-Five Years of Experience Onshoring & Reshoring

US Manufactured Premium Pharmaceutical Ingredients



- **Highly Experienced Team with Comprehensive Technical Knowledge:**
  - ✓ Chemical synthesis & purification.
  - ✓ Critical ingredient manufacturing.
  - ✓ cGMP / ICH Q7 / 21 CFR 210-211
- We provide **short-term security** and **suitability** of ingredients by **purifying offshore** chemicals.
- We provide **long-term security** by **synthesizing** our own versions of key ingredients when requested.

# BioSpectra: An Example of the Power of Private Business

## US Manufactured Premium Pharmaceutical Ingredients



- BioSpectra **quickly** develops new, key ingredients for drug formulations.
- Our success is based on our ability to **design** and **build** custom manufacturing **equipment** and **systems** for chemical synthesis and purification of a wide range of drug ingredients.
- Our private ownership allows us to take **calculated risks** to quickly **solve** critical problems in **time frames** atypical of other corporate environments.




# Proven Track Record – The BioSpectra Model

## US Manufactured Premium Pharmaceutical Ingredients

- A **proven track record** to serve as the **model** for reshoring across PA and the US.
- **Independent Progress:** All of our success with advanced systems, standards and innovations were accomplished without **any** support from government or outside investors.
- We **continue** to **develop** new processes and product opportunities **quickly** and **efficiently** based on three factors: our **culture**, **model** and **private** ownership.



# The Truth about Pharma Ingredients

Misconception	Reality	Solution
<b>All chemicals imported to the US are suitable for drug manufacturing</b>	Many chemicals coming overseas are <b>lower quality and not manufactured with the intent</b> for use in drug products	<b>These imported chemicals should be purified first</b> by a US company, ensuring their suitability
<b>It is cost effective to manage “lower-cost” offshore manufacturers</b>	It <b>costs more</b> to legitimately and effectively manage offshore suppliers	Managing legitimate US manufacturers like BioSpectra
<b>Onshoring/reshoring drug ingredients will raise drug prices</b>	<b>Raw materials</b> are a <b>small portion</b> of the overall <b>cost</b> of a final drug product	Costs can be <b>controlled by reshoring/onshoring</b> scale volumes coupled with process efficiencies
<b>Onshoring/reshoring will have a negative impact on our environment</b>	<b>Lack of environmental controls</b> in India and China are <b>destroying</b> our planet	The <b>technology is available</b> to manufacture all drug ingredients sustainably in the US
<b>Lower cost labor yields lower cost drugs</b>	<b>Lower cost labor</b> leads to <b>lower quality</b> standards at the expense of patient health	<b>Labor costs</b> are a <b>small portion</b> of the overall <b>cost</b> of manufacturing a final drug product
<b>The US lacks the knowledge to manufacture key raw materials</b>	<b>The US leads the world in new technology &amp; innovation!</b>	We need <b>Federal, State and local Government support to remove the barriers!</b>
<b>It's too late</b>	It's never too late	BioSpectra's model can lead the way 

# BioSpectra Continues to Expand

## US Manufactured Premium Pharmaceutical Ingredients



### Expansion of Research and Development- Rensselaer, NY



- This new facility will further our reshoring initiatives by developing chemical synthetic pathways for key ingredients – some of which are **only** manufactured overseas.



### Distribution Center in Northampton County, PA



- This distribution center will support expanded production of products for a secure supply chain of key ingredients for drug manufacturers in the US.



### BioSpectra commits to advancements

- BioSpectra will continue to set new standards and expectations in drug manufacturing through commitments to advance new processes, technology and product opportunities.