BISPECTRA

US Manufactured Premium Pharmaceutical Ingredients

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



Onshoring and Reshoring US Based Drug Manufacturing



- **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

- 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.



Vertically Integrated US Based Drug Manufacturing For Critical Drug Products



Benefits to Onshoring/ Reshoring Drug Supply Chains

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• 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



- 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



- 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



- 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

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

BioSpectra Continues to Expand

US Manufactured Premium Pharmaceutical Ingredients



Expansion of Research and Development- Rensselaer, NY





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.

