BISSPECTRA

History

Premium Pharmaceutical Ingredients



rapidly evolving Pharmaceutical Industry. Launched in the foothills of the Poconos and rooted in Eastern Pennsylvania work ethic and culture, BioSpectra has expanded to become a regional, multi-plant manufacturer of High Purity Pharmaceutical Ingredients located in Stroudsburg and Bangor PA, serving key pharmaceutical companies around the world. Our clients include many of the largest pharma and bio pharma companies such as Merck, Lilly, Pfizer, Abbvie, Amgen, Biogen, Regeneron, Lonza, Sanofi and J&J as well as many other smaller pharmaceutical companies and drug innovators. Our products include high purity, bulk GMP Buffers, Excipients, Active Substances, Bulk GMP Solutions and other critical and functional Fine Chemicals, required for GMP pharmaceutical processes and finished drug products. Our focus is found in the synthesis and purification of critical ingredients with high quality demands, stringent regulatory requirements, an

emphasis on Low-Bioburden, Low-Endotoxin, Low Elemental Impurities and a highly secure supply chain.

In 2001, BioSpectra acquired a plant in Stroudsburg, PA enabling us to respond to increased customer demands. By 2007, the industry's need for larger batch sizes of Biological Buffers with the highest purity and consistency led to the renovation and expansion of the Stroudsburg plant with the design, installation and validation of fully GMP, fully dedicated manufacturing suites for the manufacturing of key Biological Buffers and Denaturants with batch sizes ranging from 1,500 kg to 24,000 kg. In 2011, a second facility in Bangor, PA, was acquired. After several years of continuous renovation and upgrades, the Bangor facility has increased BioSpectra's GMP operational footprint to over 175,000 ft² with all critical operations being fully validated according to FDA guidelines. With an emphasis on multipurpose manufacturing suites designed for purification and synthesis of critical

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After
having
redefined
the standard
for compliance
and traceability
for Biological
Buffers, Excipients
and APIs, BioSpectra
is keeping pace with the
evolution of biological drug
production by expanding

our manufacturing capabilities to include bulk GMP solutions and the purification and synthesis of other critical small-molecules needed for the processing of large biological molecules. After the successful launch in 2019 of a fully validated GMP manufacturing system for ultra-high purity Sodium Hydroxide Solutions, we have embarked on an aggressive program to expand our physical footprint and manufacturing capacity. In 2020 we will complete the construction of a 40,000 ft² fully dedicated, GMP warehouse in Wind Gap, PA. This will allow us to complete the build-out of four, class 6 manufacturing suites, for bulk GMP Solutions. This new construction will also allow us to hold even greater quantities of raw materials and finished products for key accounts. Once completed, we will begin the execution of a further expansion of our reactor capacities for purification and synthesis at our Bangor site. We also intend to build two fully dedicated kilo-scale suites for

small volume custom solutions and kilo-scale quantities of small molecules. This will allow us to more fully support the need for smaller quantities of fine chemical required by many biological and synthetic drug innovators world-wide for process development, pre-clinical and early phase clinical trial work.

Currently headquartered at the Bangor facility, BioSpectra has a vision to provide the most trusted and reliable source of Premium Pharmaceutical Ingredients, manufactured exclusively at our GMP facilities in Northeastern Pennsylvania. Our mission is always to exceed customer expectations while remaining fully compliant in regard to US-FDA, IPEC and ICH Q7 Guidelines. BioSpectra is FDA registered and has successfully been inspected by the FDA on multiple occasions, as well as by many of our world-class Pharmaceutical clients, holding a stellar record with them all. As an exclusive US manufacturer of the safest, purest and most traceable versions of excipients, actives and GMP process chemicals, we seek to support the finest

