

A World Leader in Naturally Derived Products Discusses Commercial Success and New Innovations

Mr. Darren Alkins, CEO at SPL – Scientific Protein Laboratories, speaks with IPI about their continued development in their science and technical expertise to meet the demanding requirements for new applications and to realise commercial success in a timely manner.

Q: SPL – Scientific Protein Laboratories LLC (SPL) is a World Leader in Heparin and Pancreatic Enzymes. Can you tell our readers the brief history of your company, how the company got started and your growth so far?

A: SPL was started in 1976 as a branch of Oscar Mayer, a large meat producer located in Madison, the capitol of Wisconsin. Oscar Mayer launched SPL to take advantage of unused animal tissues containing pharmaceutical substances (Heparin & Pancreatin). SPL's mission has always been to be the world's leading manufacturer of high-quality Active Pharmaceutical Ingredients (APIs) derived from biological sources supplying the healthcare industries.

Our growth has been driven by the increased demand for heparin and pancreatic enzyme products. As the uses for these invaluable, essential medicines has expanded, SPL has grown to keep pace with these innovations.

SPL's original focus was on Heparin, Pancreatin, and Blood Protein products. Now, 45 years later SPL's portfolio includes Heparin and heparin derivatives, Pancreatic enzymes, Blood products, Thyroid, peptide hormones, collagen and related derivatives, molecular scaffolds, and other biologically derived products. SPL has expertise in extracting specific molecules/substances of interest from all types of biological tissues. SPL's products can meet the rigorous requirements for both pharmaceutical dosage forms, medical devices, and complex combination products.

Q: How do you fit into the landscape of drug development?

A: SPL, Scientific Protein Laboratories, is a world leader for manufacturer of high-quality Active Pharmaceutical Ingredients derived from natural sources supplying the healthcare industries. Our expertise supports development, purification, and supply of active ingredient from a diverse



range of biological sources. Because of our long history in handling, defining, and controlling these complex materials, we can produce high quality products that few others can manage. In some cases, we are the sole source. In all cases, our experience and skills managing the safety and compliance risks related to biological sources is unique and one of the best in the industry.

Q: You have placed great emphasis on expansion and diversification of your product pipeline, and corporate development programmes. Can you tell our audience how you have achieved this and what is your vision for the future?

A: SPL has expanded its product portfolio in two primary ways. First, we have built the infrastructure and capabilities to meet and exceed our customers' expectations. Second, we have formed strategic partnerships to bring new products to market. In both cases, the result is world-class technology and quality.

SPL has the scientific and engineering expertise to make any product derived from biological substances. Throughout the entire process, SPL applies the highest regulatory and quality standards to all

aspects of the process. SPL is regularly audited by regional authorities and customers. We maintain a strong reputation for high technology, reliability and quality.

Q: You offer more than 30 years' experience in manufacturing APIs from biologically-derived sources. What are your product pipelines, and how have you made a difference in the industry through your portfolio?

A: SPL's customer base includes some of the highest performing companies in the pharmaceutical industry. For decades, SPL has been supporting new indications, regulations, patient safety concerns, and global supply chain changes. SPL has developed global experience with a wide variety of complex products and their related supply chains.

The primary difference between SPL and our competitors is our science, quality, discipline, knowledge, and experience from the point of harvest, through purification of the product, up to and sometimes including the finished product.

We offer high-quality products, with excellent traceability and risk management controls. Our scientific, regulatory, and quality departments are best in class.

Q: Can you explain your regulatory and analytical support services? What are you offering, and how do you make a difference in the industry?

A: SPL has a world class fully operational QC, Micro, and qPCR laboratory. We specialize in bio-sourced materials but can work with a broad array of substances. Additionally, we have the capability to develop test methods for products, for new or existing method improvement. SPL's analytical team is key to our success with manipulating biologically derived substances from a complex supply chain. We have special expertise with the complex matrices presented by bio-sourced products.

Our regulatory group effectively supports drug filings across the globe. We also have significant experience in devices and other technologies that require biologically derived drug substances. We are best in class at bridging the gap between common pharmaceutical standards and non-drug industries.

Q: SPL offers a broad spectrum of technology capabilities in support of development and manufacturing services for the extraction, isolation and purification of naturally-derived materials and fermentation, isolation, and recovery of therapeutic proteins. Can you give us a detailed market demand, and tell us your growth potential?

A: SPL's capacity is often sold out well into the future. With each expansion and capacity increase, we establish close, long term customer relationships. We carefully select our partners to ensure we can support their needs and exceed expectations over the long term.



We judiciously manage the full supply chain, ensuring that everyone benefits and hold the finished product to the highest standards. As an example, the markets for porcine derived products (heparin and pancreatin in particular) are under pressure (globally) from the African Swine Fever (ASF) outbreak in 2019. In both cases demand for the products is at or above 2019 demand, but global raw material supply remains less than before. Our supplies and quality remain some of the highest in the world.

Many of the new products we are working on are new markets or have limited competitors. In both cases, SPL is competitive and experienced great success.

Q: What major events have occurred in the industry and what has been its effects.

A: As the population in the developed nations has aged and as more people have access to modern medical care, the demand for SPL products has been growing robustly.

We expect that these demographic trends will continue and will require SPL to continue innovating to meet this need. In addition, medical science continues to find new applications for bio-sourced ingredients. SPL has continued to develop its science and technical expertise to meet the demanding requirements for these new applications.

Q: What role do SPL and your services play on their client's journey to commercial success?

A: SPL's quality, experience and expertise enable our clients to realise commercial success in a timely manner. We apply our experience to new products and processes, but always adapt to the specific requirements of the new innovations.



Dareen Alkins

Darren is the CEO of SPL and has 32 years experience in the pharmaceutical business. He started his career at Bristol – Myers Squibb in sales, marketing and business development. He has been the president of three pharmaceutical companies. Darren is the former head of Teva US business development. Most recently, Darren was the General Manager of generics and dermatology at Sandoz US.

