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Contacts:

Code
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Alto Marketing:

Sarah Perceval – Senior Account Manager; E: sarahp@alto-marketing.com; T: +44(0)1489 557672

SP Industries

Chris Levoi – Commercial Marketing; E: chris.levoi@spscientific.com; T: +44 (0)7776-589551

SP launches SP Hull LyoStar® 4.0 R&D freeze dryer to enhance speed to market in drug development

New advanced pilot-scale lyophilizer supports rapid and highly effective freeze-dry cycle development, optimization and process scale-up



For a high-resolution image please contact sarahp@alto-marketing.com

WARMINSTER, PA (JUNE 23, 2021) – [SP Scientific Products \(SP\)](https://www.alto-marketing.com) announces the launch of its SP Hull LyoStar® 4.0 R&D and process development freeze dryer designed and built to enhance speed to market of biopharmaceutical products, such as biological drugs. The new LyoStar 4.0 results from SP's extensive lyophilization expertise and represents a significant advancement in freeze dryer engineering.

Based on a full-scale production freeze dryer to support rapid-scale-up, LyoStar 4.0 is a pilot-scale lyophilizer offering superior shelf mapping, rapid shelf freezing, unmatched process accuracy and reliability. It also includes a cutting-edge suite of Process Analytical Technology (PAT) tools augmenting SP's Line of Sight™ suite of technologies. In addition, SP's new freeze dryer uses an eco-friendlier refrigerant gas, which reduces the carbon footprint involved in lyophilization.



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Lyophilization (freeze-drying) is a key step in the production of biologics, vaccines and diagnostics, as it stabilizes sensitive biological products to extend their shelf life, whilst maintaining their quality and efficacy. Over 40% of biopharmaceutical products are now freeze-dried for storage and transport, and this number continues to grow with the development of more complex drugs. Therefore, advanced, reliable and scalable lyophilization technologies, along with Process Analytical Technology (PAT) tools, are essential to support smooth scale-up from process development through to manufacturing.

Ideal for rapid lyophilization cycle development, optimization and scale-up, the LyoStar 4.0 incorporates the very latest innovations in freeze-drying technology to protect valuable product by ensuring precise process control and robust reliability. To enable this, the LyoStar 4.0 has a number of sophisticated, upgradeable PAT tools including: LyoFlux® TDLAS Sensors for vapor mass flow measurement; AutoMTM/SMART™ Freeze Dryer Technology, a primary drying cycle optimization tool; Controlyo® Nucleation Technology giving pinpoint control of freezing point; a 3D modelling package for computational fluid dynamics and process monitoring; and Tempris® Wireless Sensors for real-time product temperature measurement.

The ability to both scale up to production and down to R&D is an important aspect in the process for developing pharmaceutical compounds. The LyoStar 4.0 was specifically designed to work in this manner with the SP Hull LyoConstellation line of production lyophilizers. Further mirroring the technology with the LyoConstellations, LyoStar 4.0 also has the same 21 CFR Part 11 compatible software (optional) and highly robust, efficient refrigeration technology. These all combine to create SP's Line of Sight approach across all its products which overcomes critical lyophilization challenges during development, scale-up and manufacturing of a biologic. Line of Sight also enables continuous process monitoring and improvement in line with Pharma 4.0™, as expected by regulatory agencies.

"Our new LyoStar 4.0 has been specifically designed and manufactured with the needs of the research and cycle development scientist in mind. It offers design characteristics similar to our large production freeze dryers to facilitate scale-up and, crucially, faster delivery of a biopharmaceutical product to market," said Ian Whitehall, CMO at SP. "SP fully understands the pharmaceutical industry's need for speed in product development. Our new SP Hull LyoStar 4.0 not only supports this, but has also been designed and



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configured to ensure faster delivery and installation, so it is fully operational as soon as possible once ordered.”

As specialists in advanced and scalable lyophilization technologies and PAT tools, SP has the broadest lyophilization range available - covering cycle development, stability, pilot and clinical batch production, through to full aseptic manufacturing and commercial production batches. The new SP Hull LyoStar 4.0 is integral to SP’s Line of Sight strategy, further enhancing this data-rich suite of equipment and technologies that increase understanding and control over the fill-finish process.

For more information about SP visit www.scientificproducts.com

About SP

SP Industries, Inc. (SP), is a leading global provider of state-of-the-art fill-finish drug manufacturing solutions, laboratory equipment, research, pilot and production freeze dryers, laboratory supplies and specialty glassware. SP's products support research and production across diverse end user markets including pharmaceutical, scientific, industrial, aeronautic, semiconductor and healthcare. Our flagship SP brands Bel-Art, FTS, Genevac, Hotpack, Hull, i-Dositecno, VirTis, Wilmad-LabGlass and Ableware offer best in class product solutions that make a difference in people's lives and together represent over 400 years of experience, quality and innovation. SP Industries is headquartered in Warminster, Pennsylvania with production facilities in the USA and Europe.