BioSpectrum ASIA EDITION
the business of Bio & Health Sciences

SP launches R&D freeze dryer to accelerate drug development market

24 June 2021 | News

SP Hull LyoStar® 4.0, a new advanced pilot-scale lyophilizer supports rapid and highly effective freeze-dry cycle development, optimization and process scale-up

SP Scientific Products (SP) 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.

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 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.