

## Complete Vial Handling and Freeze Drying Solutions for Pharmaceutical Production



# Accelerate Your Formulation Development Through to Final Product



## Delivering Your Complete Aseptic Process Solution

SP covers the complete range of aseptic processing tools and techniques, from cycle development, stability testing, pilot and clinical batch production through to full aseptic manufacturing and commercial production batches. Our expertise in processing and packaging is matched with in-depth software engineering capabilities and customer-orientated servicing and support.

## Responding to Industry Needs

SP is committed to customer-driven innovation and streamlining product development, including standard models, to enhance product quality and consistency, improve yield, and importantly accelerate time to market. SP's unique Line of Sight™ approach provides a breakthrough suite of freeze-drying equipment, with scalable lyophilization technologies and process analytical technologies (PAT) designed to enhance quality, improve productivity and increase return on investment.

## Dependable Fill-Finish Getting You to Market Faster

Fill-finish is the final stage before the product is packaged and administered to the patient. As patient treatments move away from broad population therapies in favor of the targeted treatment of smaller (personalized) patient populations, the biopharmaceutical industry is transitioning to smaller aseptic batch manufacturing processes.

Consequently, SP recognize their customers have a growing need for a complete package of rapid product development and scalable, good manufacturing (GMP) compliant, complete aseptic fill-finish production lines, optimized for small batch applications. Fill-finish is a crucial step in the biopharmaceutical manufacturing process, with small to medium batch aseptic filling and shorter "time to market" becoming increasingly important.

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## Giving You Ultimate Control for Small Batch Applications

### Injectable and Oral Products in Liquid and Powder Form

Our modular “Versa-Line” fill-finish system and Line of Sight™ freeze dryer tools, technologies and equipment to provide a customizable solution using quick delivery standard modules for vial washing, depyrogenation tunnel, filling and stoppering, freeze dryer and freeze dryer loading systems, capping, external vial washers and trayloaders, to provide an integrated full line solution.

- **Smaller footprints:** Each module is 6 feet long and standardizes isolator modules to reduce delivery time and costs
- **Consistently standardized:** Configurable based on room design and space, and operator access from one side permits wall installations to reduce personnel on the manufacturing line to save clean room space
- **Completely flexible:** Filling and stoppering modules can be quickly converted for liquid powders or syringes with a simple change of parts

With small scale and efficient design principles that adhere to cGMP quality guidelines, the SP fill-finish range specializes in low to medium speed applications. The modular standardized footprint for each piece of equipment means the entire Versa-Lines suite can be configured to create a complete manufacturing line or be customized to suit any user.



## Modular Aseptic Processing Equipment

### Vial Washers

Range of low maintenance washers for low to high throughput manufacturing, guaranteed to reduce particulates by 1000 times

### Depyrogenation Tunnels

Fully automatic depyrogenation tunnels for continuous aseptic processing of vials, syringes and ampules

### Filling and Stoppering

Filling equipment capable of volumes ranging from 100  $\mu$ L to 500 mL at up to 200 vials per minute

### Cappers

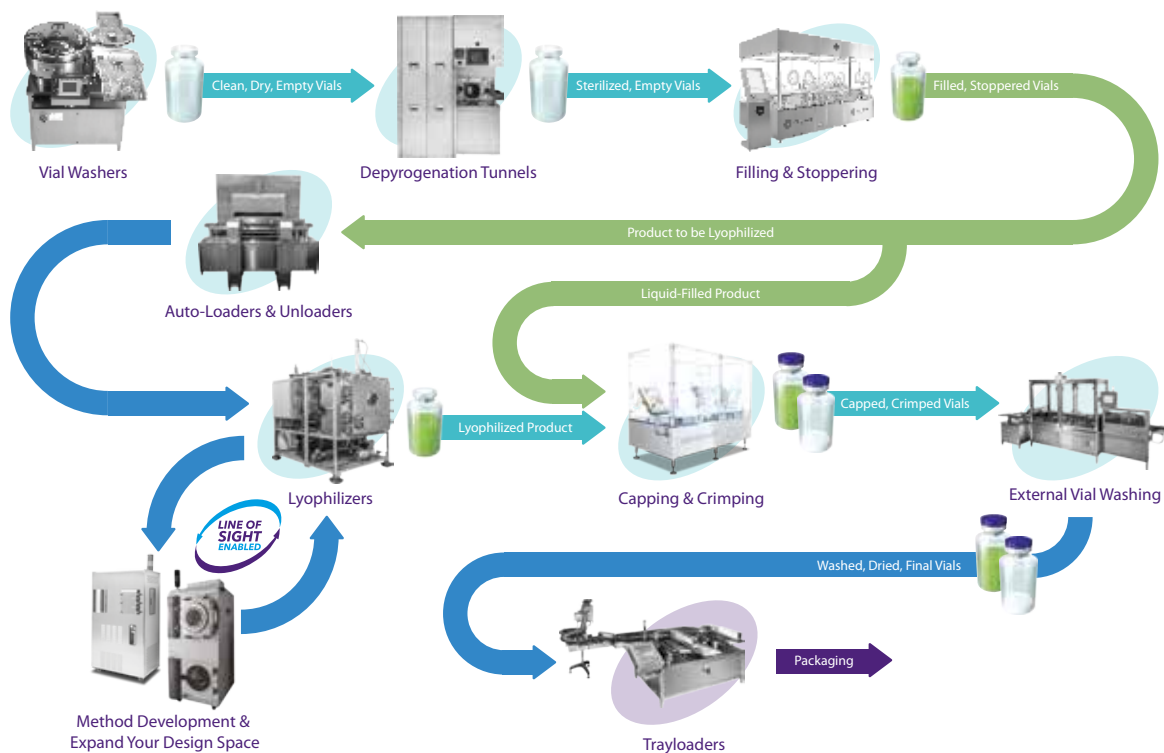
For aseptic as well as oral applications, offering dependable vial protection at speeds of 200 caps per minute

### Lyophilizers

Range of freeze dryers covering cycle development, stability, pilot and clinical batch production, through to full aseptic production

### External Vial Washers and Trayloaders

Single and dual station tray loaders to support speeds of 200 to 500 vials per minute with freeze dryers and freeze dryer loading systems





## Vial Washers

### Benefits

- **Dependably effective washing:** Guaranteed reduction of particles by 1000 times and spray manifold eliminates the risk of chipping vials
- **Suitable for almost any manufacturing space:** Small footprint and reduced water usage
- **Highly efficient and economical to run:** Simple servodriven operation with fewer moving parts reduces maintenance and dedicated recipes, to ensure vastly reduced water usage
- **Extremely flexible:** Easy and quick change between different sizes of glass or plastic vials



**RW-250**

low speed, semi-automatic vial washer with low output washing



**RW-500**

smallest automatic vial washer for low-to-medium output



**RW-800**

medium speed automatic vial washer with high output washing



**RW-1150**

High speed automatic vial washer for pharmaceutical and biotech applications

### Effective and Efficient Vial Washing

Vial washing cleans the vials of particulate matter and microorganisms; however traditional vial washers have many moving parts, which can themselves generate particulates. SP vial washers have just two moving parts in their washing chamber to ensure highly effective cleaning and their main drive is servo-driven. Each vial format has a Human Machine Interface (HMI) selected recipe with specific settings for spray time to help reduce water consumption. Vials are washed without the washing needle entering the vial, thereby eliminating the risk of vials being damaged due to misaligned or bent washing needles.

The vial washer range consists of four models to cover a wide range of production rates including a compact footprint option for laboratory and small batch applications to clean vials with as little as 1 liter per minute WFI (Water-For-Injection) usage, as well as high-speed production applications of up to 400 vials per minute. To accommodate the regulatory preference and minimize operator involvement, the smallest SP washer, combined with a depyrogenation tunnel and filling/stoppering/capping unit, forms a complete aseptic filling line of less than 13 feet long.

## Depyrogenation Tunnels

### Benefits

- **Highly effective sterilization:** Guaranteed thermic cycle regardless of pressure fluctuations
- **Efficient automatic processing:** Fully automatic, continuous aseptic processing offers increased efficiency for batch processing
- **All manufacturing requirements:** Modules available for small and large batch sizes



### Fully Automatic Sterilization

There are several different methods of inactivating pyrogens, including bacterial endotoxin's, on vial surfaces. The most common and effective way is through dry heating to above 250°C, and both manually loaded ovens for smaller batch sizes and continuous production depyrogenation tunnels have been used.

SP provides a range of fully automatic sterilization/depyrogenate and tunnels for vials, in a variety of sizes including production rates in excess of 700 vials per minute. At just five feet in length, our smallest depyrogenation tunnel is ideally suited for laboratory and small batch applications.

All SP depyrogenation tunnels over-pressurize the hot zone relative to the cooling and infeed zone to guarantee a controlled thermic cycle, regardless of pressure fluctuations within the filling suite. Additionally, they can monitor and record particle counts in the infeed zone, hot zone and cool zone continuously during the batch run.

## Filling and Stoppering

### Benefits

- **Ideal for containment and sterility:** Compatible with Restricted Access Barriers (RABs) or isolator enclosures
- **Exceptionally flexible:** Available for manual or semi-automatic de-bagging and de-lidding for pre-sterilized glass as well as cleanroom unscrambler's for ophthalmic containers
- **Compliant with manufacturing regulations:** 21 CFR Part 11 and audit trail capable



### Versatile and Complete Sterile Filling Solutions

SP offers a choice of machines and dispensing methods for liquid filling of oral and ophthalmic bottles, vials, syringes and cartridges. All offer the dependable sterility, accuracy and speed essential for the pharmaceutical sectors, whilst also meeting the highest quality and accuracy expectations of GMP and FDA regulations.

Our LI, BI and SY filler lines can fill up to 200 vials per minute, and work with stainless steel, ceramic rotary piston or peristaltic pumps. Driven by PLC-controlled individual servomotors, these are constructed from a single piece of 316 stainless steel to ensure superior accuracy and repeatability throughout the entire batch. The filling equipment is capable of filling volumes ranging from 100 µL to 500 mL, with statistical as well as 100% in-process weight control.





## Filling and Stoppering

### Versatile and Complete Sterile Filling Solutions

#### LI Linear Fillers



LI Fillers enable linear filling, stoppering, tip placement, pump inserting and crimping or closing machines for bottles and vials up to 400 vials per minute. Systems are available for manual or semi-automatic debagging, manual, semi-automatic or automatic de-lidding for pre-sterilized glass as well as cleanroom unscrambler's for ophthalmic containers.

#### Features

- Compact footprint
- High-speed production capabilities
- Wide product range

#### BI Rotary Fillers



The BI Filler is a 1-up filling, stoppering and capping system for 2-100ml vials with output of up to 30 vials per minute, and able to work up to a 500ml vial size. BI Fillers enable rotary filling, stoppering, tip placement, pump inserting and crimping or closing machine for bottles and vials up to 100 vials per minute. The compact in-line design features two filling nozzles, a dual stoppering-inserting station and two crimping heads for aluminium caps.

#### Features

- Compact footprint
- Available for 2-100 mL vials
- Filling range and speeds

#### SY Syringe Fillers



The SY Syringe Filler is a versatile, robot filling and plunging machine for glass and plastic syringes, cartridges and vials in nest. It can process up to 200 units per minute with a maximum of 10 nozzles. This system can incorporate an IPC statistic check weighing unit. In addition, complete line solutions with de-baggers, de-lidding, de-nesters, labellers and rod-inserters are available. The cleanroom style robot is used to position syringes for filling and stoppering, and also available for VHP cleaning option.

#### Features

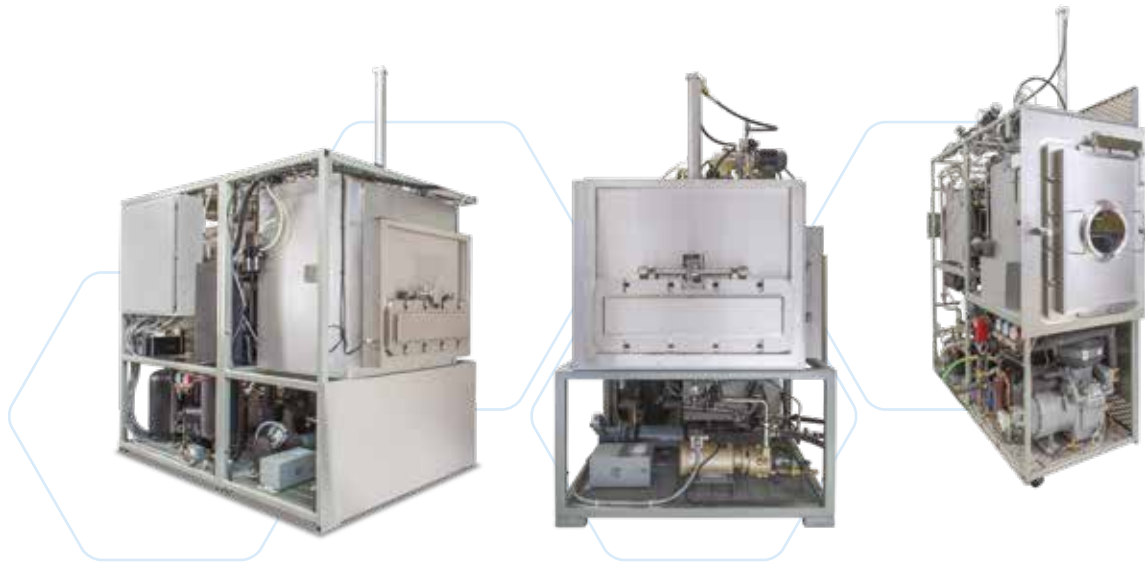
- Automatic nest unloading and loading of tubes
- Cleanroom robot to position syringes for filling and stoppering
- De-nesting, plunger insertion and labelling of syringes and cartridges options available



## LyoConstellation™ Freeze Dryer

### Benefits

- **Configured to order:** Short lead-times to get you to market quickly and safely
- **Suitable for most throughput requirements:** Range of freeze dryers with different shelf sizes from 1 m<sup>2</sup> to 13 m<sup>2</sup> and accommodates vials up to 100ml
- **Scalable and transferrable:** SP Line of Sight technologies, PAT tools and software facilitate scale-up from development to clinical phases
- **Compact footprint:** Ideal for most pilot scale areas; integrates with filling lines and semi-automatic systems



### Development, Pilot and Production Freeze Dryers

LyoConstellation represents a brand new range of development and pilot freeze dryers, configured to order for faster delivery and specifically designed for aseptic operation. When handling high value API, and with a need to bring product to market as quickly and safely as possible, LyoConstellation addresses early stage development under aseptic and low particle controlled conditions. The product therefore behaves in the same manner once it is ready for scale-up, and then commercialization.

Powerful equipped as standard to provide higher capacity, broadened equipment capability and expanded design space, LyoConstellation models S10, S20, and S30 are all equipped with the same advanced suite of Line of Sight technologies as other SP R&D freeze dryers, providing data for full process and product life cycle management. The LyoConstellation range also fully integrates with SP filling line and semi-automatic loading systems offering best manufacturing freeze-drying practices, to achieve faster product progression from development to commercialization.

## Capping Machines

### Benefits

- **Compact design:** Suitable for almost all manufacturing facilities
- **Dependable vial protection:** Vertical force control during cap crimping and torque control/strain gauge feedback for screw capping applications
- **Ideal for containment and sterility:** Compatible with Restricted Access Barriers (RABs) or isolator enclosures
- **Compliant with manufacturing regulations:** 21 CFR Part 11 and audit trail capable



### Linear and Continuous Rotary Motion Capping

The CRS, BI and LI models enable processing at 200 caps per minute for aseptic applications. Crimp cappers control the vertical force during the closing operation by means of servo drives. For screw capping, torques can be monitored and recorded using a strain gauge option to increase vial protection.

## External Vial Washers

### Benefits

- **Effective and safe cleaning:** Specialized transport system with enclosure to prevent moisture ingress and potential bacterial contamination
- **Compact and flexible:** Small footprint systems designed for vials from 2-125 mL; changeover for different vial formats takes just 15 minutes
- **Easy to use:** Recipes use servodriven adjustments to guarantee repeatable positions of the vials in relation to the cleaning solution



### Compact In-line Decontamination

External vial washers are regularly used to clean the outside vial surfaces to minimize false rejects during inspection, and to clean vials filled with potent drugs. The SP range of compact in-line vial decontaminating machines includes the EVW-60 for up to 100 vials per minute, and the EVW-100 for throughputs in excess of 400 vials per minute. The EVW-100 can also have glove ports, a wash down wand and an air handling system with bag in and bag out filters to ensure sterility and containment.

Before washing, the vial cap is enclosed and sealed to prevent the water and cleaning agent from entering the cap area (even at 90-psi pressure), thereby eliminating potential future bacterial contamination. Importantly, conveyor belts are not used to transport vials, as they are notoriously difficult to clean. The external vial cleaning process can be validated, as the position of the cleaning nozzles in reference to the vial position is servo driven and repeatable by recipe.

## Row-By-Row and Semi-Automatic Loading

### Benefits

- **Fully compliant with latest cGMP standards:** The bridge plate and transfer plate never move through the gray space
- **Easy decontamination:** Designed to ensure easy cleaning and complete surface exposure during the decontamination process for effective sanitization
- **Reduced/no human intervention:** Only human intervention on the row-by-row or semi-automatic loading systems is through gloves to optimize GMP aspects of freeze dryer loading
- **Ideal for containment and sterility:** Both high-speed as well as low-speed freeze dryer loading systems are designed for isolation to protect product from the operators; and with containment the operators are protected from potent products



### Flexible Solutions for Small Batch and High-Speed Applications

#### Row-by-Row Loading

For full line vial applications that include freeze dryers, SP offers a unique row-by-row (RxR) loading system for higher-speed applications, accommodating loading speeds up to 400 vials per minute.

#### Semi-Automatic Loading

SP's semi-automatic loading system is specifically designed for smaller batch applications that include freeze dryers.

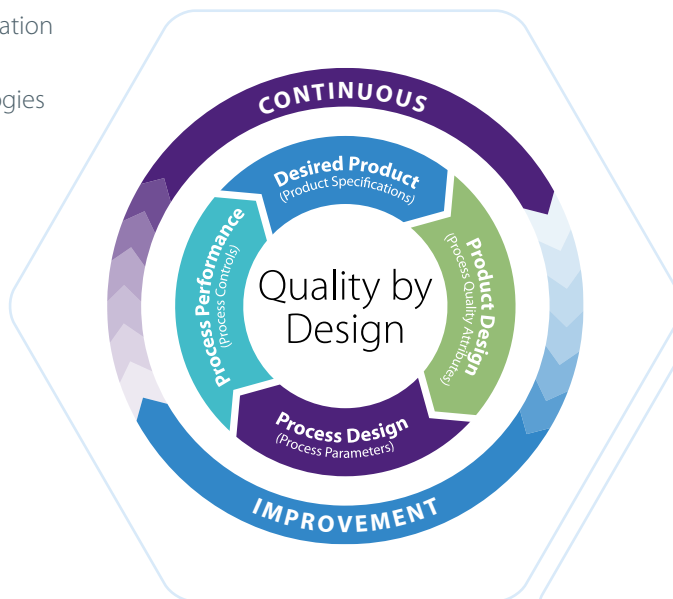




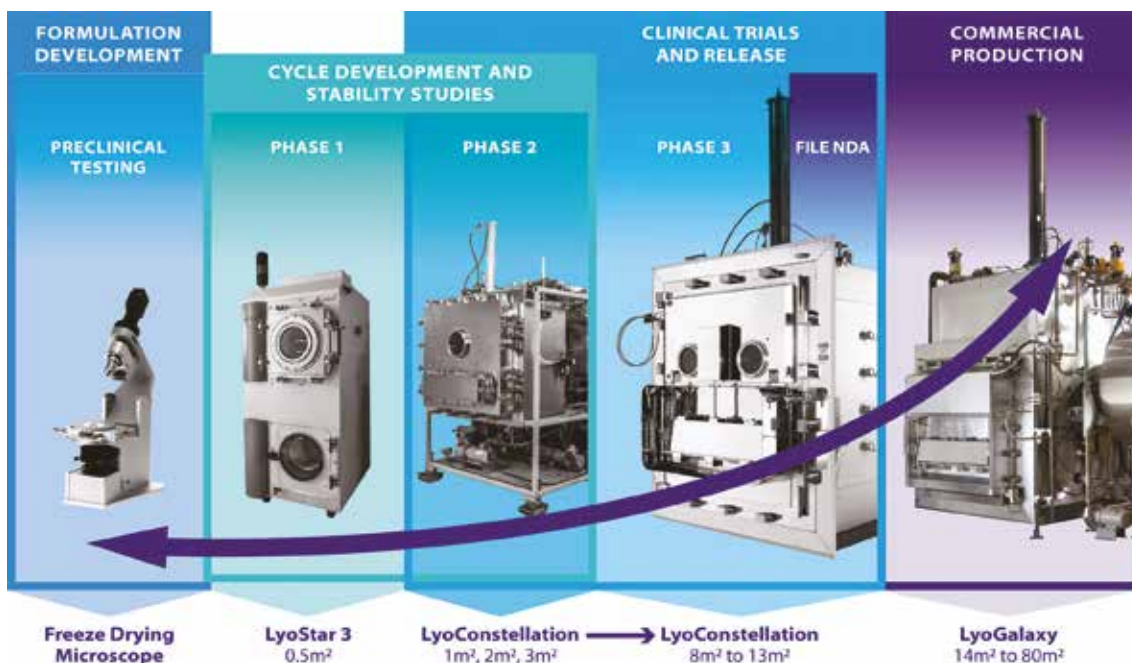
## The SP Line of Sight™ Approach

Line of Sight is a data rich set of lyophilization technologies and process analytical technology (PAT) tools designed to overcome critical lyophilization challenges during development, scale up and manufacturing of biologic products. It also enables continuous process monitoring and improvement as expected by regulatory agencies.

Each element of the Line of Sight suite helps lyophilization scientists to better understand different facets of the freeze-drying process. By using Line of Sight technologies across all the different products, SP uniquely enables development scientists to create new freeze-drying cycles, and transfer their products and processes quickly and confidently from one scale to the next, and even from one facility to another. Should any unexpected deviation in a production cycle occur, Line of Sight technology enables a detailed analysis of the process, allowing scientists to decide whether the batch can be safely released, potentially saving many millions of dollars.



## Development and Scale Up Using Scalable Technologies and Process Analytical Technology (PAT) Tools



### Lyophilization Systems

#### Freeze-Drying Microscope

Allows observation of the sample structure during drying and heating so the exact point of collapse can be determined

#### LyoStar™ 3 Freeze Dryer

The industry standard for cycle development and cycle optimization activities

#### LyoConstellation™ Freeze Dryers

Family of larger production freeze dryers that not only perform cycle development but offer fully aseptic operation

#### Freeze Drying Contract Services

A collaborative service for a range of lyophilization contract research and development services, from pre-formulation through to full-scale production and freeze-dried product analysis

### Line of Sight Process Analytical Technology (PAT) Tools

#### ControlLyo® Nucleation Technology

Precise control of the freezing point

#### AutoMTM/SMART™ Freeze Dryer Technology

Primary drying cycle optimization tool for in-depth product information

#### LyoFlux® TDLAS Sensors

Accurate measurement of vapor mass flow for calculation of critical product attributes

#### Tempris® Wireless Sensors

Real-time accurate and reliable product temperature measurement



## LyoStar™ 3 Freeze Dryer

### Applications

- Formulation development and stability studies
- Cycle optimization and scale-up
- Laboratory research and development and/or small API production freeze-drying

### Benefits

- **Decreases cycle development time and conserves valuable API:** Using SMART and AutoMTM tools
- **Easily scalable:** Using Line of Sight technologies, PAT tools and software facilitate scale-up
- **Provides additional product and process information:** Such as dried layer resistance, heat flow, mass transfer and how different freezing protocols impact cake resistance
- **Maximizes process control and repeatability:** Line of Sight PAT tools enable process accuracy and reliability, and batch consistency

### Process Development in an Research and Development Freeze Dryer

The LyoStar 3 is an R&D and process development freeze dryer that provides unmatched accuracy, reliability and ease-of-use. Configured with the latest innovations in freeze-drying technology, the LyoStar 3 delivers pinpoint process control and robust reliability to protect your valuable product. Its exclusive combination of instrumentation and flexible software meets the demands of the most discriminating lyophilization scientists.

LyoStar features shelf temperature accuracy of  $\pm 5\text{mTorr}$  ( $0.5^{\circ}\text{C}$ ) or better and vacuum control within 0.1% of set-point. Its robust and ultra-reliable refrigeration system enables shelf pull down from ambient to  $-40^{\circ}\text{C}$  in less than 25 minutes.

With optional Line of Sight optimization technologies and PAT tools, such as SMART™ and ControlLy™ Technology, the LyoStar is a more advanced development freeze dryer than any other system currently available.

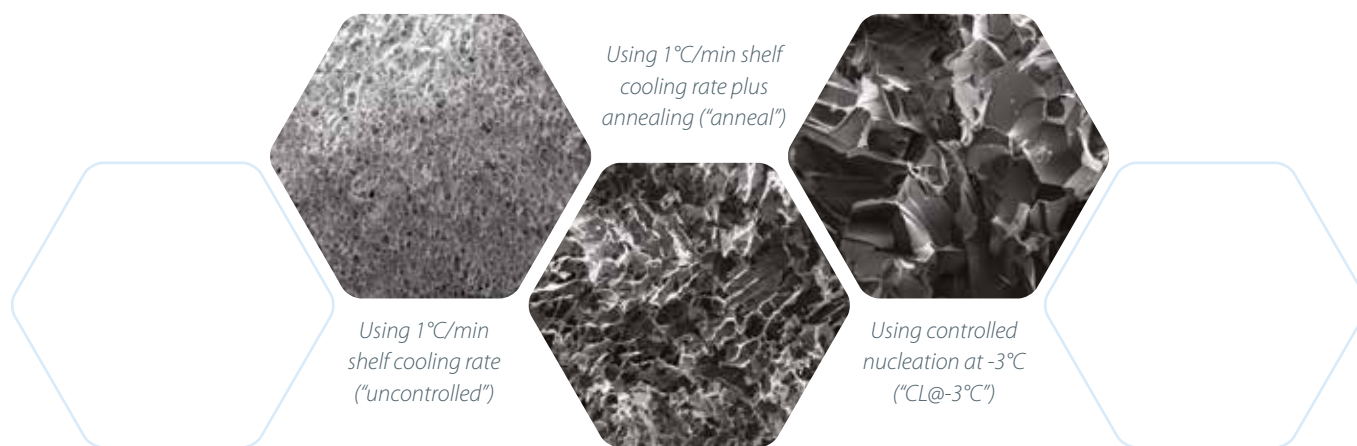


## ControLyo® Technology

### Benefits

- **Improved inter- and intra-batch product quality:** QbD approach ensures consistent homogeneity; shorter reconstitution time; better cake appearance
- **Scalable technology:** Easily retrofitted on equipment that is equipped with steam in place (SIP)
- **Increased productivity and economic benefits:** Decreased cycle time by enabling controlled ice nucleation to occur at warmer temperatures
- **Reduced vial breakage:** Inducing nucleation at warmer temperature of -4°C to -6°C with improved and more consistent cake appearance

### SEM (Scanning Electron Microscopy) Images of Sucrose, 75 mg/mL, Processed:



*Images reprinted with kind permission of Dr. Margit Gieseler at GILYOS GmbH*

### Freeze All Vials Uniformly and Consistently Every Time

Freezing is a highly variable process, and this variability is one of the most common challenges in freeze-drying scale-up. SP's ControLyo Technology offers an effective solution by ensuring instantaneous, controlled ice nucleation at a higher temperature, which minimizes super cooling and yields the largest possible ice crystals. This, in turn, reduces the primary drying time and increases product homogeneity.

By tightly controlling the freezing process, ControLyo Technology improves product quality, shortens drying times, and requires no formulation change or introduction of foreign material into the vials.

## SMART™ Freeze Dryer Technology

### Benefits

- **Increases efficiency and reduces development time:** Eliminates trial and error approach
- **Improves product life cycle management:** Increases product and process knowledge; conforms to regulatory expectations by adopting QbD approach
- **Improves return on investment:** Use PAT tools to provide broader product understanding



*Return of investment (ROI) illustration of development effort using conventional method vs SMART technology*

### Accelerating Primary Drying Optimization

SP's SMART freeze dryer technology is a primary drying optimization tool with wide industry acceptance. Manometric Temperature Measurement (MTM), a patented technique for measuring rise in pressure, is used to determine critical product attributes such as cake resistance and product temperature at the ice interface amongst other parameters. These attributes are critical to understanding long-term product stability. AutoMTM allows researchers to run their own pre-determined cycle, but still collect the critical process data and product parameters calculated from MTM data. This technique is a valuable tool to help understand how an existing freeze-drying process can be further optimized.

Eliminating the trial-and-error approach normally involved in developing new lyophilization cycles, SMART freeze dryer technology enables experts and novices alike to develop new cycles quickly while also ensuring product quality, efficiency and process robustness.



## LyoFlux® 200 TDLAS Sensor

### Benefits

- **Enables easy scale-up:** Line of Sight technology can be applied from laboratory to production scale
- **Enables product quality improvements:** QbD approach enhances understanding of product attributes and their impact on product quality
- **Maintains aseptic conditions:** Non-invasive measurement ensures sterile environment maintained



LyoFlux® 200.

LyoFlux® is a registered trademark of Physical Sciences Inc., Andover, MA, USA and image used by kind permission.

### Freeze-Drying Monitoring and Control Sensor

The LyoFlux 200 TDLAS (Tunable Diode Laser Absorption Spectroscopy) sensor is a Line of Sight PAT device for the real-time monitoring of product attributes such as temperature and resistance to vapor flow, in laboratory, pilot, and production scale lyophilization cycles.

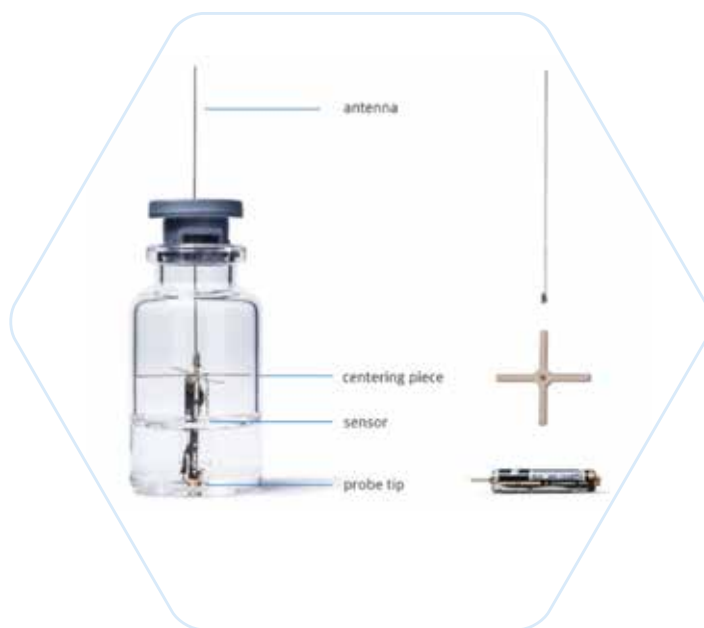
Unlike other types of measurement sensors, the LyoFlux TDLAS sensor is non-invasive, so users can determine the required product attributes without human intervention, avoiding any compromise of product sterility.

All measurements are made real time and non-invasively without introducing any bias other types of measurement sensors could present. The ability to use this technology during development and then within production scale freeze dryers, provides users with the flexibility to obtain the needed product attributes such as product temperature and product resistance to vapor flow, without human intervention and compromising product sterility in an aseptic environment.

## Tempris® Wireless Sensor

### Benefits

- **Reliable data for process monitoring:** Direct product temperature measurement
- **Scalable technology:** Can be used in any freeze dryers
- **Prevents contamination:** Wireless, cleanable and sterilizable sensors for use in aseptic manufacturing



*Tempris wireless sensor assembly for product temperature measurement. Tempris® is a registered trademark of iQ-mobil solutions GmbH, Holzkirchen, Germany and images are used by kind permission.*

### Real-Time Product Temperature Measurement

Traditionally, thermocouple wires have been used to measure product temperatures in freeze dryers, but these are difficult to position within vials creating unreliable data and issues with sterility. Tempris sensors enable wireless real-time temperature measurements. Being cleanable and sterilizable, they also prevent any contamination of product in pilot or commercial manufacturing. In addition, as they are wireless they can be used in systems protected by Restricted Access Barriers (RABs) or full isolation.

Tempris sensors enable greater cost efficiency and time-savings with reproducibility and are practical at all stages throughout the entire production process from development to scale up and technical transfer.

## Contract Research and Development Service Partnership

### From Pre-Formulation to Full Scale Production and Freeze-Dried Product Analysis

Through partnership with Biopharma Group, SP can offer a collaborative service for contract research and development services to our global lyophilization biopharmaceutical customers. Offering industry-leading expertise, this consultative approach covers all aspects of freeze-drying from pre-formulation through to full-scale production and dried product analysis.

Each customer project will have a work program and budget appropriate to the size and stage of your project, from a single cycle or individual analysis, or to agree a complete formulation development program, augmenting customer's in-house expertise and working with you to make your project a success. The unique characteristics of each product type, formulation and application mean that every project presents a different and new set of challenges.

With a longstanding partnership, SP are confident you can entrust your project to Biopharma Group to benefit from not only the many years of combined experience, but also the breadth and depth of cumulative knowledge. By combining sophisticated analytical techniques with this wealth of in-depth knowledge, you can be confident your particular freeze-drying project progresses smoothly - product characterization, formulation development, cycle development, specialist analysis and process optimization and scale-up.



## SP's Customer-Centered Philosophy

### Our People Make the Difference

SP service professionals offer your organization a depth of expertise that is truly unique. We are recognized experts in applications, methodologies, lab processes and many other areas that directly impact your day-to-day operations. All our service professionals are qualified to support every instrument, software and application product that SP has brought to the market.

### Local Presence with Global Expertise

Together with our channel partners, SP operates in countries all over the globe, with a dispatch system to optimize coverage by service professionals, and immediate telephone support ready to assist you with your SP products. We have also introduced features such as Google glasses for some product lines to allow remote and real time, technical guidance and troubleshooting by video.

### Parts When and Where Needed

Our dedicated logistics specialists ensure the quality and availability of parts, allowing SP to achieve greater on-time delivery performance for service parts to locations throughout the world.

With SP, your solution is just a call, email or video communication away.

### Comprehensive Service Agreements to Control Your Costs

We have a comprehensive range of service plans, including customized options as required, to suit specific needs and budgets. All are backed by the assurance, safety, and security provided by an ISO 9001:2015 certified company.

With an SP Service Agreement, you save money compared to per-incident services. No matter how many repair visits or replacement parts you need, your annual agreement cost covers it all - so you can maximize uptime through preventative maintenance services and customized service offerings.



Research, industry and healthcare professionals throughout the world rely on SP for a synergistic collection of fill-finish drug manufacturing solutions, freeze dryers, durable benchtop equipment, laboratory apparatus and scientific glassware to keep their manufacturing and research running smoothly and efficiently.

Headquartered in Warminster, PA, with over 400 combined years of experience, quality and innovation, SP has manufacturing locations throughout the United States and Europe. SP are a trusted partner by leading organizations in Pharmaceuticals, Life Science, Higher Education, Ophthalmic, Petrochemical, Clinical Diagnostics, Food & Beverage Production, Environmental Testing and Monitoring and more.

**SP Market Leading Brands of Scientific Products Include:**

*Bel-Art | FTS | Genevac | Hotpack | Hull | i-Dositecno | Service | Virtis | Willmad-LabGlass*



**Contact SP:**

**Corporate Headquarters**

SP Scientific Products  
935 Mearns Road  
Warminster, PA 18974 USA  
Toll Free: +1-800-523-2327  
Local: +1-215-672-7800  
Intl: +1-845-255-5000  
hello@spindustries.com

**[www.scientificproducts.com](http://www.scientificproducts.com)**

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