

LyoStar® 4.0

Research & Development Freeze Dryer

A freeze dryer engineered with your science in mind. Developed with cutting-edge lyophilization technologies to expedite your workflow and get your biologics to market faster.

LINE OF SIGHT ENABLED

biopharma group

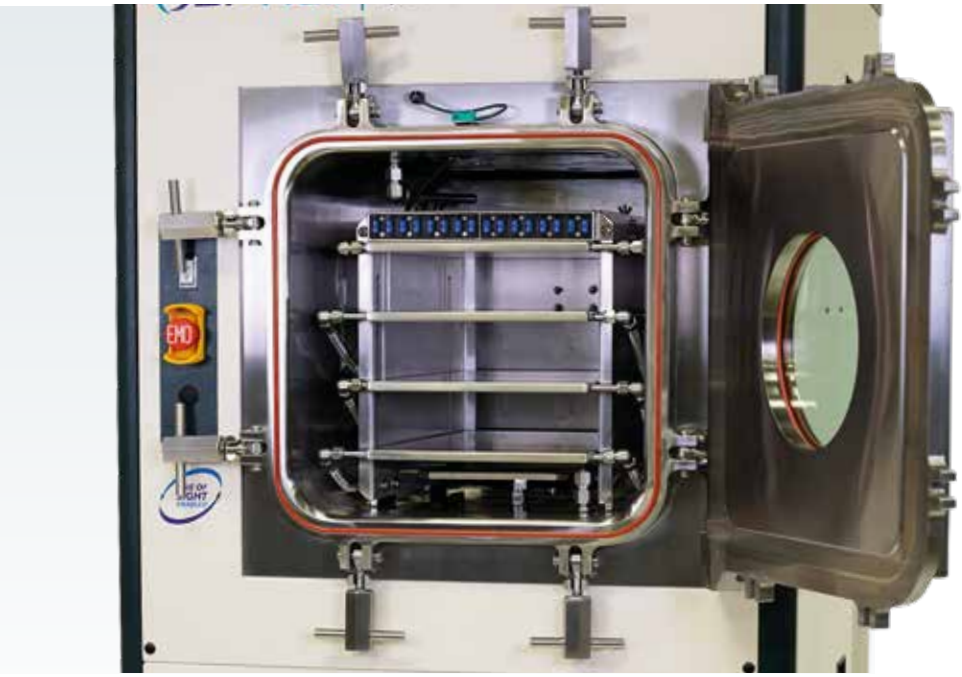
SP Hull

The Ultimate Breakthrough in Freeze-Drying

The SP Hull LyoStar® 4.0 Process Development Freeze Dryer is more than a lyophilization aid, it's designed and built to speed your biologics to market - with significant cost savings. Our decades of experience and unmatched expertise means the LyoStar® 4.0 freeze dryer technology gives your biologics the advantage they need to succeed.

Now more advanced than ever, featuring:

- Sophisticated instrumentation set, with advanced cycle development and optimization features to decrease cycle development time and conserve valuable, active pharmaceutical ingredients (API)
- Provide critical quality attributes (CQA) such as product temperature at the ice interface, T_p and product temperature at the bottom of the cake, T_b
- Additional invaluable product and process information such as dried layer resistance, heat flow, mass transfer, and how different freezing protocols impact cake resistance
- Advanced, reliable, and scalable lyophilization technologies, along with Process Analytical Technology (PAT) tools, support smooth scale-up from process development through to manufacturing



Scale, Don't Fail!

Configured with the latest innovations in freeze-drying technology, the Hull i-Dositecno LyoStar® 4.0 from Scientific Products is the most effective choice for formulation screening, cycle development, optimization and scale-up. Delivering pinpoint process control and reliability to protect your most valuable products, the exclusive combination of Line of Sight™ Technologies and robust software meets the needs of the most demanding lyophilization workflows.

Continuously Advancing Freeze-Drying Technology

The LyoStar® 4.0 enhances the proven technology and capability of the renowned LyoStar® 3 offering even more development tools, as well as the significant advantages of ControLyo® Technology to control nucleation during the freezing step for product uniformity and LyoFlux* automatic zero velocity offset (ZVO) for tunable diode laser absorption spectroscopy (TDLAS).



Software for Scale-up

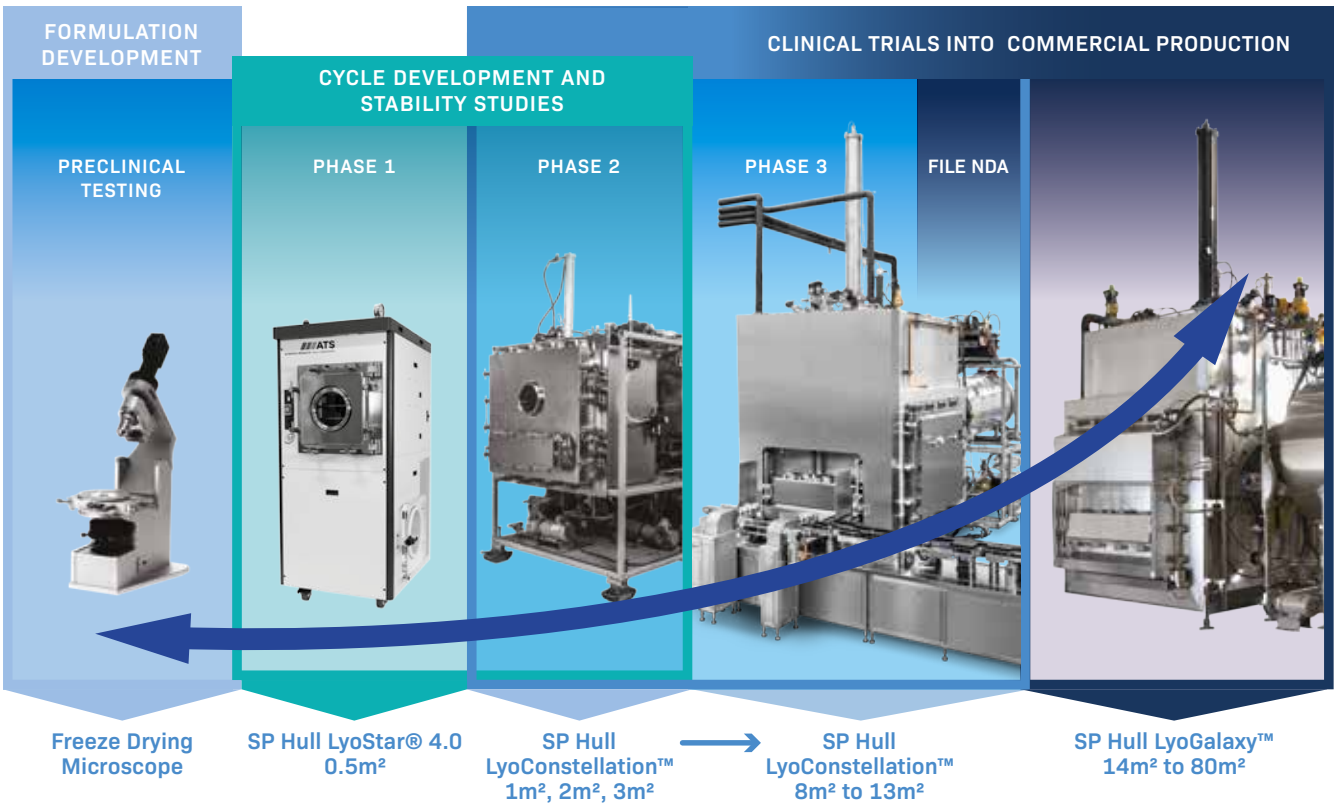
The LyoStar® 4.0 comes complete with our versatile and 21 CFR Part 11 compatible LyoS™ 2.0 control system software. LyoS™ 2.0 also runs our production lyophilizers, so you can be sure it will make light work of your cycle transfer and scale-up processes.

To ensure product consistency, LyoS™ 2.0 lets you retain complete control of temperature and pressure thanks to incorporation of best practices in instrumentation and use of methods for the detection of the primary drying endpoint, including Pirani-capacitance manometer convergence and/or pressure rise testing.

Going Green

The LyoStar® 4.0 was designed with a more environmentally-friendly refrigeration system to help comply with sustainability and environmental impact legislation. An eco-friendly refrigerant gas with a global warming potential under 14000 helps to maintain superior performance with reduced environmental impact.

Simplifying Scale-up for Rapid Results



Take our cycle optimization tools, put them together with our LyoStar® 4.0 and have the best tools at your fingertips and the data to support it.

This powerful combination of equipment and software allows the research and development scientists to:

- Control nucleation - and therefore ice crystal size and resistance - at a pre-determined temperature
- Utilize SMART* freeze drying technology to optimize the primary drying cycle
- Collect valuable, critical process and product quality attributes
- Study pre-existing formulations and determine the impact of controlled nucleation on the product

LyoStar® 4.0 + Line of Sight™ PAT Tools =
Exceptional Cycle Optimization & Data Driven Processes

No Lyophilization Task Too Large!

Meet your goals with confidence and ensure your products get to market safely. Scientific Products Line of Sight™ brings a revolutionary approach to lyophilization optimization with a trusted suite of scalable freeze-drying and PAT tools. Our innovative PAT tools can be easily embedded into your LyoStar® 4.0 enabling an accurate comparison between all scales of manufacturing, from just a few vials…to thousands!

These technologies include:

- SMART*/AutoMTM freeze dryer technology to optimize the primary drying cycle
- ControLyo® Technology giving pinpoint control of the freezing point
- LyoFlux* TDLAS sensors for precise vapor mass flow measurement
- Tempris* wireless sensors for real-time product temperature measurement

Designed with Biologics in Mind

When product stability is paramount, it's important that you have a development freeze dryer you can rely on. The LyoStar® 4.0 was purpose-built to meet the increasing number of biologics requiring lyophilization, while limiting the traditional trial and error approach – saving you time and money.

The LyoStar® 4.0 helps you mitigate risks associated with development workflows, while streamlining lyophilization scale-up, thanks to real-time, data-rich product and process insight.

Get Set for Success with Superior Performance

Designed and manufactured with the needs of research and cycle development scientists in mind, the LyoStar® 4.0 lyophilizer is robustly built to withstand continuous use.

Based on a full-scale production freeze dryer, the LyoStar® 4.0 minimizes issues associated with scaling-up, allowing you to recreate production freeze-drying processes on a much smaller scale. Additionally, built-in shelf temperature and vacuum control offers superior shelf mapping and rapid shelf freezing for unmatched process accuracy and reliability.

Take the Easy Route to Validation

With extensive documentation and onsite Site Acceptance Testing (SAT) and IQ/OQ validation support, the LyoStar® 4.0 always meets the needs of pharmaceutical regulations – giving you confidence in your product. Additionally, a more comprehensive factory-initiated System Integration Test (SIT) program and Factory Acceptance Testing (FAT) are available.

Make SMART* Choices from the Start!

Developed by leading lyophilization scientists at the University of Connecticut and Purdue University, Scientific Products Line of Sight™ SMART* freeze dryer technology is the "expert system" you've been waiting for! SMART* optimizes your freeze-drying cycles at the touch of a button, and from the very first laboratory experiment.

- Monitors product temperature at regular intervals
- Selects the optimum chamber pressure and shelf temperature
- Identifies the end of the primary drying and automatically steps into secondary drying

SMART* output parameters include product temperature at the ice interface, T_p, vapor pressure at the ice interface, P_{ice}, product resistance to vapor flow, R_p, product temperature at the bottom of the vial, T_b, dried-cake layer, L_{dry} are some of the critical quality attributes generated by the software. The critical product temperature such as T_c provides the algorithm with a target product temperature for the software to ensure that the drying process remains below the collapsed temperature at which if exceeded, can have a detrimental effect on the product quality and long term stability. A sound understanding of the formulation thermal characterization is a critical part of the freeze-drying process. Poor understanding of the formulation will result in less than optimum drying conditions and in most instances will trigger a red flag to regulatory bodies.

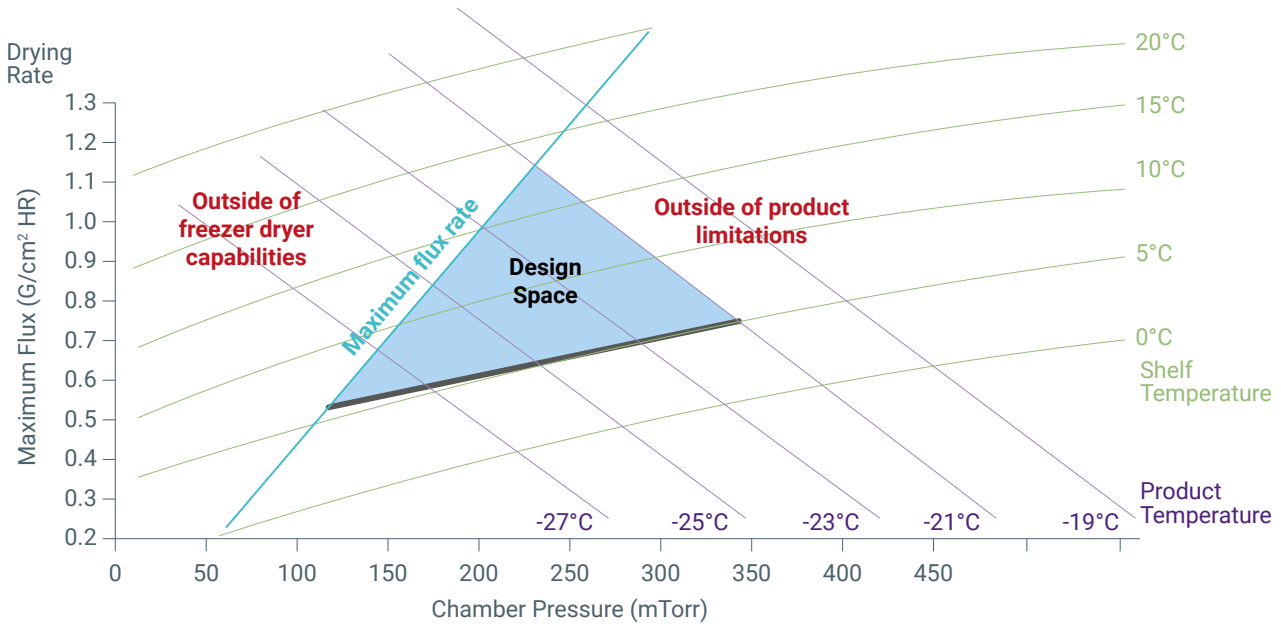


Illustration of design space

Cycle development times reduced by as much as 79%

Annual cycle development costs reduced by 60%

Simplify Scale-up with Advanced Process Insight

For an instantaneous view into product quality and cake morphology, product resistance (R_p) is the other critical quality attribute you need to know about. But characterizing R_p is not so easy when it comes to primary drying.

SMART* overcomes the typical challenges associated with determining R_p, to provide accurate data at the exact time of measurement. Structural changes as a function of temperature, such as collapse, micro-collapse, and cracking and shrinkage within the product cake can be easily assessed by SMART* R_p data.

Increase the Return On Your Investment

SMART* significantly reduces the time and cost of cycle development, eliminating the traditional trial and error approach, to improve return on investment.

While SMART* selects the right cycle for you, if you're looking to run your own pre-determined cycle but still want to collect the critical process data and product parameters calculated by SMART*, our innovative AutoMTM feature helps you do so.



ControLyo®: Controlled Nucleation at Its Best!

Our patented ControLyo® nucleation technology gives you complete control of the nucleation process. Ensuring repeatability in product uniformity, ControLyo® is ideally suited to biologics production.

Technology that Works with You

Nucleation is the initiation of crystallization of water during the freezing step, and needs to be tightly controlled. If uncontrolled, nucleation will occur at random times during the freezing step, resulting in inconsistent pore sizes, inter- and intra-batch variability, and longer primary drying cycles just to name a few of the disadvantages. All of which negatively impact product quality and most importantly scalability.

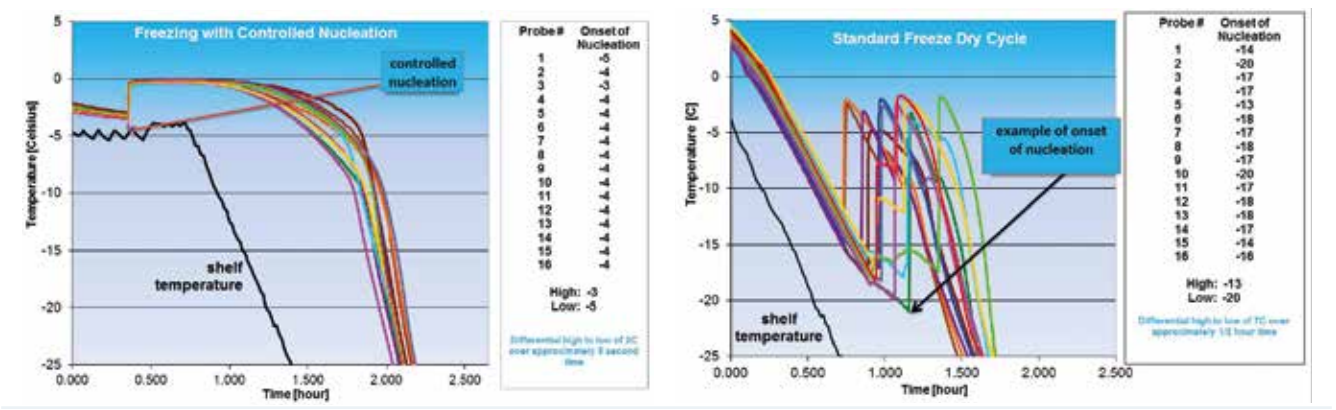
ControLyo® freezes all vials uniformly and consistently, for superior quality and unparalleled product uniformity.

- Dry faster - reduce primary drying time by 3% for every 1˚C increase in nucleation temperature
- Eliminate freezing stress - reduce protein aggregation for better stability of protein formulations
- Reproduce results with ease - replicate from one freeze dryer to another, enabling more efficient scale-up

The following quote is from a publication by the FDA:

"Controlled ice nucleation resulted in a significant reduction in the primary drying time, improved cake appearance, cake morphology, reduced specific surface area, vial-to-vial homogeneity and reduced reconstitution time."

Awotwe-Otoo, D., Agarabi, C., Read, E.K., Lute, S., Brorson, K.A., Khan, M.A., Shah, R.B., Impact of controlled ice nucleation on process performance and quality attributes of a lyophilized monoclonal antibody, International Journal of Pharmaceutics (2013), http://dx.doi.org/10.1016/j.ijpharm.2013.04.041



Comparison Screens Showing Thermocouple Trending Using ControLyo® Technology (Left) vs Uncontrolled Freezing Process (Right)

Install It, Sense It, Trust It – with Tempris* and LyoFlux*

Forget Invasive Monitoring Techniques. Get LyoFlux*!

Save time and money, and determine critical attributes such as temperature and resistance to vapor flow without intervention.

The Scientific Products Line of Sight™ LyoFlux* TDLAS, a near-infrared (NIR)-based PAT tool ensures the LyoStar® 4.0 delivers real-time, continuous monitoring. To accelerate and streamline your lyophilization process, the LyoFlux* TDLAS offers:

- Real-time calculation of average product temperature and resistance
- Highly sensitive endpoint determination for both primary and secondary drying
- Continuous mass flow determination
- Assessment of heat transfer coefficients of vials
- Simplify equipment capability characterization using minimally far less experiments SAVING time and resources

Need a Wireless Temperature Monitoring Solution? No Problem!

Working perfectly with your LyoStar® 4.0, Scientific Products' Line of Sight™ Tempris* Wireless Sensors advance your existing lyophilization workflow with accurate product temperature measurements, placement, and cutting-edge process analytical technologies.Giving unparalleled product protection throughout the entire production process, Tempris* Wireless Sensor features include:

- Real-time product temperature monitoring
- Hot & cold spot monitoring
- Options for scale-up & transfer
- Data for regulatory submission



Application Expertise at Your Service

Unparalleled Support and Training at Our Education Center of Excellence

We recognize the investment you have made purchasing and installing our systems. We will help you maximize the return on your Scientific Products equipment by assuring your personnel are fully trained in operation and maintenance. Our training courses can be customized to fulfill all of your service and learning needs.

Start-up Service and Operator Training

On-site system start-up, initial training and assistance is conducted by an Scientific Products Field Service Engineer once the unit is in its final location, with all required utilities connected.

Training objectives include: system diagnostic testing, leak-rate testing, and function testing, installation and services check, cycle management, operator software training, and operator maintenance.

Hands-on Training



Our laboratory course focuses on following the freeze-drying process - from formulation and thermal analysis to cycle development and optimization, packaging and troubleshooting all presented by subject matter experts in the field of lyophilization. Attendees have the chance to optimize their learning experience by using tangible applications in a controlled setting and access to the different freeze dryer equipment.

Course objectives include: Cycle development and optimization, formulation considerations and characterization, creating, running and troubleshooting freeze-drying cycles, and considerations for transferring freeze-drying cycles from one lyophilizer to another. An in-depth structure for participants to develop more detail knowledges and skills for all users.

Remote Training

A seven-module package scheduled in segments at your convenience and designed to facilitate discussion on theory, application, and best practice.

Course objectives include: data analysis and problem solving using real-life case studies, best practices, and principles of good freeze dryer design from the latest research. Ideal as an introductory to lyophilization and serves as a refresher for experienced users.

Flexible Options for Customized Lyophilization

The LyoStar® 4.0 is easily customized to suit your exact development needs. Our standard model comes complete with the following features:

- Dual rated chamber ASME/PED for ControLyo® Technology
- Nationally Recognized Testing Laboratory (NRTL) certified for standard products
- SMART* freeze dryer technology & AutoMTM technology
- Vacuum ramping during primary drying
- Batch reporting
- Automatic leak-rate & function testing
- Automatic stoppering and backfill with adjustable stoppering pressure
- Primary drying endpoint detection provided by:
  - Pirani / capacitance manometer differential
  - Pressure rise testing

Optimize for your specific applications with our superb range of options:

- ControLyo® Technology
- Sample extractor
- 21 CFR part 11 compatible software
- LyoFlux* TDLAS
- Tempris* sensors
- Validation and documentation packages
- Solvent package
- Easy clean room and isolator interface
- Cleanroom configuration
- Solvent package
- Foam drying package



When you choose SP, you choose expertise, reliability, and quality

With a history that spans 100+ years, SP's story is defined by our legacy of expertise. Our esteemed portfolio of brands includes FTS, Genevac, Hotpack, Hull-iDositecno, VirTis, Bel-Art, Wilmad, Service, and Training. With proficiencies that span a range of industries and applications, our specialized knowledge and experience ensures that no matter where you are in your journey, we can support your needs.

Specialized Expertise

We take pride in our reputation as leaders in freeze-drying/lyophilization, complete aseptic fill-finish solutions, centrifugal evaporation and concentration, temperature control/thermal management, laboratory consumables, apparatus and glassware.

Putting the Customer First

We inspire confidence in our customers by applying our decades of experience to truly understand their needs and provide support throughout the lifecycle of pharmaceutical development and production, as well as in diagnostics, life sciences and applied sciences applications including research, industrial, aeronautical, semiconductor and healthcare. As a renowned leader in the industries we serve, our mission is to deliver results that empower our customers to help improve the lives of people globally.

Dedication to Quality

Our processes ensure accuracy, performance, and compliance when it matters most. Our solutions are designed with excellence as a defining characteristic to ensure longevity of your investment.

As part of ATS, SP leverages the core values of the ATS Business Model (ABM) to drive our purpose: People, Process, and Performance. By engaging, empowering, and enabling our PEOPLE to build the best team; we align to implement and continuously improve robust and disciplined business PROCESSES throughout the organization; in order to yield world-class PERFORMANCE for our customers and shareholders.

SP is part of ATS Life Sciences Group, an integrator and enterprise solutions provider delivering solutions across the life sciences spectrum from discovery to at-scale manufacturing. Together, we deliver results that empower our customers to help improve the lives of people around the world. Our collective history spanning 100+ years has equipped us with the knowledge and experience to empower our customers with solutions to unique and complex problems.

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