

# Pharma Line Freeze Drying Systems



Integrated perfection of freeze dryers and loading systems



## We create values

Experience, expertise and innovation for your pharmaceutical production

#### Martin Christ – Specialists for pharmaceutical freeze drying

Cutting-edge technologies and innovative ideas are prerequisites for achieving excellent results. Reliability in the process means high-quality execution to guarantee secure and aseptic production. High-quality active pharmaceutical substances pose complex requirements for freeze dryers. We successfully meet this challenge.

As a leading international innovator, we at Martin Christ are continuously advancing our components and processes. Intuitive process control in detail is a given with our freeze drying systems, as is the use of new process optimization techniques.

Due to the acquisition of Motus — one of the leading solution provider of advanced loading systems for freeze dryer — we are able to offer optimal complete solutions consisting of freeze dryers with suitable loading systems for almost all tasks.

Continuous technical innovations like our automatic loading and unloading system LyoShuttle or the wireless temperature measurement system WTMplus are just two of the results of our successful advancements in this field.

Are you currently using one of our pilot or lab devices?

Then you are already familiar with our professional operations and individualized support. Martin Christ provides comprehensive, solution-oriented service.

Take advantage of our innovative spirit and years of experience with freeze drying systems.



## Reliable and process-oriented

Impressive concept for your freeze dryer

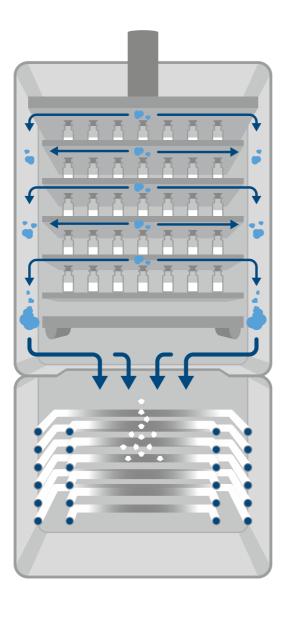
#### Optimized system design

For GMP processes in pharmaceutical applications, we offer the Zeta freeze dryer series featuring the dual-chamber principle, developed by us. The big integrated intermediate valve separates the two parts: product chamber and ice condenser. The large opening provides ideal flow conditions for water vapour. The dual-chamber system is especially beneficial for automated and validated CIP.

For our customers, using the Zeta freeze dryer means increased performance, reduced process times and greater cost-effectiveness. Temperature-sensitive materials can be dried gently and reliably.

The impressive system concept combines all of the benefits essential for an automated and validated process:

- Optimal water vapour transport to the ice condenser
- SCADA system LPCplus for data capture and upper-level controls
- Wide range of fully integrated PAT tools
- Utilizes production space efficiently with vertical arrangement of the freeze dryer
- Easy loading and unloading with the innovative LyoShuttle
- Easy access to the ice condenser



## **Compact freeze drying systems**

Zeta — the pharmaceutical series for production facilities



#### Zeta – the new standard

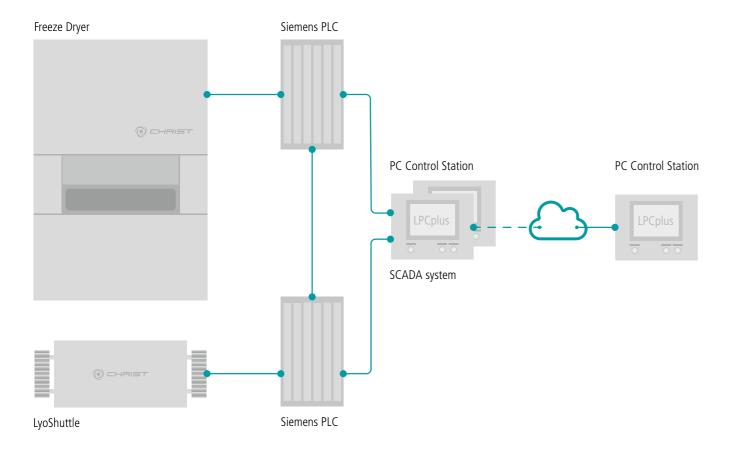
The Zeta product series includes freeze dryers that have been specially designed for cGMP production of pharmaceutical products. They cover production sizes from 1 to 22 m<sup>2</sup> and vials from 2R up to 50H. Also completely to be integrated in an isolator system. The standardised freeze dryer system Zeta makes project implementation fast, inexpensive and uncomplicated. The modular standard makes indivdualised solutions possible.

Zeta		Zeta-1	Zeta-2	Zeta-4	Zeta-6	Zeta-10	Zeta-13	Zeta-23
Max. shelf area	$m^2$	1.1	2.2	4.1	5.8	10	13	23.1
Number of shelves		2 – 5	4 – 6	5 – 8	6 – 8	6 – 10	7 – 9	8 – 11
Shelf dimension (W x D) mm		500 x 450	600 x 600	600 x 850	850 x 850	850 x 1,200	1,200 x 1,200	1,200 x 1,750
Ice capacity	kg	12	24	45	63	111	141	251
Batch volume (ca.)	1	7.8	15.2	29.0	40.8	72.8	94.0	169.2
Number of vials	2R	4,880	9,546	18,056	25,624	45,150	57,663	103,257
	10R	2,100	4,116	7,840	11,040	19,670	25,398	45,738

Remarks: Technical changes reserved / Batch volume: for 10R-vials and 1 cm filling volume

## **Application-optimized automation concept**

Combined process visualisation and data management



#### Optimal combination of standards and our experience

The Martin Christ automation concept combines industry standards in process automation with a focus on freeze drying systems for the pharmaceutical industry and the decades long experience of our specialists. The result is optimal control of freeze drying systems, including manufacturer independent communication with integrated unit operations.

#### A coordinated system:

- Siemens PLC process control
- Martin Christ in-house LPCplus process visualization system
- Profibus for sensor convectivity
- Ethernet for visualization and remote access

#### Safe, flexible, expandable, and cGMP compliant:

- System control from several operator stations
- Scalability for controlling multiple freeze drying systems
- Integration of the LyoShuttle system and interfacing with other external systems
- Intrinsically safe control elements for the safety-related functions
- GMP compliant integration of PAT tools
- Application of all standards in the pharmaceutical industry such as Gamp5 and cGMP
- Audit trail und batch report
- Recipe management

## **Optimized process visualization**

LPCplus – user-friendly SCADA system



#### Process visualization with LPCplus

The SCADA software LPCplus has been programmed in house and is continuously developed for all freeze drying applications.

Our user-friendly software for process and system control provides an uniform user interface for all freeze dryer functions, as well as the LyoShuttle system and associated administration tasks.

- LPCplus software developed in compliance with all regulations relevant to the pharmaceutical industry
- Process control system can run on a Windows PC
- Remote access available
- CIP, SIP and FIT processes configurable in LPCplus

- Process visualization
- Process documentation
- Data backup and recovery
- Recipe administration
- User administration
- Full integration of all PAT tools

## **Optimal process monitoring**

Well-designed, fully integrated PAT tools



#### **LyoCoN** – controlled nucleation

Precision freezing of all vials — that is the controlled nucleation solution LyoCoN from Martin Christ. At the press of a button, crystallization of all the vials in the freeze dryer is initiated.

- Ice vapour is generated from the product, so no additional external substances (such as WFI) are required
- GMP compliant process
- No media (exhaust air or gas) that could contain active substances or product to be treated
- Usable in pilot systems that are not pressure-resistant

#### **LyoCam** – camera system

Video recordings of the product at variable intervals, depending on the process steps or as event-controlled recording — LyoCam brings greater transparency to the freeze drying process. Monitoring and analysis of freeze drying is easy and uncomplicated with this technology from Martin Christ.

- High-end full HD industrial camera
- Cold light LED lamps to avoid energy input
- Completely integrated with LPCplus process visualization
- Intelligent image storage, with image frequency linked to special process events
- Identical timestamp to other logged process parameters
- Up to four cameras can be used in LPCplus
- Observation of loading, unloading and vial closure processes

#### **MTMplus** – manometric temperature measurement

The product temperature is one of the most critical parameters in freeze drying. It influences the shape of the ice structure, the speed of the freeze drying process and can initiate the thawing process. The Manometric Temperature Measurement system MTMplus, optimized by Martin Christ, can optimally monitor the temperature.

- The product temperature is online calculated during the measurement
- Non-invasive method
- Reduced risk of product damage
- Easily retrofittable in many Christ freeze dryers

#### **WTMplus** – wireless product temperature

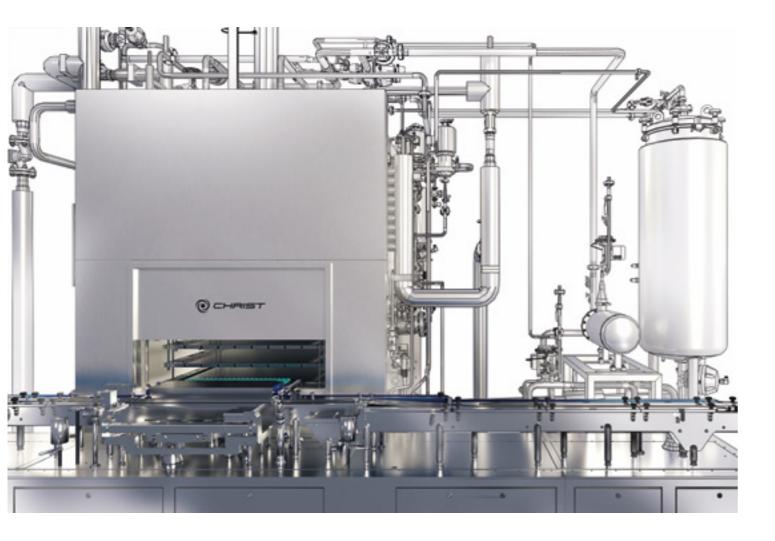
The wireless product temperature measurement system WTMplus from Martin Christ makes wireless sensor-based product temperature measurement possible for freeze drying. Wireless sensors are placed directly in the vials during loading and report product temperatures to the system controller during the entire drying process.

- Low influence of product temperature due to passive construction without batteries and very low power levels
- Power supply to the temperature sensor via interference-free radio signal in the 2.4 GHz frequency range
- Any probe location can be set in LPCplus
- Up to 16 sensors for monitoring at various probe positions
- Guaranteed service life of 100 cycles for the entire sensor
- GMP design of the antenna and sensor
- Fully integrated in the SCADA system



## **Vision for efficiency and success**

The powerful concept is the starting point and foundation of your project



- Experienced partner for the whole life cycle of the freeze dryer
- User Requirement Specification as the basis for project work
- Custom concepts
- Flexible equipment variants
- Flexible refrigeration systems

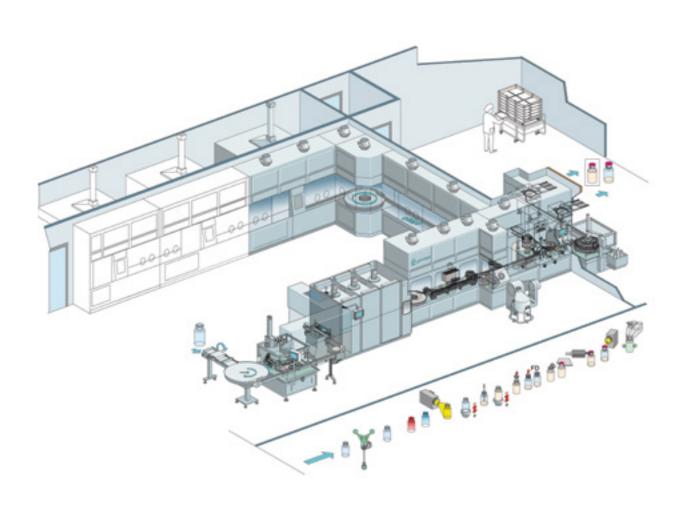
#### Unique projects deserve special attention

We support you from the first idea all the way to its implementation as it's essential that your freeze dryer and the loading and unloading system match your requirement profile perfectly. It is therefore crucial that we talk to each other. Our employees are the ideal people to contact for this. Together, you will find out exactly what you need.

Having an experienced partner like us at your side means we can help guide you through the entire life cycle of your Martin Christ freeze dryer. The User Requirement Specification (URS) is not just a document for us, but rather the basis of our project work—and we take this responsibility seriously.

## **System integration**

Optimal processes with modular system components



#### Optimally combined to meet your requirements

Your defined requirements are the basis for planning your freeze drying system from Martin Christ. High quality of the final product is always our main focus.

The comprehensive process of producing the active substance solution, filling in vials, transporting to and from the freeze dryer with automatic loading/unloading and capping requires optimal selection of individual machines.

We have developed a best partner concept for all of the other process steps required. In the immediate environment of loading and unloading and in cooperation with filling and finishing specialists, together we develop the process system that you need.

- Integration of system technology in the process flow
- Simple and reliable automated
- Best partner concept for optimal complete solutions
- Flexible process automation integration

# **Maximize Productivity**

Loading and unloading systems for optimal process performance



Our loading and unloading systems complement our product range perfectly. They are individually adapted to the needs of our customers, taking into account the capacity of the freeze dryers as well as all relevant requirements, including GMP regulations. Our offer ranges from manual solutions to semi- and fully automatic frame loading systems to fully automatic loading and unloading systems based on the push-pull principle.

Martin Christ's loading and unloading systems are specifically designed to transport pharmaceutical products safely and efficiently. These capabilities were further enhanced by adding loading and unloading manufacturer Motus Engineering to our family of companies. Our wide range of systems includes pilot to production sizes and allows for customized adaptation to any layout and project-related requirements. High performance and reliability are fundamental features of our solutions that ensure maximum process reliability. Our frame loading systems boast excellent efficiency and flexibility.

We offer different solutions from semi-automatic to fully automated systems that meet a diverse range of requirements. These solutions are ideal for medium-sized batches and retrofit projects as they can be seamlessly integrated into existing infrastructures.

Fully automatic vial handling is possible thanks to our push-pull systems, especially at high filling speeds and without the need for operator intervention. We can adapt the various system configurations, from the classic push-pull system to our innovative LyoShuttle system, to best suit your individual requirements.

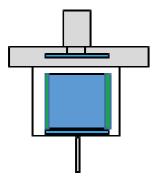
In addition, we use containment technologies to ensure the highest safety standards when handling hazardous products and sterility in demanding environments. These technologies play a crucial role in ensuring the safety of operators and products, especially in sensitive production environments.

Choose from a variety of solutions of loading and unloading. You can have them set up to work systematically with your upstream and downstream equipment.

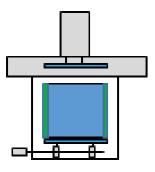


# Push-pull systems for production freeze dryers

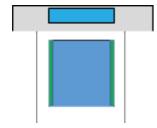
Highest efficiency and quality



Push-Backpusher (PBP) System



Push-BackChain (PBC) System



Push-InsidePush (PIP) System

Our advanced push-pull systems for production freeze dryers come with a range of innovative features to significantly increase the efficiency and quality of your production processes. The batch loading allows for precise arrangements of vials in the freeze dryer, which not only optimizes the available space, but also greatly increases the overall efficiency of your processes.

Our loading and unloading systems move vials at impressive speeds, both when loading (up to 450 vials per minute) and when unloading (up to 600 vials per minute).

The systems ensure accurate vial counting and placement, reducing errors to an absolute minimum. We offer various designs such as unload pushers (PBP), chain push systems (PBC) and LyoShuttle (PIP), which are carefully selected and customized to suit production requirements. Overall concepts are based on a variety of standard assemblies to be perfectly customized to your specific requirements.

Proper integration of loading and unloading ensures reliable buffering of vials and enables a smooth production process. Our systems allow multiple series of vials to be unloaded simultaneously and at high speed, which is crucial to increasing your production performance. We offer flexible solutions for connection to a filling line, both after filling and to the capping machine. When multiple freeze dryers need to be supplied, our distribution systems can be used efficiently to precisely direct the vials to the appropriate freeze dryers.

Integration with containment solutions such as RABS or isolators ensures that hazardous and sensitive products are handled safely in controlled environments. Format parts with anti-static properties minimize the risk of electrostatic discharge and ensure your sensitive products are perfectly transported.

- Maximum performance up to 450 vials/min
- Precise counting and exact batch formation
- Flexible single and multi-row unloading
- Seamless integration into overall filling lines
- Efficient distribution systems for multiple FD

## LyoShuttle

A cutting-edge loading and unloading system

The LyoShuttle system represents the pinnacle of innovation when it comes to row-by-row loading and unloading of freeze dryers. It is the optimal choice for this task.

Our LyoShuttle system employs cutting-edge technology to streamline the loading and unloading process of freeze dryers. A battery-powered wireless robot is responsible for efficiently handling this task. This robot utilizes a toothed belt drive to move horizontally along a set of rails positioned at a consistent loading level, adjacent to both the left and right sides of the shelf package. Communication between the loading robot and the controller occurs through secure wireless communication channels. This innovative technology ensures that no moving components are located inside the freeze dryer system.

During the loading process, the robot pushes the vial package onto the shelf. After the freeze drying cycle, the shelf package is raised slightly. The LyoShuttle robot then moves beneath the loaded shelves to a designated parking position behind the shelf package. The shelf to be unloaded is subsequently moved to the unloading height (maintaining a constant loading level), and the robot pushes the vial package back to the conveyor belt.

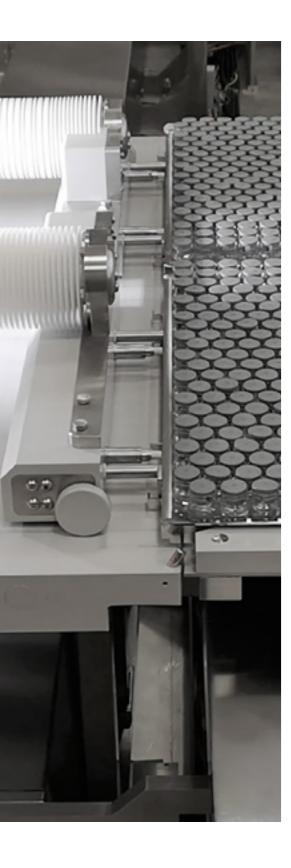
In essence, our system operates exclusively in front of, behind, and beneath the vials, eliminating any moving parts above the vials containing the product. The innovative LyoShuttle technology ensures that no moving components are situated within the freeze drying system. Its compact design allows for easy access to all components, simplifying the cleaning process. We have taken all GMP considerations into account in the design of the LyoShuttle system, with a particular focus on compact construction for use in isolators, excellent accessibility, and outstanding cleaning and decontamination capabilities.

- No moving components above the vials
- Robust operation with minimal moving parts
- Compact footprint
- Easy to clean and decontaminate
- Designed for operation within isolators



## Frame loading systems

Efficient and customizable solutions for the pharmaceutical industry



The pharmaceutical industry is currently experiencing a growing need for frame loading systems, which help to raise the transport process to a significantly higher level of performance. These systems stand out thanks to their ability to harmoniously combine efficiency and flexibility in various applications. This versatility makes it a crucial option for optimizing vial handling. These solutions are particularly suitable for medium-sized batches and retrofit projects, as they can be seamlessly integrated into existing infrastructures.

Our frame loading systems are versatile and can be used for both smaller freeze dryers and production lines with multiple freeze dryers. Rail systems for transport vehicles do not require integration into the building floor. Our systems enable optimum loading for both swing doors and slot doors. The working height can be adjusted as required, and it is easy to seamlessly integrate maganizers (frame-loaders) downstream of the filling machine.

The frames can be picked up by an autoclave to ensure the highest hygiene standards. Versions with cRABS and washdown comply with the most stringent safety and hygiene standards during the loading and unloading process.

Semi-automatic frame loading systems provide excellent balance between automation and manual interaction. They are ideal for applications where flexibility and adaptability is required without impacting efficiency or precision. These systems are a valuable addition to production plants that require a combination of automated and manual processes.

Fully automatic frame loading systems allow the various process steps to be carried out without manual intervention by the operator to ensure maximum production safety.

- Flexible and customizable designs
- High production safety and product quality
- Fulfilment of CMP requirements
- Cost-effective solutions
- Seamless integration into existing infrastructures

### **Containment**

Safety and efficiency in pharmaceutical production

Safety is a top priority in pharmaceutical production. Integrating containment technologies plays a critical role in protecting employees, ensuring product quality, and meeting regulatory requirements. The seamless integration of loading systems into isolators and RABS systems significantly reduces risk to both the operator and the product.

Meeting these requirements requires a variety of measures. RABS systems with LF-units create a controlled environment in which samples can be taken without interfering with the production environment. Another critical aspect is the implementation of monitoring solutions that enable real-time monitoring and can immediately detect and correct deviations. We offer innovative systems for integrating monitoring into isolators, including automated and documented sampling without operator intervention.

The interface linking to upstream and downstream machines optimizes the production process and minimizes the risk of errors. Inward transfer areas act as security locks and serve as access control points to the production environment. Careful planning ensures that only authorized personnel and proper materials are available.

Trust our extensive experience in integrating containment technologies to take your pharmaceutical production to the next level.

- Integration of loading systems in isolators
- Development of RABS systems including LF-units
- Innovative monitoring solutions
- Interface connection to machines both upstream and downstream
- Design and implementation of inward transfer solutions



## **Global Service**

Service Network in over 70 countries worldwide



#### **Lifetime support by Martin Christ**

At Martin Christ, we attach importance to high service quality, and offer comprehensive services for all aspects of our products.

Our goal is to ensure optimal functionality and long service life of your system by consulting, supporting, or implementing.

Decades of experience enable us to act quickly and competently.

Check it out for yourself...

- Specialised and certified service technicians on site
- Online support for problems
- 24/7 hotline for technical solutions to problems
- Short response times in case of malfunction or fault
- Calibration of all sensors, incorporating local standards
- Wear parts and critical spare parts available for at least 10 years
- Planning and coordination of maintenance activities
- Comprehensive retrofits and upgrades to ensure system reliability

# Our product spectrum

Comprehensive program of freeze dryer systems



- Pilot freeze drying systems for process development and optimization, with ice condenser capacities from 4 to 16 kg.
- Freeze drying systems for industrial production, with ice condenser capacities from 20 to 500 kg, individualized systems planning including loading and unloading.
- Manual, semi-automatic and fully automatic frame loading systems to fully automatic push-pull loading and unloading systems from pilot to production size.
- Freeze drying systems for routing applications, research, and development, with ice condenser capacities ranging from 2 to 24 kg.
- Rotary vacuum concentrators for routine applications, up to evaporation in the High End area of pharmaceutical research.



#### Martin Christ Gefriertrocknungsanlagen GmbH

An der Unteren Söse 50 37520 Osterode am Harz

Tel. +49 (0) 55 22 50 07-0

info@martinchrist.de www.martinchrist.de