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CHRIST

Pharma Line Freeze Drying Systems



Epsilon Z – the new standard



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. 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

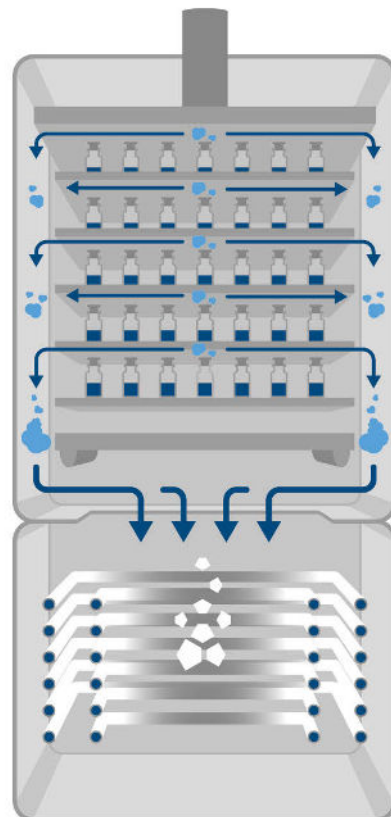
Optimized system design

For GMP processes in pharmaceutical applications, we offer the Epsilon Z 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 Epsilon Z 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



- Optimal vapour flow
- Optimized automation concept
- Integrated PAT-Tools
- Easy scale up and tech transfer
- Space saving design



LyoShuttle

Innovative loading and unloading system



The LyoShuttle system is the right choice

We understood that loading and unloading is a critical process step in fill and finish lines, therefore we developed an innovative complete solution to overcome the limitations of existing systems.

A battery-powered wireless robot performs the loading and unloading in the LyoShuttle system. It uses a toothed belt drive to move horizontally on a set of rails mounted at the constant loading level alongside left and right the shelf package. The loading robot communicates with the controller via protected wireless communication. This innovative technology ensure that no moving parts are located inside the freeze drying system.

For the loading process the robot pushes the vial package on the shelf. After the freeze drying cycle the shelf package is raised a few centimetres. The LyoShuttle robot moves beneath the loaded shelves into a parking position behind the shelf package. The shelf to be unloaded can then be moved to the unloading height (constant loading level) and the robot pushes the vial package to the conveyor belt. In summary, we only move in front, behind and beneath the vials and there is never any moving part above the vials filled with the product. For GMP reasons it is desirable to avoid moving parts above the vials.

The freeze dryer can be made lower as there is lower additional height for a loading bar required. This innovative technology ensure that no moving parts are located inside the freeze drying system. The compact design provides easy access to all LyoShuttle components, so they are easy to clean.

All GMP aspects have been consistently taken into account in the design of the LyoShuttle system. Particular attention has been given to compact construction for use in isolators, along with good accessibility and excellent cleaning capability.

- No moving parts above the vials
- Robust operation with no chains or bars
- Close shelf spacing
- Compact and easy to clean
- Design for use in isolators

LyoShuttle – loading step



The LyoShuttle robot pushes the vial package on the shelf.

LyoShuttle – unloading step



The shelves move up. The LyoShuttle robot drives behind the shelf package. The shelf to be unloaded moves on constant loading level.



The LyoShuttle robot pushes the vial package out of the freeze dryer.



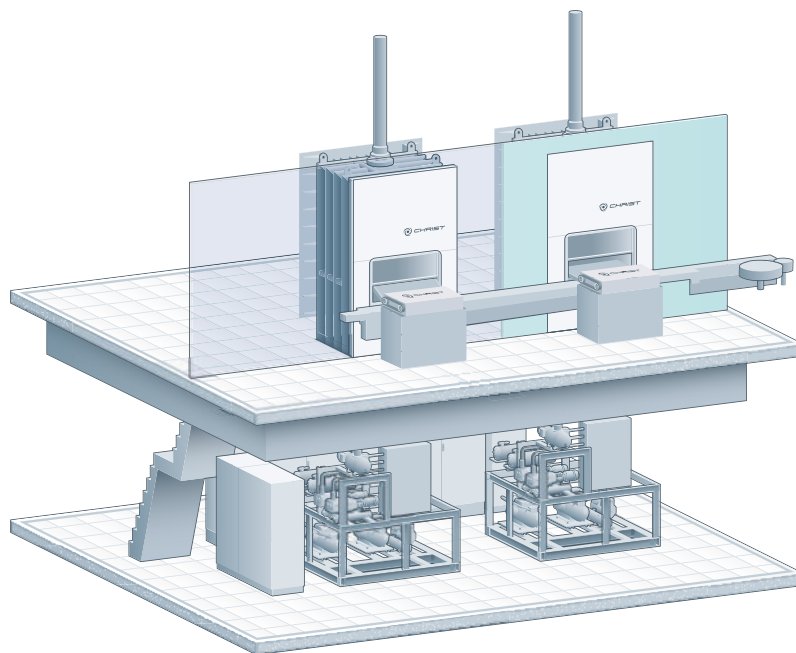
Product video:

Check out the functionality of our LyoShuttle system.

martinchrist.de/Lyoshuttle

Compact freeze drying systems

Epsilon Z – the pharmaceutical series for production facilities



Epsilon Z – the new standard

The Epsilon Z product series includes freeze dryers that have been specially designed for cGMP production of pharmaceutical products. They cover production sizes from 1 to 22 m² and vials from 2R up to 50H. Also completely to be integrated in an isolator system. The standardised freeze dryer system Epsilon Z makes project implementation fast, inexpensive and uncomplicated. The modular standard makes individualised solutions possible.

Epsilon		Z-1	Z-2	Z-4	Z-6	Z-10	Z-13	Z-23
Total shelf area	m ²	1.1	2.2	4.1	5.8	10	13	23.1
Number of shelves		5	6	8	8	10	9	11
Ice capacity	kg	12	24	45	63	111	141	251
Batch Volume (ca.)*	l	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	2,110	4,116	7,840	11,040	19,670	25,398	45,738

*Remark: for 10R-vials and 1 cm filling volume

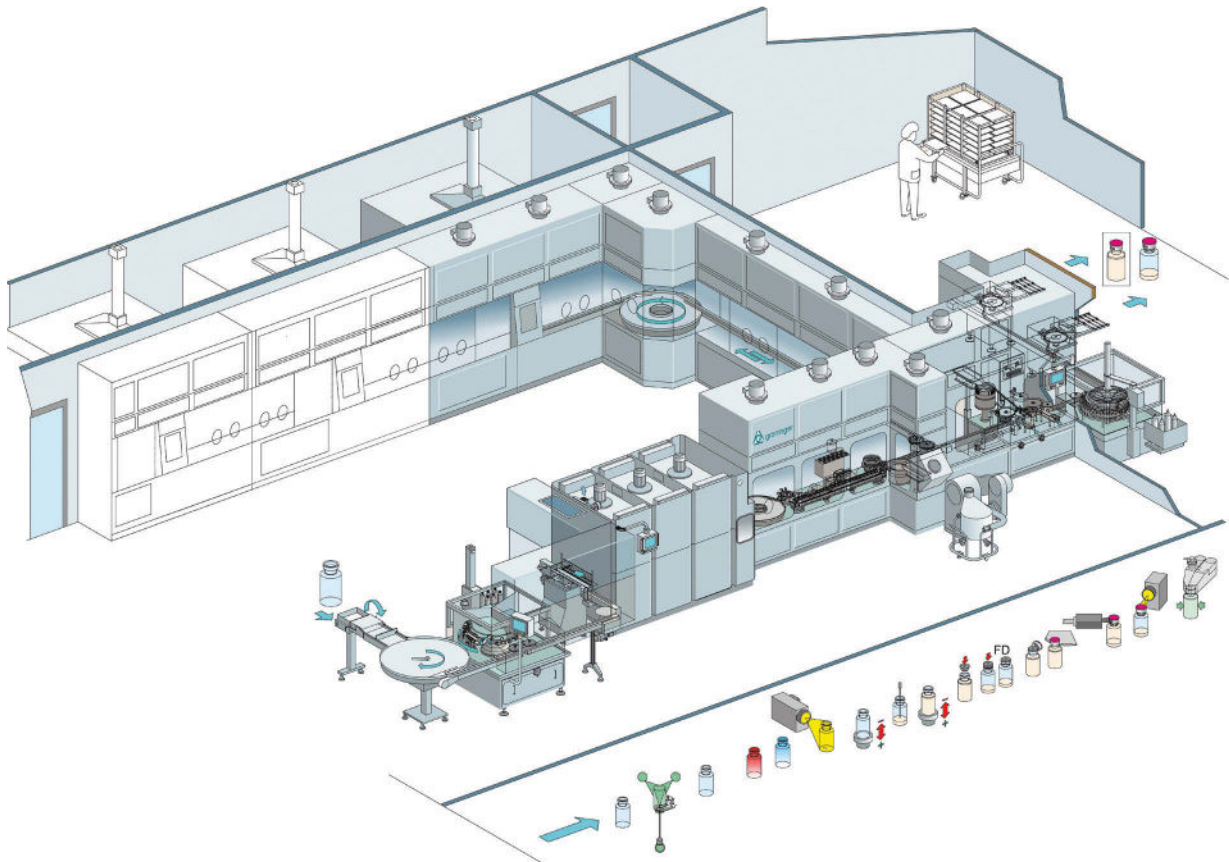
Project management by Martin Christ

Your User Requirement Specification (URS) is the basis of our project work. Starting in the planning phase, we review options for implementing your needs in accordance with GMP requirements. We are by your side from planning through the end of the lifecycle of your Martin Christ freeze drying system.

- Project manager support in defining requirements and project realisation
- Planning and documentation of individual process steps
- Continuous project manager support for qualification

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.

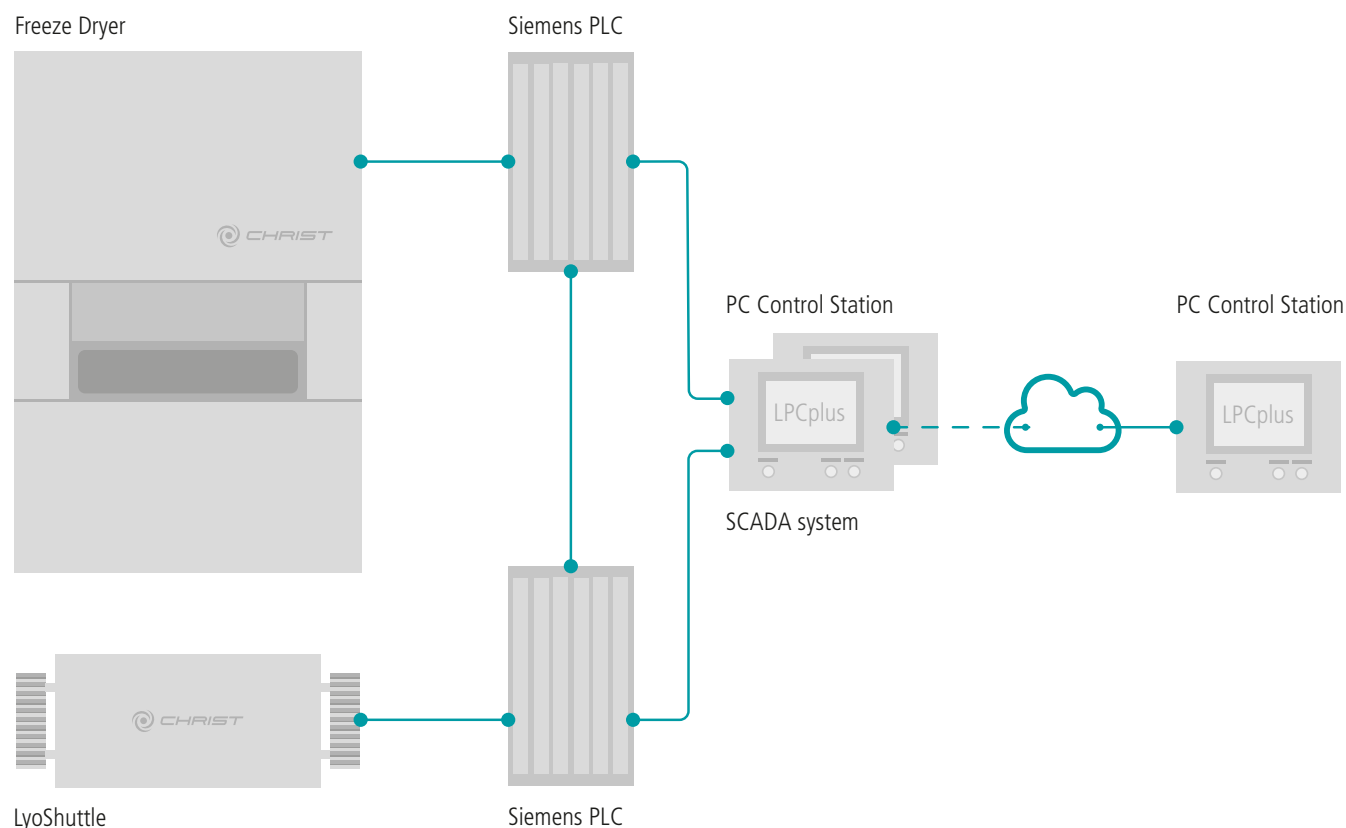
The comprehensive process „production of the active substance solution – filling in vials – transport to and from the freeze dryer with automatic loading/unloading – capping” requires optimal selection of individual machines.

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 LyoShuttle
- Best Partner concept for optimal complete solutions
- Flexible process automation integration

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 connectivity
- 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

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

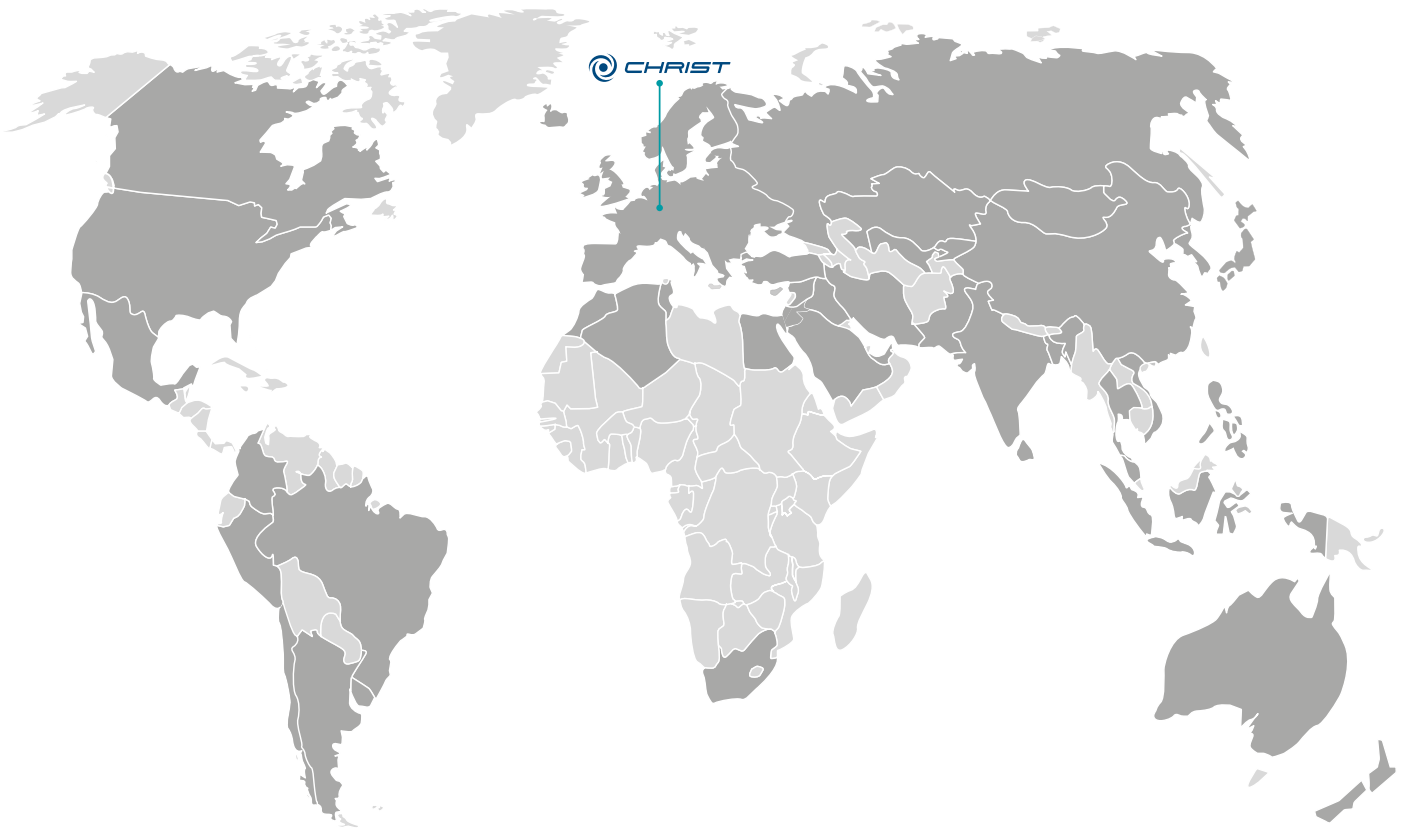
The wireless product temperature measurement system WTMplus from Martin Christ makes wireless sensor-based product temperature measurement possible for freeze drying. Wireless sensors are placed directly in the vials during loading and report product temperatures to the system controller during the entire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



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



1 Freeze drying systems for industrial production, with ice condenser capacities from 20 to 500 kg, individualized systems project planning including the LyoShuttle loading and unloading.

2 Pilot freeze drying systems for process development and optimization, with ice condenser capacities from 4 to 16 kg.

3 Freeze drying systems for routine applications, research, and development, with ice condenser capacities ranging from 2 to 24 kg.

4 Rotary vacuum concentrators for routine applications, up to evaporation in the High End area of pharmaceutical research.



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