

### **VERTRIEB DURCH:**



### Ihr Anbieter für Geräte im Bereich Labor, Mikrobiologie und Industrie.

### Wir sind für Sie da:

E-Mail: office@rieger-iv.at Telefon: +43(1) 728 00 52 Fax: +43(1) 728 69 16 Rustenschacher Allee 10, 1020 Wien, Austria

### www.rieger-iv.at





# Freeze Drying Systems for Pharmaceutical Production



Customised Solutions Designed & Made in Germany

www.martinchrist.de



## We Create Values

Martin Christ is a world leader in the development and manufacturing of freeze dryers, with over 65 years of experience.

We want to present to you now the centrepiece of our company – the area in which all our expertise and experience come together: We are talking about the construction of customised systems for sterile production of pharmaceutical products.

In this sector too, the name Martin Christ stands for utmost customer satisfaction all over the world. We develop and manufacture to the highest pharmaceutical standards to provide the best benefits for our customers. Our corporate strategy is focussed on your applications.

We see ourselves as a worldwide leader in innovation. We constantly secure our position as an international leader in freeze drying by means of technological innovations, such as our wireless product temperature measurement system WTMplus. Dozens of patents held by our company provide irrefutable evidence of this.

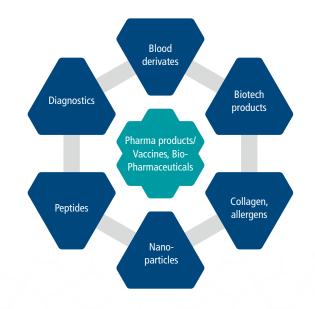
In aseptic (bio-)pharmaceutical production, freeze drying (lyophilisation) is the gentlest fill and finish process, which eliminates the need to maintain the cooling chain for the – often highly sensitive – active substances. Around 60 % of these products, such as special cytotoxic substances and antibodies, require freeze drying to attain adequate shelf life. These are typically aqueous formulations, although components of alcohols and other solvents are gaining in importance. If this is the only way to form a solution of the API, then the process chain – which also includes the freeze dryer – must be designed to be chemically resistant and to comply with appropriate safety requirements.

Due to the high value of these active pharmaceutical substances, the requirements on the reliability and the technical implementation are extremely stringent. Aseptic production over the entire process chain demands fully automatic loading and unloading, possibly in isolators, as well as a sterilisable freeze dryer design. Highly potent drugs require specific solutions to prevent discharge, towards both the operator and the environment.

Here at Martin Christ, process control systems which are both detailed and yet intuitive are just as integral to our approach as the use of modern process enhancement methods, for example controlled nucleation and the best available Process Analytical Technologies (PAT).

We are quite at home in virtually all industry sectors, albeit due to demand a particular focus exists in the areas of pharmaceuticals and the biotech sector.

We would now like to invite you in the following pages to learn a little more about at the developments outlined above.



Find out how exciting, innovative and pioneering German engineering can be, and come and share in our fascination for this technological showpiece in our company.

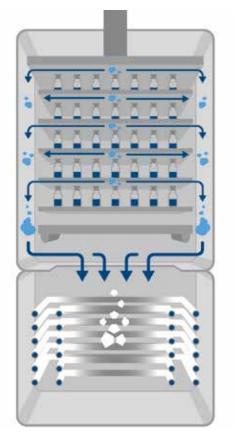
Best wishes, Martin Christ

# **Process-Oriented and Safe**

# Optimised system design for aseptic production of active substances

For GMP processes in the fields of pharmaceutical, diagnostic and specialist applications we offer the double-chamber principle, developed by us, with a large opening to the ice condenser positioned below the drying chamber. The large cross-section creates ideal flow conditions for water vapour.

Especially at the start of the drying process, undesirably large pressure differences between the drying chamber and the ice condenser chamber can occur if the opening is not large enough to handle the enormous quantities of water vapour released during drying. A large opening reduces processing times, significantly increasing the performance and cost-effectiveness of the system. Temperature-sensitive materials can be dried reliably with this design.



Martin Christ double-chamber principle with optimised vapour flow and compact construction, the lowest pressure plate serves as an intermediate valve

#### **Convincing design**

The double-chamber system is particularly advantageous when automated and validated CIP is necessary in the dryer.

- Large opening and short paths between drying chamber and ice condenser chamber mean optimum water vapour transport
- high efficiency leads to superior cost-effectiveness
- Reduced operating costs due to minimal chamber volumes, which means cheaper components such as vacuum pumps and compressors can be used according to consumption
- Low pressure drop between drying and ice condenser chambers, so even sensitive and difficult substances with low eutectic point or solidification point can be dried safely
- The ice condenser can be accessed and checked easily through the chamber door, no "Black box"
- easy validation for compliance with all national and international regulations
- Vertical arrangement allows the chambers to be lowered and therefore an effective usage of available floor space, and individual adaptation is possible



Ice condenser chamber with CIP-/SIP-piping

# **Compact and Effective**

#### Advantages of the Martin Christ Epsilon DS freeze dryers:

- Customised, and space-saving due to compact frame design
- Process specific system configurations such as door designs with door-in-door variants, or slot door and separate inspection door
- Automation with Siemens S7 and user-friendly process visualisation LPCplus
- Safe operation than ks to redundant systems
- Effective and validated CIP cleaning
- Integrated, fully automatic filter test (FIT)
- Pressure chamber > 2.5 bar for steam sterilisation (SIP) from 121 °C up to 135 °C
- Hydraulic-pneumatic door locking system
- Thoroughly tested prior to delivery, reduced assembly times and test sequences on site
- 100 % made in Germany, long-lasting and robust components, optimised total cost of ownership







Tell us your task requirements – we will be pleased to advise you at no obligation.



# **Customised System Layout**

The main criterion in selecting a freeze drying system is the desired quality of the final product. Combined with other requirements, for example with regard to incorporation into process sequences, space requirements, high cost effectiveness, and compliance with all relevant legal requirements.

Based on our tried and tested double-chamber principle, we plan and implement your requirements: product-oriented, process-optimised and adapted for each individual application.

#### Your process decides

The integration of the system technology into the process flow must be guaranteed. To achieve this we offer different versions:

- Compact, mono-block systems
- Two-level installation, tailored to the building design
- Customised door designs (pass-through systems, door-in-door solutions, small loading door and inspection door)

#### Safety for the operator and the batch

The risk of batch failures due to contamination of the final product must be eliminated. The same applies where necessary to reliable personnel safety in the case of e.g. cytostatic agents.

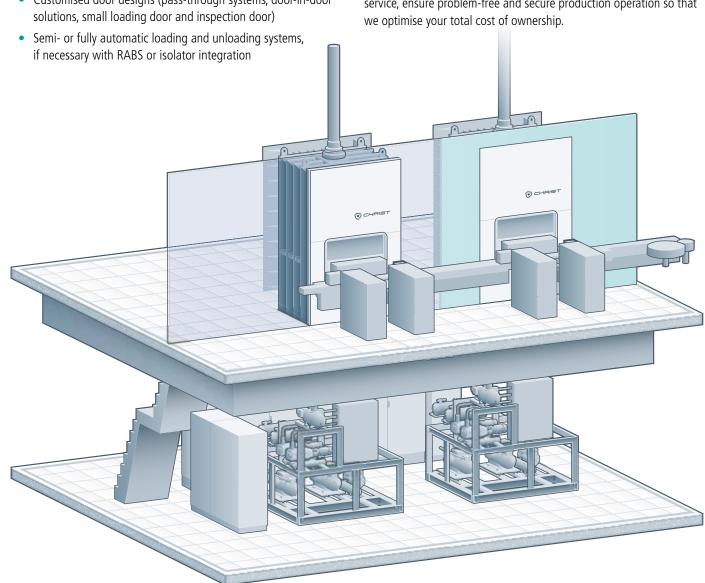
For these requirements automatic loading and unloading systems, combined with RABS or isolator systems, are the method of choice.

#### Long-lasting and future-proofed

All system components are designed for a long production lifetime of the system. The process automation is flexible in its design and allows the implementation of additional and future functions, especially with regard to new PAT-tools.

#### Cost optimised

Long-lasting and robust components, combined with our specialised service, ensure problem-free and secure production operation so that



# **Detail Engineering at the Highest Level**

#### Tailored and energy-saving refrigiration systems

Cooling systems of production freeze driers normally use standard commercially available piston compressors, which are equipped with up to six independent cooling systems depending on the size of the system. As an alternative when power requirements are high, screw compressors can be installed.

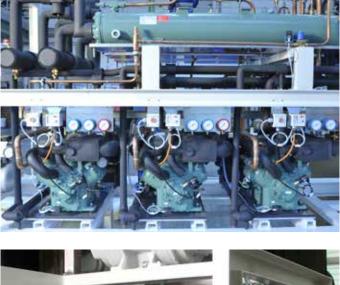
During the freezing process the entire cooling system works primarily for shelf temperature control, and during the drying process – depending on the process section – mainly on the ice condenser.

The intelligent energy management over all phases of the freeze drying balances the heat supplied with the necessary cooling power and leads to low energy consumption.

Redundancy in the cooling system is provided as standard in the case of larger systems.

#### **Optimal vacuum for secure processes**

Our freeze drying systems are equipped with rotary vane pumps from leading manufacturers as standard. Even in the vacuum system in the case of larger systems redundancy is built in as standard. In systems with more than 160 kg of ice condenser capacity, in addition to the rotary vane pumps a Roots pump is used for rapid evacuation times. Optionally, oil-free vacuum pumps are also used.





#### Best quality shelf design

The shelves for the pharmaceutical product are made from highquality stainless steel. They are welded together with the latest laser methods and achieve a surface finish of Ra  $\leq 0.6\,\mu\text{m}$ . The eveness is  $\pm$  0.5 mm over the entire shelf.

The FEM-optimised design used results in a robust and yet weightsaving layout. Heating and cooling times are reduced. The temperature distribution on the shelf and over the entire set of shelves is  $\pm$  1 Kelvin. This temperature distribution is being demonstrated by shelf mapping as part of the acceptance process at our factory.

The number of shelves is variable according to the client's requirements or the required number of drying flasks, as well as the ratio of total shelf area to ice condenser capacity.

#### Loading door in aseptic design

In the sterile area the freeze dryer is generally equipped with a slot door, and on the machine room side with a swing door for maintenance.

The slot door enables a constant loading level, which is necessary e.g. for automatic loading and unloading of the freeze dryer.

The optimally designed Martin Christ solution is characterised by a very compact construction, which is easy to be cleaned as well.

The slot door enables a simple interfacing of the freeze dryer to an RABS or isolator system.

For particular situations a door in door solution (slot door in the swing door) is possible. This further reduces the space requirements of the overall system.





# **Cleaning and Sterilisation**

Cleaning of the freeze dryer is normally carried out automatically with Cleaning in Place methods – or CIP for short. In this method the entire drying chamber including the shelves, hydraulic cylinder bellows and the ice condenser chamber with the ice condenser coils can be reached by the integral conical nozzle system. This fully automatic cleaning process is validated and complies with the ISO 13408 guidelines.

In recent years the circulation method with its reduced volume flow has become more and more industrial standard.

Process sequence (example):

- 1 Cleaning step in the continuous method (pre-cleaning), sequential control of the nozzle tubes
- 2 Cleaning step in the circulation method (primary cleaning) The ice condenser chamber is half filled with WFI. The CIP circulation pump forces the water to circulate
- 3 Cleaning step in the continuous method (final rinse), sequential control of the der nozzle tubes

The volume of media required is between approximately  $2 \text{ m}^3/\text{h}$  to  $5 \text{ m}^3/\text{h}$ , depending on the size of the system. The cleaning sequence can be adjusted in a flexible manner using the Martin Christ LPCplus process visualisation software.

By precise positioning of the CIP piping with the CIP nozzles this method achieves optimal cleaning results, which have been verified by a standardised Riboflavin test. A cleaning validation of the ice condenser as well is is easily possible by means of the patented double-chamber design – easy access via the inspection door.



CIP nozzle piping in a steam sterilizable freeze dryer (shelves coupled in pairs to enlarge the usable distance).

# ... Are Batch-Winners!

The CIP process is normally followed by steam sterilization, or SIP (Sterilization in Place). Again, this process is validated and runs fully automatically.

Steam sterilization and cleaning process use the same set of piping.

By exact determination of the cold spot in the overall system (on the ice condenser drain) and monitoring of the temperature at this point, the sterilization process is controlled in an adjustable manner using the LPCplus process visualisation software (pressure or temperature, duration).

The filter integrity test (FIT) is usually used to test the proper operation ("integrity") of the sterile aeration filter at regular intervals.

The steam-sterilizable freeze dryers from Martin Christ have fully automatic filter testing already integrated in the unit controller.

Generation of the test water – to check the integrity of the filter membrane – is carried out using the existing sterile steam for the SIP method.

Additional protection can be ensured by using a second sterile filter in series. The functioning of the automatic test execution remains unchanged.



Easy access to ice condenser, optimized cleaning process



Double filter integrity test (top left and centre) with test water preparation (reservoir on the right)

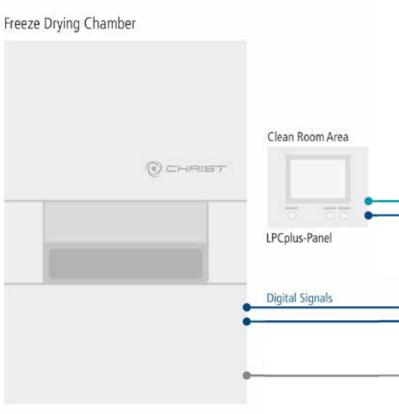
# **Application Optimised Automation Concept**

The Martin Christ automation concept combines the standards of leading process automation solutions with the focus on the freeze drying processes of the pharmaceutical industry. This results in a corresponding system for both the process viualization and the process data management.

- Siemens S7-400 control system
- Process visualization with the Martin Christ LPCplus process control system
- Integration and interfacing of loading and unloading with other external systems
- Operation of several stations, e.g. in the clean room and the control room
- Intrinsically safe control elements for the safety-related functions of the pressure vessel
- Communication with Profibus at the sensor level
- Ethernet for communication to provide visualization and remote access
- Scalability for controlling multiple freeze drying systems
- Application of all standards in the pharmaceutical industry such as Gamp5 and cGMP

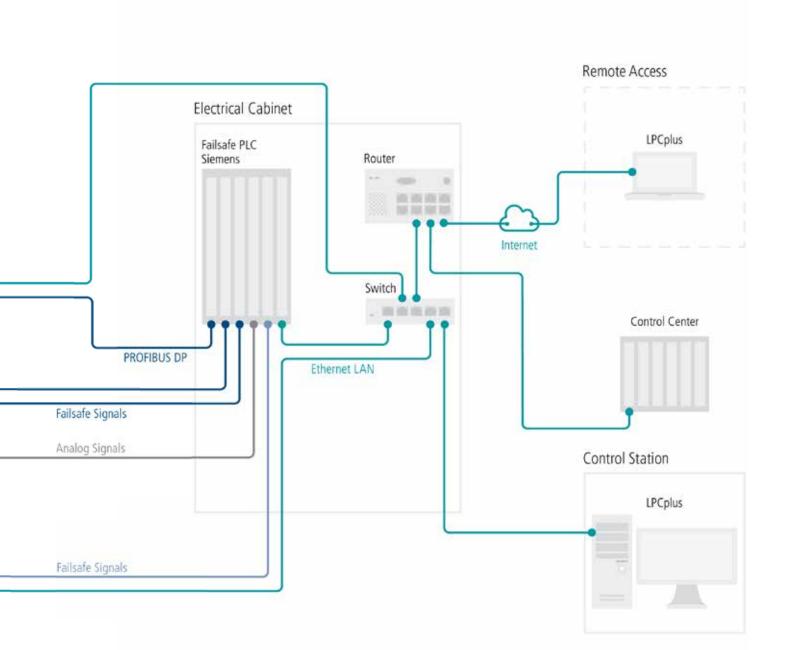
The combination of industry standards in process automation and the decades long experience of our specialists leads to the optimal control of freeze drying systems, which includes the manufacturer independent communication with integrated unit operations.





#### Loading, Unloading System





# **Process Visualization Specific to Freeze Drying**

Production freeze dryers in the pharmaceutical industry should offer more than just comprehensive monitoring of running processes – e.g. functions for quality assurance. Martin Christ units feature fully automatic process control with direct parameter adjustment to give you optimal protection against spoiled batches of your valuable products.

#### Process visualization with LPCplus

Our user-friendly software for process and system control provides a uniform user interface for all freeze dryer functions and associated administration tasks. The SCADA software package LPCplus has been continuously developed in house over 3 decades and optimised for the freeze drying process. It supports the following functional areas:

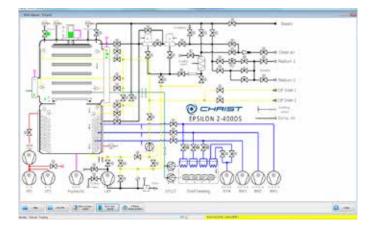
- User interface for process control (of manual, fully automatic and program-controlled drying processes)
- Process visualization
- Process logging (measurement data and audit trail)
- Process documentation
- Data backup and recovery
- Administration of freeze drying programs and recipes
- User administration

The LPCplus software has been developed in compliance with the provisions of Regulation 21 CFR Part 11 of the FDA with regard to data stored in electronic form.

The process control system LPCplus can be run on Windows-based PC operating systems. Remote access is of course possible, e.g. for maintenance tasks.

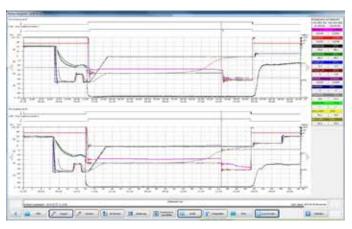
The CIP, SIP and FIT processes are configurable using LPCplus and are executed fully automatically.



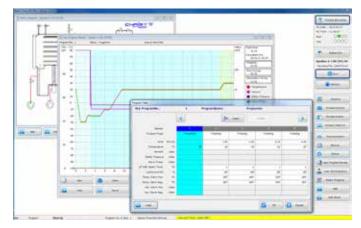


Some highlights of the process control and visualization software package LPCplus:

- Intuitive system operation with language selection
- Context-sensitive help function (integrated detailed operating instructions)
- Optimised for touchscreen and mouse/keyboard operation
- Analysis of multiple freeze dryer runs with parallel display of process graphics, zoom function
- All current process events shown in tabular form (logbook) with filter function
- Graphical generation of drying programs (recipes)
- Determination of glass transition temperature/freezing point with suggested drying vacuum (especially for process optimization in pilot systems)
- Fully automatic process sequence, including cleaning and sterilisation process
- Prevention of unauthorised changes of set values, configurations and programs due to detailed user administration
- 6 user levels
- Tamper-proof binary formats and a single audit trail for optimal data and process integrity
- Remote control from a PC workstation using client/server architecture
- Free configuration of messages and alarms, forwarding possible via e-mail and/or SMS



Process comparison for recipe optimisation



Graphical generation of drying programs

# **Superior PAT tools for quality assurance**

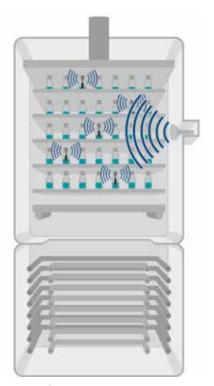
The need for monitoring of freeze drying processes has gained in importance since the PAT initiative. In addition to the validation of consistent processes, process optimisation is also a central consideration in this.

Even in the basic version our freeze drying systems are equipped to handle many PAT-tools, or optionally they can be very easily adjusted to do so.

All PAT-tools are completely integrated into our LPCplus process control and visualization software and can therefore be used for control and for optimizing the processes. All data are of course archived in a GAMP 5-compliant format in the process log.

#### Product temperature

The product temperature is one of the most important variables for process control and monitoring. As well as the classic, cable-linked method with robust PT100 sensors we also offer the wireless based WTMplus technology. By using small GMP compliant measurement sensors without a power supply, the measurement of the product temperature is also possible in practice, even in production batches. The measurement data are also fully integrated into our LPCplus process control system.



Principle of wireless product temperature measurment



WTMplus wireless product temperature sensors

#### Pressure increase test

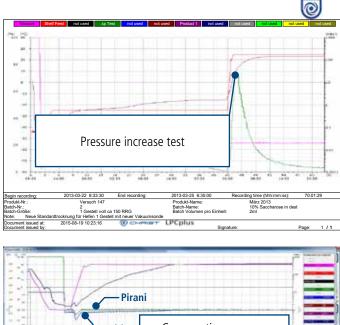
The transition between the primary and secondary-drying phase can be determined with the pressure increase test. Due to the special design with the ice condenser integrated directly underneath the product chamber, the pressure increase test can be performed without any additional components.

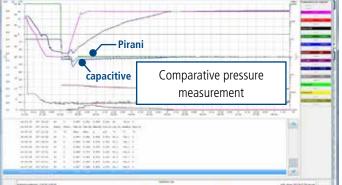
If the pressure increase in the product chamber when the intermediate valve is closed is below a limit value, there is no longer any sublimating ice present in the product and the secondary-drying phase can be started automatically. The entire process is controlled and documented by the controller fully automatically. All parameters can be adjusted by the user.

#### **Comparative pressure measurement**

Also, by using two different vacuum measurement probes (Pirani and capacitive measuring principles) the end of the primary drying phase can be predicted. If the difference in the pressure measurements is less than a preselected limit, the secondary-drying phase is automatically started. The measurement probes used are CIP/SIP-ready.

In addition to the PAT-tools described, other measurement methods, e.g. mass spectrometers can also be easily incorporated.





12.



# **Loading and Unloading Solutions**

#### Automatic loading and unloading

In aseptic production automatic loading and unloading of the freeze dryer has become almost indispensable.

In most cases, so-called conveyor push pull systems are used for this. A belt system transports the vials from a filling machine to the freeze dryer. A pusher moves the vials row by row through a slot door on to the shelves. At the end of the freeze drying process the freeze dryer is unloaded. A pusher travels up to the end of the shelf and pulls the vials over the shelf back on to the belt system for onward transport.

These push-pull systems can be used within RABS and isolators.

When multiple freeze dryers operating in parallel are used, transfer carts or special solutions such as clean room robots become practical.

#### Semi-automatic loading and unloading

To provide safe transport of the vials taking into account the clean room classification a transport trolley is a suitable cost effective solution.

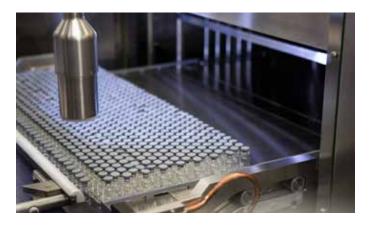
Depending on the design of the trolley the vials can be transported continuously from the filling line to the freeze dryer under LF conditions. A height-adjustable transport tray on the trolley is brought into contact with the shelves of the freeze dryer, which allows the frames holding the vials to be securely placed on the shelves.

To unload, the linked frames are manually withdrawn from of the freeze dryer onto the tray of the trolley.

#### Manual loading and unloading

The freeze dryer is loaded manually using frames or dishes. The dishes are used in the so-called bulk drying process.

These days, purely manual handling is only used in pilot scale processing or for specialist applications. It is sometimes used in the manufacturing of veterinary medicines.







# Innovative LyoShuttle Loading and Unloading Systems

The existing product line of company Martin Christ is enhanced by the new, automatic LyoShuttle loading and unloading systems. The patent-pending innovative solution is available in two versions, which essentially differ in the drive technology employed.

#### LyoShuttle systems from Martin Christ offer outstanding advantages to ensure product quality and production reliability:

#### No moving parts above the vials

Many common systems have an unloading bar that moves above the vials filled with the product. For GMP reasons it is desirable to avoid moving parts above the vials. With the LyoShuttle system from Martin Christ, the shelf package is raised a few centimetres to allow unloading of the vials. The LyoShuttle system moves the unloading bar beneath the 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). With LyoShuttle, there is never any moving part above the vials filled with the product, even after stoppering. In summary, we only move in front, behind and beneath the vials.

#### No additional space necessary above the vials

With the usual push-pull systems, up to 50mm of additional space above the stoppered vials – for each shelf – is necessary for unloading freeze dryers with an unloading bar. This makes the freeze dryer 50 to 100cm higher than usual, significantly increasing production costs. The unloading bar of the LyoShuttle system can also move below the shelves loaded with vials. No additional space is necessary above the vials, so the freeze dryer can be made lower.

#### Variable shelf spacing

Another advantage compared to other systems is that the shelf spacing can be adapted to the vial height for unloading. Among other things, the smaller spacing allows suspended vials to be secured directly in hexagonal groups after stoppering. This effectively avoids glass breakage.

#### Lateral guides independent of the shelves

With commonly available systems, the lateral guides for the vial set are joined to the shelves at fixed distances. As a result, the vial arrangement deviates from the ideal hexagonal grouping, depending on the diameter and tolerance of the vials concerned. This can lead to wedging of the vials on the shelf or even glass breakage. With the LyoShuttle system, the spacing of the lateral guides can be adapted to specific vial dimensions individually for each formula.

#### Compact, easily cleaned and isolator-compliant construction

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 or LAF units, along with good accessibility and excellent cleaning capability.

# It's All In The Drive

The two versions of the innovative LyoShuttle system differ in the type of drive technology that is used. As a basic principle the moving parts of the LyoShuttle system are not connected to the overall system and can move independently of the shelf position. This yields significant advantages compared to other commonly available push-pull or push-push systems, along with distinctly smaller space requirements. The Martin Christ LyoShuttle system therefore offers considerable advantages compared to systems from other vendors. Individual functions, such as adjustable lateral guides, are optional and can be implemented according to specific requirements.

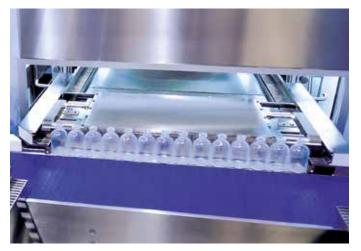
### LyoShuttle drive

In the **LyoShuttle drive** version, loading is controlled by a loading robot that can move horizontally with toothed belt drive. All of the components have been selected based on cGMP considerations.

The loading robot moves on a set of rails mounted at the constant loading level alongside the shelf package. Motive force is provided by battery-powered electric motors. The batteries are charged when the robot is in the parked position. The loading robot communicates wirelessly with the LyoShuttle system.

Thanks to the flexible and space-saving construction, the **LyoShuttle drive** option is particularly suitable for small and medium-size production freeze dryers.

Loading – LyoShuttle drive



Unloading – LyoShuttle drive

### LyoShuttle rapid

The **LyoShuttle rapid** version works with two synchronously operating linear motors joined together by a loading/unloading bar.

The active components (coils) of the linear drives are located alongside the shelves in the freeze dryer and on the loading table. The passive components (permanent magnets) of the linear motor are mounted on the movable runners. The two runners are connected by a bar that can move the vial package into and out of the freeze dryer. Closed-loop control is provided by two lasers positioned behind the freeze dryer, which are used to determine the exact positions of the two runners.

The innovative electromagnetic drive technology is nearly frictionless. Moving parts are reduced to a minimum, making the overall system especially easy to maintain. If necessary, the loading carriage can also be cleaned and sterilised in the freeze dryer.

The sturdy construction also allows large forces to be applied. The **LyoShuttle rapid** system is ideally suited to medium-size and large freeze dryers for pharmaceutical applications.



Loading – LyoShuttle rapid



Unloading – LyoShuttle rapid

# **Isolation Technology for Demanding Aseptic Requirements**

#### Barrier technology isolator

The main reason for using an isolator in the freeze drying process is to provide the highest possible levels of protection for the product and operator safety. This is achieved by a negative or positive pressure cascade over the length of the isolator as required by the application.

In the case of a production line within the isolator, the freeze dryer with an automatic loading and unloading system is integrated into the production flow and connected to the isolator in a gastight manner.

#### Barrier technology RABS-systems

A further type of barrier technology is provided by RABS systems (RABS = Restricted Area Barrier System ).

In a similar way to the isolators, they are equipped with a solid machine casing, sealed safety doors and glove ports. A range of different safety features and ventilation principles is available.

A Martin Christ production freeze dryer for aseptic production can be combined with both systems. Our tradition is to work closely together with the appropriate world-leading manufacturers.



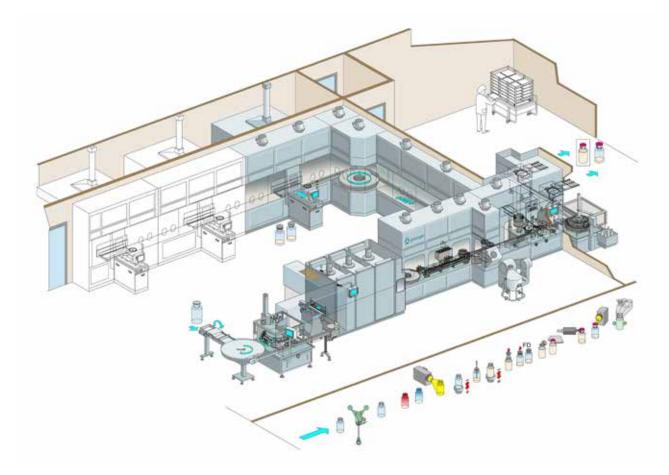


# **System Integration**

Pharmaceutical freeze drying under sterile conditions is only part of the operations chain: production of the active substance solution, filling in vials, transport to and from the freeze dryer with automatic loading/unloading, and capping.

Specific product or process requirements and existing conditions often lead to the selection of optimal individual machines that cannot be provided by a single supplier. This is where our "Best Partner" concept comes into play – we generate added value for our customers not only in the immediate environment of loading and unloading, but also in cooperation with filling and finishing specialists. A good example of this is loading and unloading systems, such as the LyoShuttle system we have devolped, which eliminate the need for an operator in the immediate vicinity of the active substance.

In addition, we are familiar with carrying out projects as a consortium member. We also work on turnkey projects for general contractors.



Sterile filling and freeze drying of pharmaceutical products (process chain – freeze dryer systems seen from the rear) Image source as example: Groninger GmbH, Crailsheim

# **Special Solutions are Our Standard**

As a leading manufacturer Martin Christ offers the experience, the flexibility and expertise to implement both standard market options as well as customized special solutions on any scale. Here are some examples:

- Alternative cooling systems, such as those with screw-type compressors, LN<sub>2</sub> cooling via heat exchanger or directly for ice condenser
- System implementation for drying of solvent-based substances
- Integrated systems for toxic products
- Extensive PAT-tools including WTMplus wireless product temperature measurement
- Semi-automated and fully-automated loading concepts including integration into RABS or isolator systems
- Alternative arrangement of the ice condenser, e.g. to the side
- Vacuum system with dry running pumps
- Variable adjustment of the shelf spacing
- Alternative CIP designs
- Frames for cleaning, sterilization and storage directly in the drying chamber
- Fully redundant systems, including process control



Frames which can be automatically cleaned and sterilized by CIP/SIP in the freeze dryer



Modification of a freeze dryer for bulk API in order to support use of an IR camera for process monitoring combined with adjustable shelf spacing

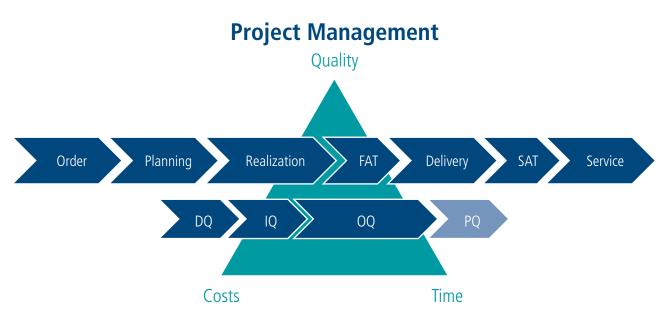
# GMP-Compliant Documentation Right From the Start

You describe your requirements for the freeze dryer and its fitted equipment in a URS (User Requirement Specification). Already in the tendering phase we will explain the possible implementation of these often GMP-critical requirements. We will make proposals which support your manufacturing.

After placing the order the agreed performance features are developed and documented in relation to the URS – if necessary in a traceabality matrix.

Carried out in the context of a joint Factory Acceptance Test (FAT), agreed characteristics from the IQ and OQ are repeated and documented.

After the installation of the freeze dryer in your facility the test procedures – where necessary – are repeated. Finally, in a joint Site Acceptance Test (SAT) it is confirmed again that the freeze dryer can fulfill its task requirements at the installation location.



In the context of a DQ (Design Qualification) and by using the above documentation, a layout, the P&ID and the list of utilities clearly documents the fact that you and Martin Christ have a common understanding of the project.

Changes to a released DQ will be tracked by us in the Change Management system.

After completion of the freeze dryer our specialists test the entire system – even before the FAT – to complete the IQ (Installation Qualification) as well as the OQ (Operational Qualification).

For the implementation of a PQ (process validation) with the customer, we are available to provide assistance with our qualified personnel if necessary.

You can also be supported by our service in the subsequent life cycle through documented regular maintenance work as well as revalidations for a permanently successful production.

# **Project Management**

In addition to providing first-class "Made in Germany" system quality, the professional realization of your project is taken as read. Our internationally experienced project managers assist you over the entire duration of the project and beyond. In addition to balancing the project items quality, cost and time, our primary goal is your satisfaction.

As soon as the planning phase, you have a project manager as a contact ready to assist you as needed in order to define your plant design, control concepts and qualification procedures.

The individually tailored project plan is divided into several phases. The project progress in the individual phases is mapped out and monitored by us based on milestones. Our process-oriented structure enables us to put effective countermeasures into place at an early stage in the event of potentially conflicting goals. The responsible project manager will accompany you throughout, from the Design Qualification stage through the implementation of the change process, the qualification right through to the Site Acceptance Test at the installation site. The entire project team is at your disposal during the project implementation with solid experience in the area of pharmaceutical freeze-drying and the upstream and downstream process engineering.

We look forward to a cooperative partnership!



# **Qualified Support, For Life!**

But should repair work ever be necessary, we are on-site in a short time. We ensure this worldwide through the use of a network of in industrial plant engineering and service experienced engineers and technicians – together with competent partners, who are regularly trained by us in our factory.

We use high-precision helium leak detectors to check your freeze dryer for vacuum tightness. We also check your cooling system for leaks in accordance with the provisions of international legislation. All of our service technicians have suitable technical expertise and are certified in this regard. To minimise unplanned downtime, we perform maintenance for all of our systems in accordance with procedures specific to the system or device concerned. We support you by keeping track of due dates and remind you when your maintenance service contract is up for renewal. We calibrate your systems and equipment in compliance with good manufacturing practice (GMP) using certified measuring instruments, and we certify conformity for you. Our advanced, automated high-bay warehouse enables the prompt provision of all available spares and wearing parts, and as a matter of course we supply only original parts.

We can deliver by express or courier service on request.



# **We Provide Application Expertise**

#### We offer complete solutions.

This also includes the implementation of sample drying processes and process optimisations with customers' products. We also test new solutions available on the market, such as in the field of packaging materials or PAT.

In our on-site laboratory we have equipment available with different performance levels and fittings.

If necessary we engage qualified specialists in the relevant disciplines, e.g. pharmaceutical or biotechnology.

The organization of scientific seminars is a tradition at Martin Christ. We invite external experts with different specializations, who can inform participants of the current state of the art in research and technology.

On request, we can also run in-house seminars at your premises. Let us show you what we can do!



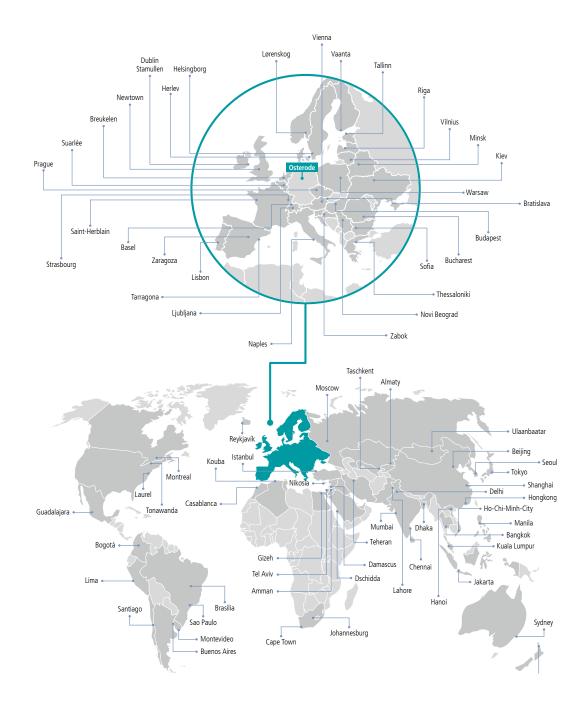
Lab technician removing samples during the ongoing FD process



User training in the application lab

# **Global Service for Local Reliability in Production**

Martin Christ systems are operated successfully in more than 70 countries worldwide. An international network of partners is available to provide service and qualification work. Our specialists can also work remotely or operate on site quickly and on a worldwide basis.



#### Selected locations of our company representatives.

For information about our representatives and contact data, visit www.martinchrist.de

# **Our Product Spectrum**

With a unique and broad graduated range of equipment and accessories, we can supply freeze drying systems and vacuum concentrators for every application. Let us show you what we can do!



- 1 Freeze drying systems for industrial production with ice condenser capacity from 20 to 500 kg; custom system design including loading and unloading system (image shows inspection door).
- 2 Pilot freeze drying systems for process development or process optimisation with ice condenser capacity from 4 to 16 kg.
- 3 Freeze drying systems for routine applications or R&D with ice condenser capacity from 2 to 24 kg.
- 4 Rotational vacuum concentrators for applications extending from routine to evaporation concentration in the high-end range of pharmaceutical research.



#### Martin Christ Gefriertrocknungsanlagen GmbH

An der Unteren Söse 50 37520 Osterode am Harz

Tel. +49(0)55225007-0 Fax +49(0)55225007-12

info@martinchrist.de www.martinchrist.de