

OPTIMA

LYO SOLUTIONS FOR PHARMA EXPERTS

Member of





OPTIMA

For uncompromising pharmaceutical applications

Optima Pharma develops and manufactures filling, sealing and process technology for pharmaceutical products. Highly sophisticated, fully automated systems from Optima Pharma are used to process blood plasma products, vaccines, oncology and biotech products in prefilled syringes, vials, bottles and cartridges. Non-sterile pharmaceuticals and diagnostics are further applications of Optima Pharma. The company's extensive technology portfolio includes washing machines, sterilization tunnels, filling and sealing, robotic product handling and other functions. Freeze drying systems and isolator technology are part of the turnkey systems by Optima Pharma.

Thanks to state-of-the-art freeze drying methods, pharmaceutical products are becoming more and more durable today. Freeze drying systems from Optima Pharma are offering a wide range of modern processes to meet the necessary requirements. Optima Pharma accompanies you from the start all the way to the implementation of the ideal freeze drying system for your needs and applications. This includes initial- and laboratory testing as well as the detailed development of all necessary processes for drying.

OPTIMA packaging group GmbH

<p>> 300 Service-Employees worldwide</p>	<p>2250 Employees worldwide</p>	<p>85% Export</p>	<p>Family-owned Third generation</p>
<p>>100 Patents worldwide</p>	<p> 14 International Locations</p>	<p>350 Mio. € Turnover (in 2017)</p>	

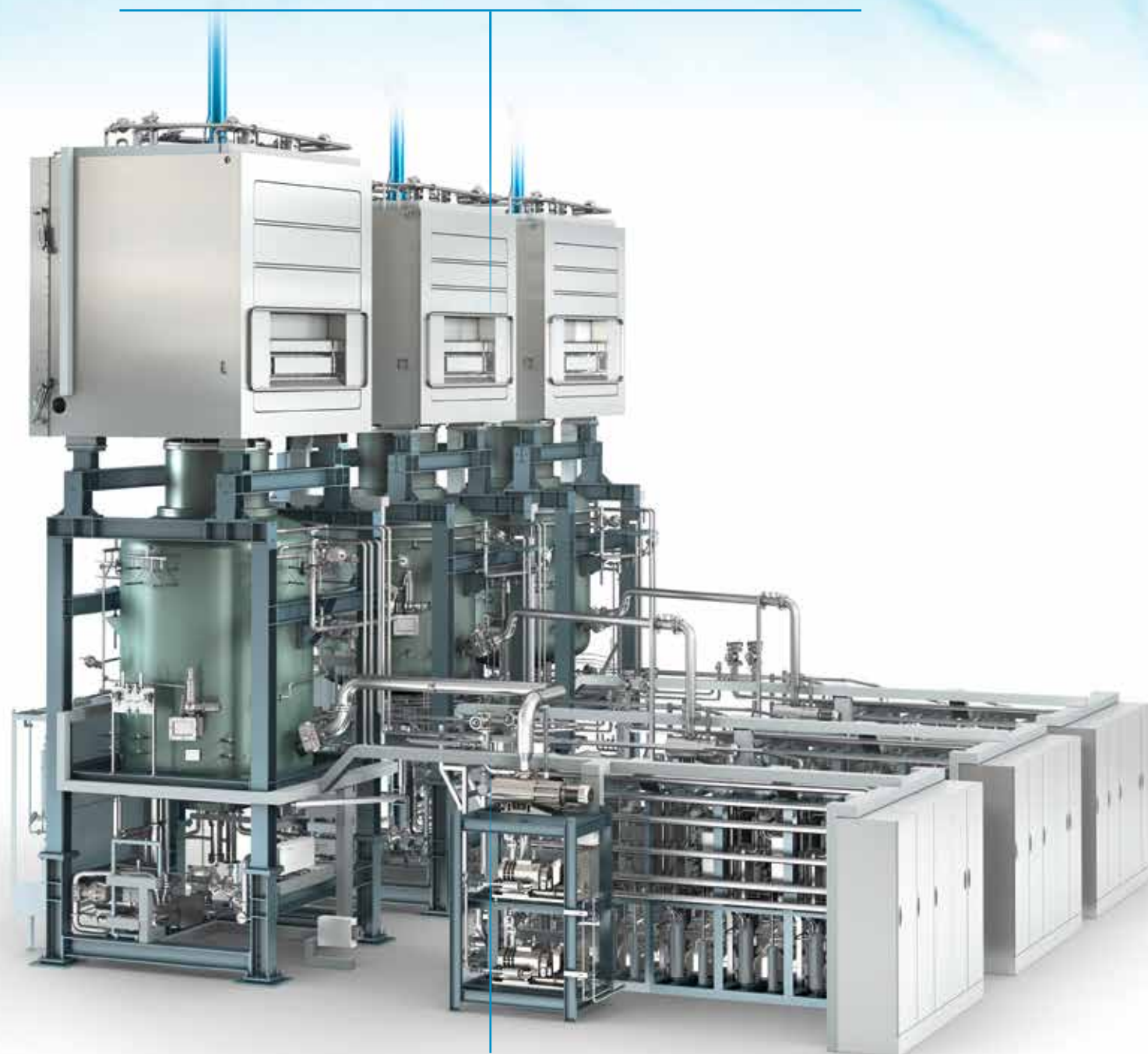
LYO SOLUTIONS

Contents

Individual System Solutions	6
LYO / CS	8
LYO / C	10
LYO / S	12
LYO / D	14
Shelves	16
Process Technology	18
SCADA Solutions	20
Quality Management	22
In-House Assembly	24
Service Performance	26
Service Partnership	28
Turnkey Solutions	30



From start to finish
Optima is your partner
to design the perfect
freeze-drying system.



Stephan Reuter

Managing Director, OPTIMA pharma GmbH – Mornshausen

Lyophilization Solutions

The lifetime of highly sensitive pharmaceutical and biotechnical produced medication can be significantly extended with freeze drying. Therefore, the production of many pharmaceuticals is inconceivable without it. The OPTIMA portfolio includes freeze dryers / lyophilization systems that can be used for the mass production of pharmaceuticals as well as the processing of small batches. The state-of-the-art Optima Pharma building meets the requirements with the latest technologies. The following media are available for all necessary processes: pure steam, CIP medium and liquid nitrogen. The assembly, commissioning and the FAT are completed in the two-story halls, facilitating tests and the machine check-out under real life conditions. Saving you valuable time during the on-site installation, qualification (IQ, OQ) and the final performance test (SAT).

From start to finish Optima is your partner to design the perfect freeze-drying system. Starting with the recipe optimization and developing systems that are tailored to your needs while also guaranteeing the highest production safety with the latest technologies and a scientific approach.



LYO
Expertise

GMP AND PROCESS ORIENTED DESIGNED SYSTEM

TURNKEY SOLUTIONS

PROCESS BASED 3D ENGINEERING

SCADA SYSTEM

IN-HOUSE ASSEMBLY

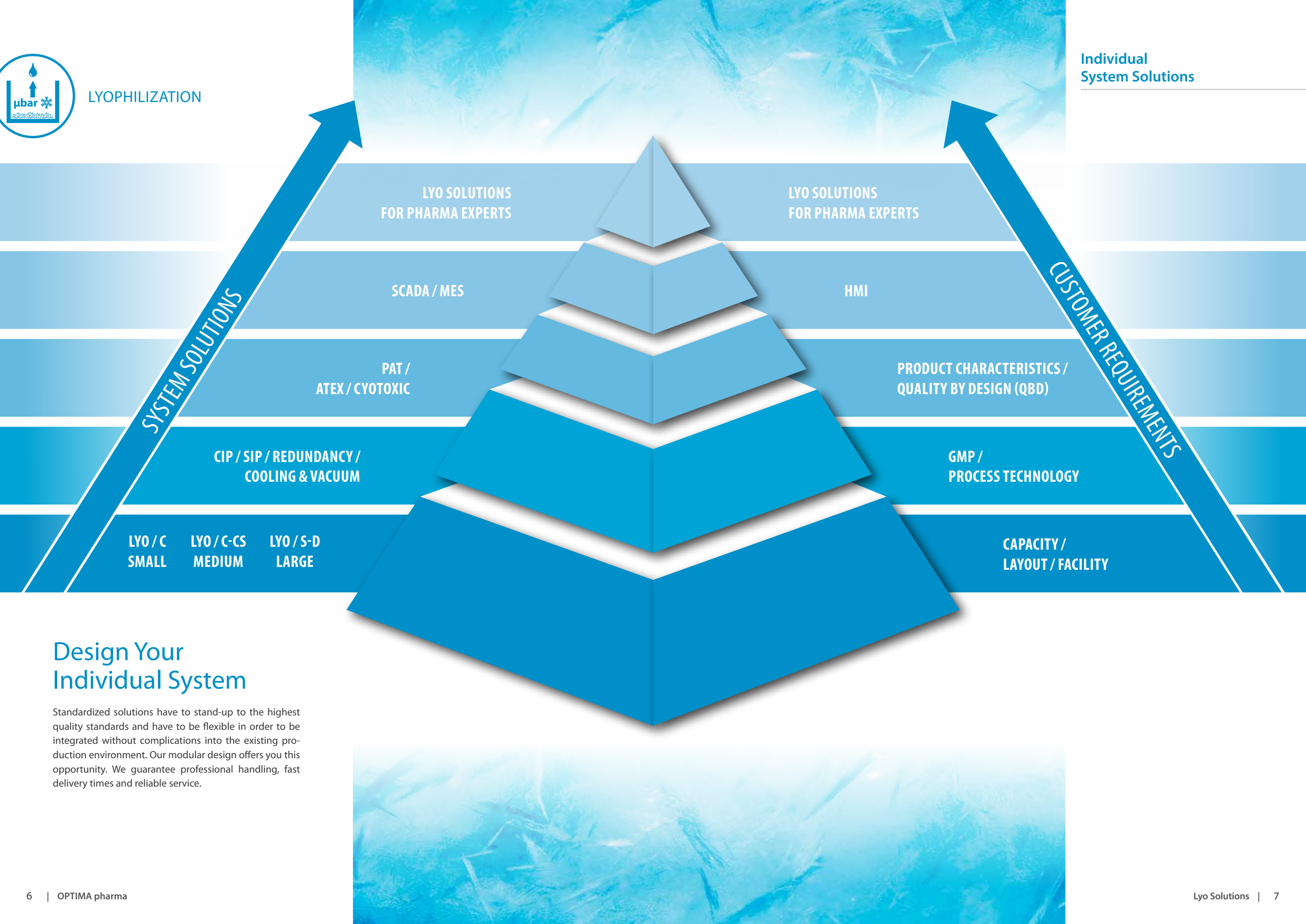
ON-SITE SUPPORT

SAFE QUALITY MANAGEMENT



LYOPHILIZATION

Individual
System Solutions



Design Your Individual System

Standardized solutions have to stand-up to the highest quality standards and have to be flexible in order to be integrated without complications into the existing production environment. Our modular design offers you this opportunity. We guarantee professional handling, fast delivery times and reliable service.



LYOPHILIZATION

Economic Freeze Drying of Small Batches

LYO / CS

The Optima pharma freeze dryer CS targets maximum flexibility. It is tailored to products that are new on the market and therefore produced in small to medium size quantities. The freeze dryer CS is designed to fit into existing buildings and can be flexibly configured for an optimal production layout. Due to its compact design, the CS freeze dryer is also very economical. The installation can take place with a monobloc or a dual bloc design ensuring a safe and fast installation.



LYO / CS

Your Advantages:

- Single chamber system
- Minimum space requirement
- Multiple layout options
- Pass through* all in / all out
- Condenser left / right
- Monobloc or dual bloc design
- Fast installation on-site
- Flexible retrofitting into existing production machines
- Easy installation of multiple freeze dryers
- Optimized for Optima Pharma turnkey systems
- Manual and automatic loading
- Shelf space up to 30m²
- Easy to adjust and integrate into customer's production facility
- Designed for applications with future technologies (mass spectrometer / controlled nucleation)
- Optional: SIP/CIP
- Engineered in Germany – made in Europe

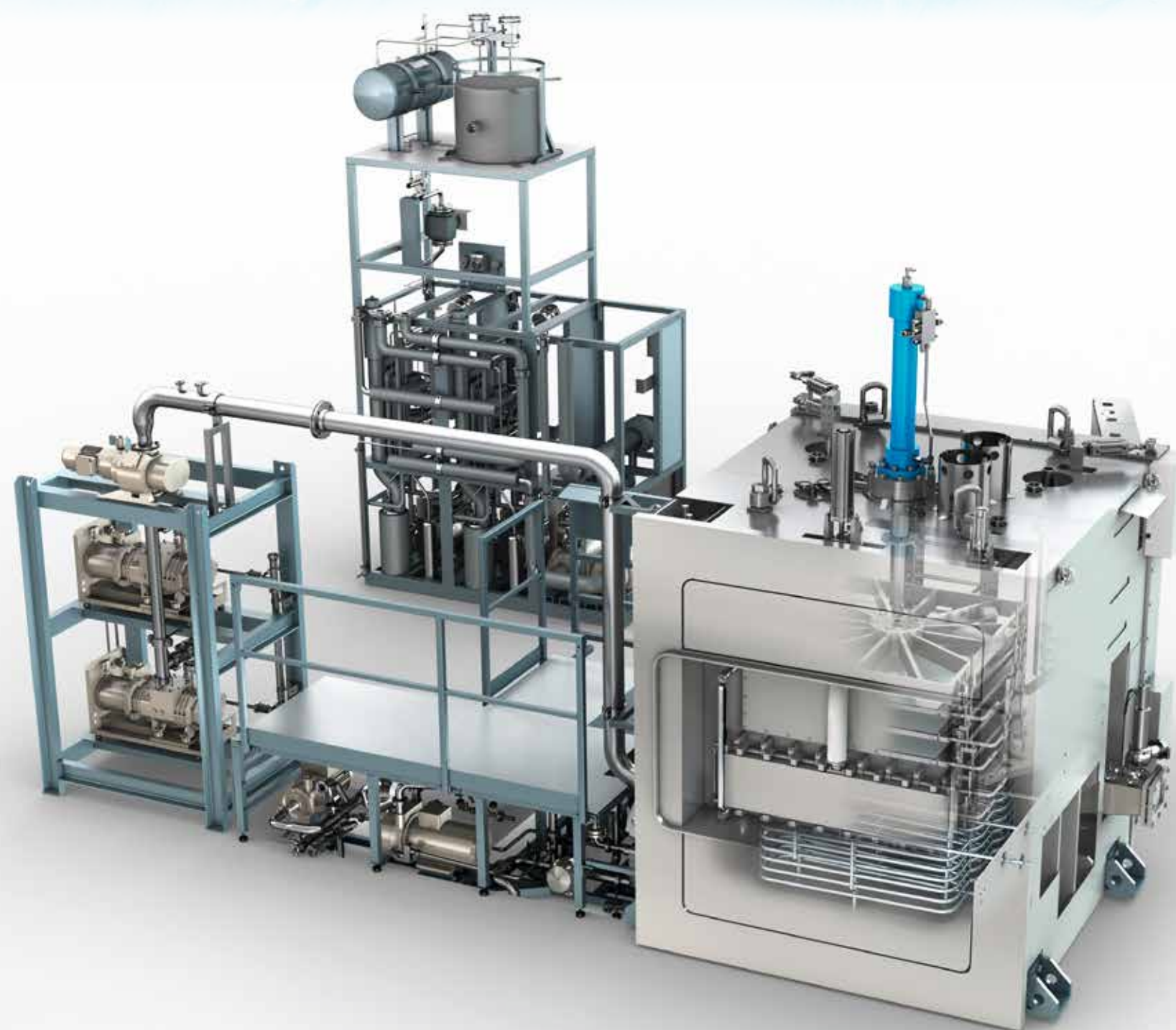


LYOPHILIZATION

Compact and Flexible

LYO / C

Are you looking for a versatile, space saving machine to meet all of your needs? Then the Optima freeze dryer C is the perfect machine for you. This system combines a space saving design and highest flexibility. The compact freeze dryer fits easy into a multi machine concept and is optimized for the installation into your existing machine line. The Optima freeze dryer C can be loaded manually or automatically. In addition, the model C includes a condenser inside the product chamber with an integrated intermediate valve.



LYO / C

Your Advantages:

- Condenser is located inside the product chamber (internal condenser)
- Space saving footprint
- Integrated intermediate valve
- Pass through* all in / all out
- Optimized for installation into existing production facility
- Manual or automatic loading

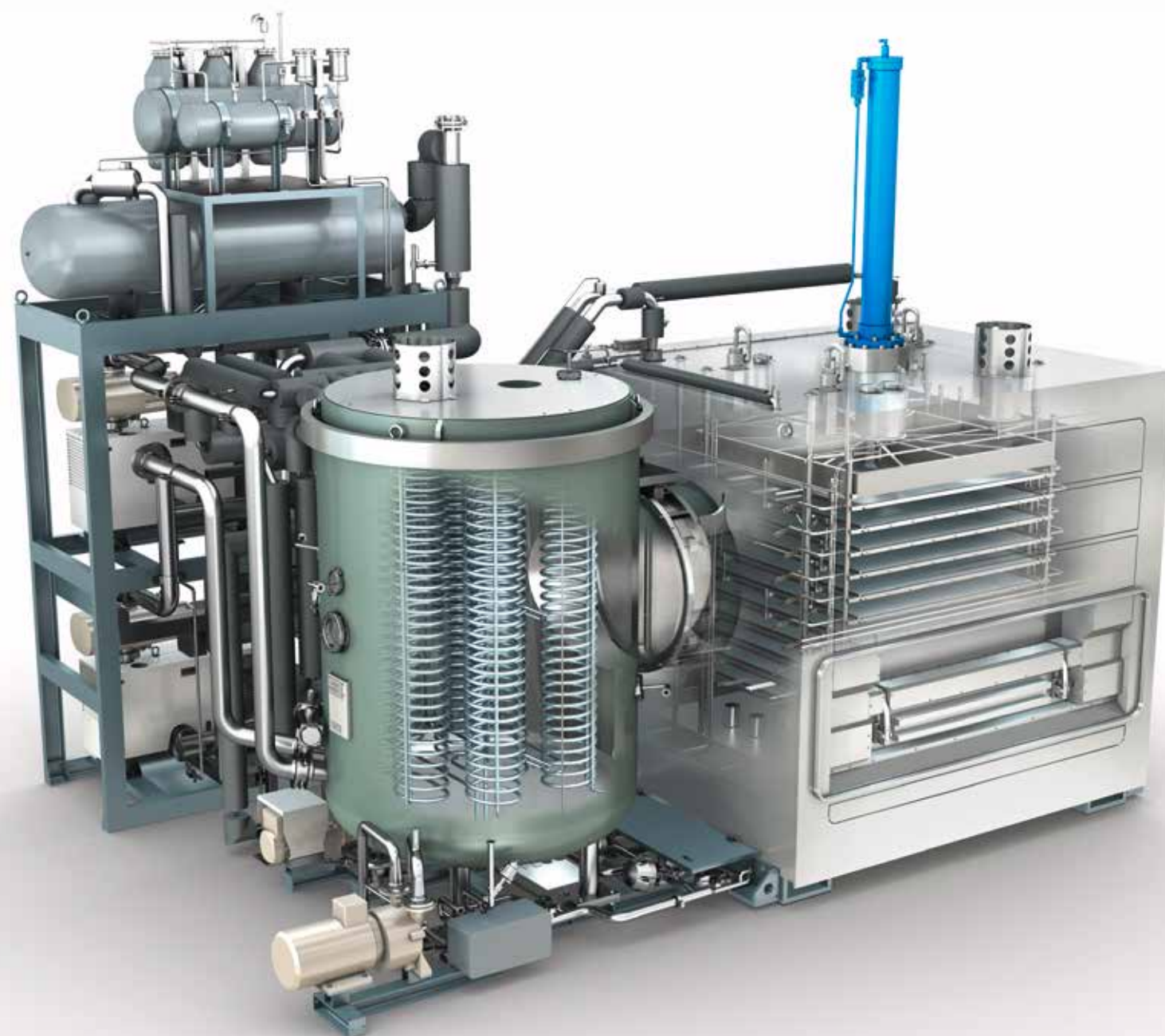


LYOPHILIZATION

Safe Freeze Drying of Large Quantities

LYO / S

Do you need a high-performance freeze dryer for a large project? Optima Pharma also offers a solution for this application – the OPTIMA LYO/S. This freeze dryer permits the safe lyophilization of large quantities with an installation friendly design and maximum flexibility. The chamber is designed as a separate housing with an intermediate valve as a separate component. The freeze dryer OPTIMA S can be loaded manually or automatically.



LYO / S

Your Advantages:

- The chamber designed as an independent housing or vessel
- The condenser is designed as an independent housing or vessel
- The intermediate valve is a separate component
- Flexible installation
- Manual or automatic loading
- Adjustable and easy to fit in customer's production facility



LYOPHILIZATION

Suitable for Functional Floor Separation

LYO / D

Due to its special two-story design the freeze dryer D is very easy to integrate into an existing machine concept. The small footprint permits installation even with limited space. The freeze dryer design offers you the option of a functional separation for your cleanroom and the machine section. Your personnel benefits from a service door that can be integrated on the side.



LYO / D

Your Advantages:

- The chamber is designed as an independent housing or vessel
- The condenser is designed as an independent housing or vessel
- The intermediate valve is a separate component
- Installation through two stories
- Optional service door on the side (Pass through design)
- Adjustable and easy to fit into existing facility



LYOPHILIZATION

Reduce Your Production Cost

The temperature profile during the freeze-drying process is controlled by heated shelves. 100 percent of the usable space on our shelves are evenly cooled by convection. The shelves are manufactured by Optima Pharma with the latest calculation tools and innovative technologies. Our patented design increases the output as well as the reliability and at the same time reduces the production costs. Each shelf has a serial number that permits the traceability of all parts and manufacturing phases. The inspection of the raw material and tests during the manufacturing process guarantee absolute reliability and longevity of the shelves.

Shelves

Your Advantages:

- Reliable design with 316L
- Maximum surface quality
- High dimensional accuracy
- Safe and functional assembly
- Reinforced mesh stainless steel hosing "Made in Germany"
- Highly accurate guidance and positioning system for the loading system
- Mass reduced pressure table in frame structure design
- Constant temperature distribution



LYOPHILIZATION

State-Of-The-Art Process Technology for Effective Freeze Drying

From the first idea to the delivery we handle the workflow and process technology procedures to ensure that your idea is developed into the best possible freeze dryer for your requirements. The process technology procedures are influenced by a variety of parameters. Identifying and adjusting these parameters accordingly will optimize your processes and therefore, increase your production efficiency. Based on these results and in cooperation with you, we will develop an individual or overall solution for an even more efficient production.



Process Technology

Your Advantages:

- Optimized cooling coils for different cooling concepts.
- Effective CIP cleaning according to VDMA guidelines
- State-of-the-art and environmental friendly cooling agents
- Effective vacuum systems (dry and oil sealed) also for ATEX applications
- Sterilizable ventilation systems including in-Sito-filter tests (two filters)
- High performance CIP system with frequency-controlled pump technology
- Heat exchanger in the drainage system to reduce the waste water temperature and reduce the sterilization time
- Heating and cooling systems for the shelves



LYOPHILIZATION

Connect Your Production Processes with Scada Systems

A paperless production. Complete data integrity. The dream of every machine manufacturer. With our SCADA systems you can be a step closer to this dream. Our SCADA solutions offer you the opportunity to connect your production processes with different operating programs. As your automation partner, we know every required aspect from recipe development to the needs of the operators and the service crew. Optima high-tech production machines include SCADA and HMI solutions that are tailored to your production needs and are easy to operate. No matter if it is a freeze dryer or a fully integrated automation or a process solution for turnkey lines – in close cooperation with you – we develop solutions that can be installed anywhere. Our SCADA systems can be expanded at any time without running the risk of a technology break or starting a complete new project development.

Additional information to this subject can be found in our brochure "SCADA SOLUTIONS FOR PHARMA EXPERTS"



SCADA Solutions

Your Advantages:

- Expandable for complete production lines
- Multiple PC-stations available
- Flexible recipe administration with Simatic batch for freeze dryers
- Audit trail
- Easy to use operator interface
- Easy to read batch report
- Ability to easily review historic trends and alarms
- High scalability
- Easy connection to on-site systems
- GAMP 5
- Programmable according to ANSI/ISA-88
- FDA CFR 21 part 11
- Tailored to the highest quality standards of the pharmaceutical industry



LYOPHILIZATION

Quality Assurance Starts In-House

You are constantly faced with new requirements for quality assurance. Therefore, you have to be able to rely on your partner. Optima Pharma is your reliable partner. The machines pass all coordinated qualification tests at Optima or at the customer's site.

We even go one step further: Was the installation conducted correctly? Does the machine reach its target during continuous operation and was the machine validation completed properly? Was your machine revalidated after an update? We are only satisfied once all questions are answered with "yes".



Quality Management

Your Advantages:

- Compliance of current standards (GMP/FDA)
- Documented, qualified machines and equipment as the basis for the validation
- Rebuilds according to current guidelines
- High machine efficiency

Services:

- Qualification support at Optima Pharma or on-site
- Creation and implementation of IQ/OQ test sheets
- Support during re-qualification after changes or rebuilds by means of change control procedures
- Qualification activities can be completed before shipment



Starting Production Faster

How? With a real-time installation and tests at Optima Pharma. This is possible due to our state-of-the-art two-story assembly hall that is also suitable for two-story machines. Your machine will be adjusted to your requirements on-site including simulated malfunctions. Assembly and disassembly, as well as the shipment preparations are all completed in-house. The equipment is transported in an enclosed truck, so that your machine arrives safely at your facility. This will also reduce the installation time on-site and therefore the timespan until production.



Your Advantages:

- Installation of the machines under realistic conditions
- "Single and double floor" machine installation
- Fault simulations
- Assembly / disassembly handled completely in-house



LYOPHILIZATION

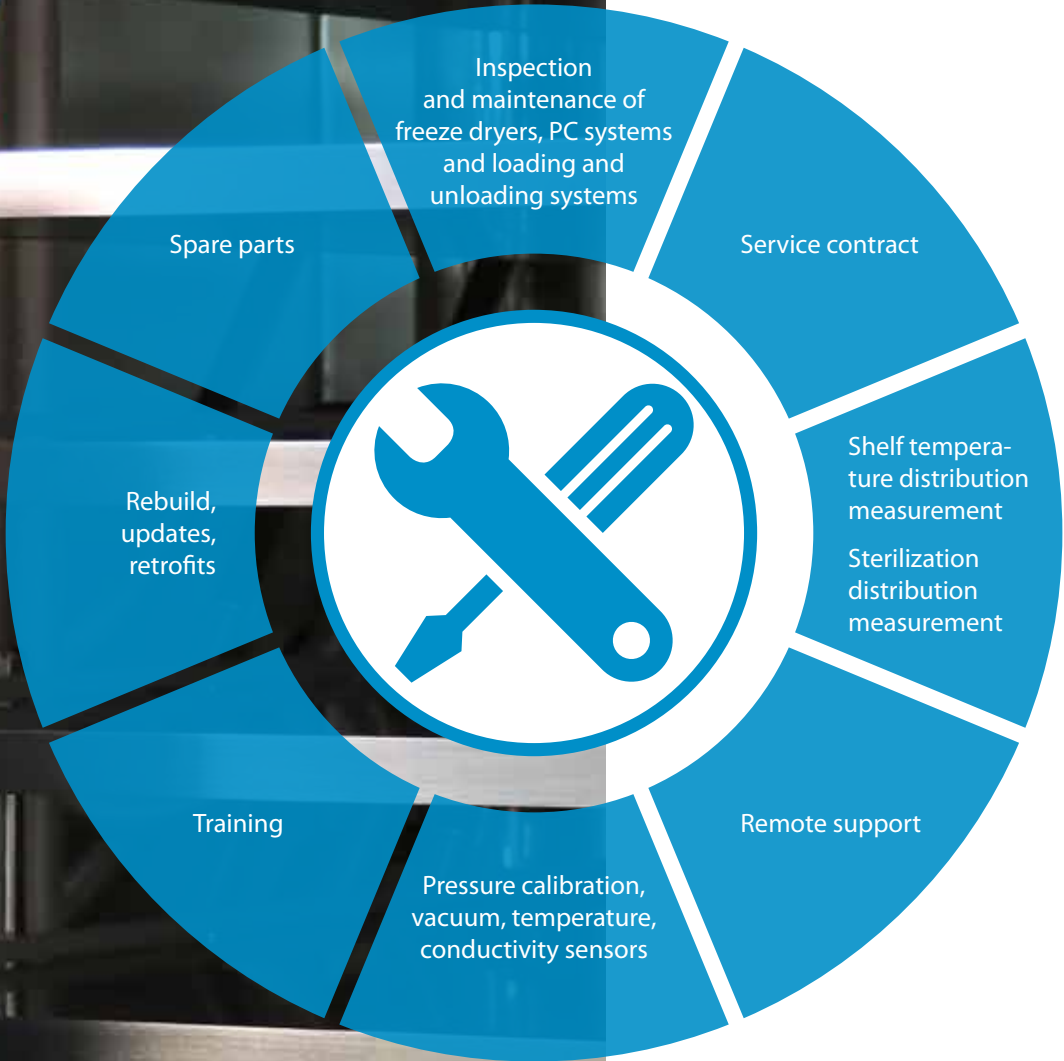
A Strong Service Package for Safe Processes

Process safety is also a matter of service. With our expert team and the worldwide available service network of Optima Pharma you will reduce the risk of machine downtime to a minimum. At the same time, our 24-hour customer service is always available, as well as an extensive spare parts supply, delivered to you quickly. Electronic spare parts catalogues, extensive technical documentation and operation manuals, as well as our remote service make it easy to work on your machinery. Service starts with the installation of the machine. You will receive the appropriate training tailored to your needs at Optima Pharma.

And, it is not always necessary to invest in a new machine. Innovative machine upgrades and individual rebuild packages will bring your machine up to speed on the latest technologies. Ask for one of our service packages. We are happy to help you.



Service Performance





LYOPHILIZATION

Create Your Individual Service Package

You decide the service scope, we put together different performance packages including our contractual services – from standard service activities to integrated full service solutions. You decide which service is the right one for you. You will profit from reliable package prices. Regular maintenance ensures a high production quality and increases the lifespan of your machine. Our experts will be at your site during the complete lifecycle of your machine. We always keep an eye on your requirements, your objectives and your success.



Routine Life Cycle

Complete support during the production phase:

- Retrofits and upgrades
- Process and efficiency optimization
- Maintenance services
- Personal on-site support
- Calibration service
- Spare parts service
- Remote support and hotline

Standard Service Activities

Basic Life Cycle

Planning of all repeat maintenance procedures:

- Control system and monitoring
- Archiving of all documents
- Remote support and training
- Spare parts service

Basic-Contract

Full Service Life Cycle

Our services at a fixed price. As a service provider we take on the full responsibility for the maintenance budget with the following services:

- Maintenance according to VDLI 2890
- Requalification measurements
- Spare parts supply according to contract
- Online support
- Training

Full-Service-Contract

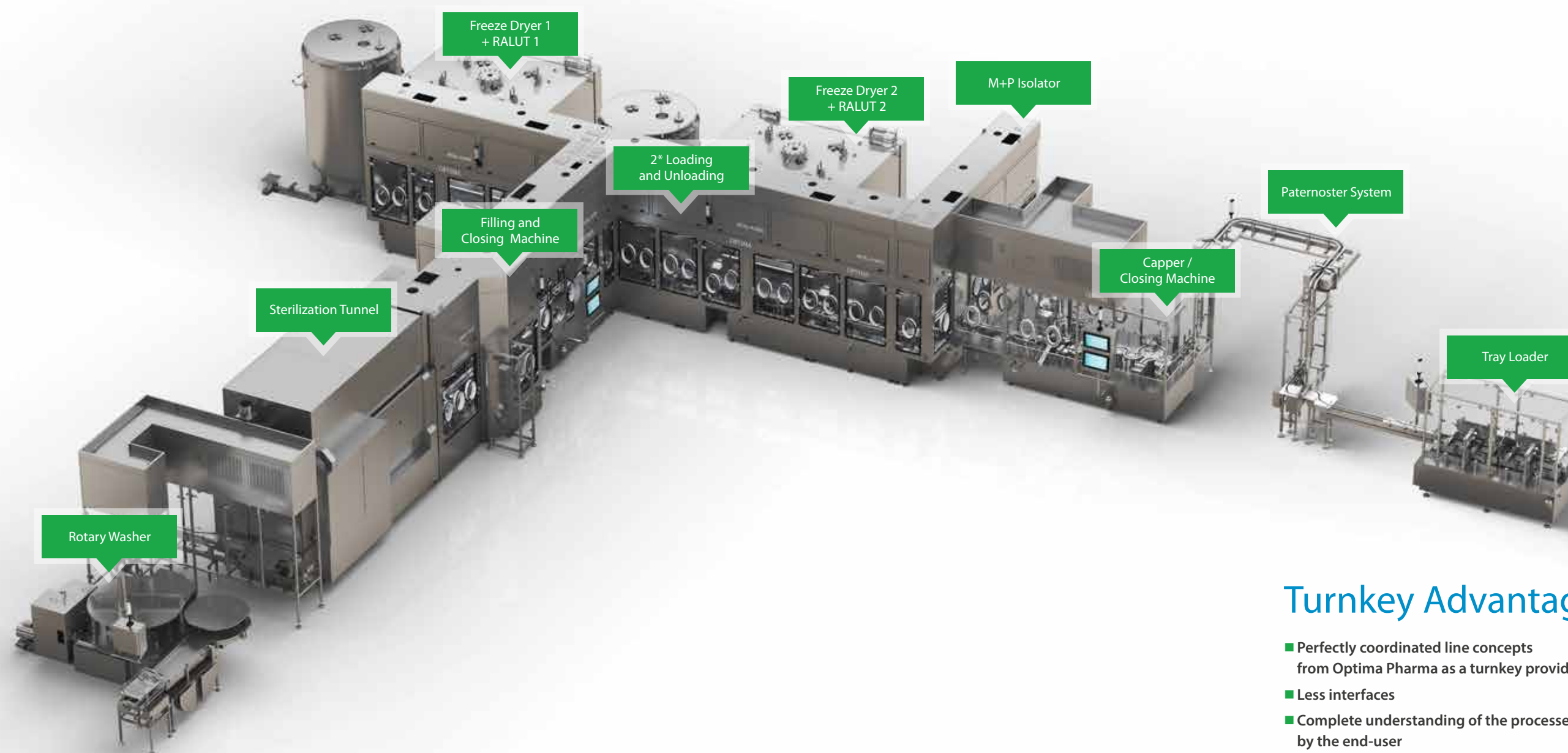
Service Partnership



Turnkey Line with Isolator and Freeze Dryer

WMR 1800 | SHT 9 SKZ | VFVM 18000 | 2 x RALUT | 2 x Freeze Dryer S-23 |

M+P Isolator | VVM 2428 | M 2424



Turnkey Advantages

- Perfectly coordinated line concepts from Optima Pharma as a turnkey provider
- Less interfaces
- Complete understanding of the processes by the end-user
- Fast solution findings and decision making
- Tailored proposal package

More Information:

www.optima-packaging.com/pharma