



OPTIMA

**SMART SOLUTIONS FOR PHARMA EXPERTS-
VIAL FILLING EXPERTISE**

Member of

PACKAGING VALLEY
Germany

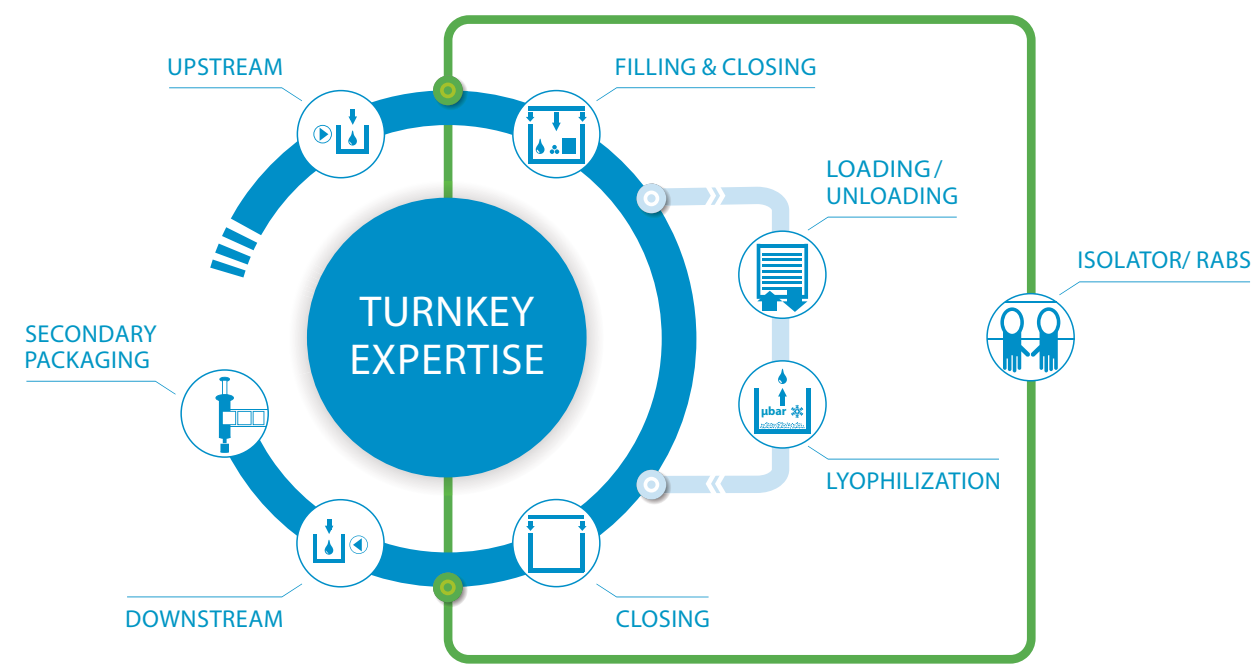
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OPTIMA







For uncompromising pharmaceutical applications

Optima Pharma develops and manufactures highly flexible filling, closing and process technology for pharmaceutical products. Exceedingly 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 pharmaceu-

ticals and diagnostics are additional 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 technologies complete the extensive turnkey systems by Optima Pharma.



OPTIMA packaging group GmbH

2450 Employees worldwide 	> 400 Service-Employees worldwide 	> 85% Export 	Family-owned Third generation
>100 Patents worldwide 	19 national & international Locations 	> 400 Mio. € Turnover (in 2019) 	

VIAL FILLING EXPERTISE

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As a technology leader in a complex environment, we possess the knowledge for the entire supply chain.

This includes complete lines, specialty solutions and demanding standard machines for the primary packaging range.

Jürgen Rothbauer

Managing Director, OPTIMA pharma GmbH

Smart
Solutions for
Product Loss
Minimization

Vial Filling Expertise

Optima Pharma offers an innovative machine portfolio for the filling and packaging of sterile liquids and powdery products in vials and cartridges. Isolators and freeze dryers are perfectly complementing the product portfolio. Intelligent process equipment significantly reduces process- and downtime of your machines. Intelligent filling and closing processes support the minimization of product loss per batch.

LEADING ROLE AS A SOLUTION PROVIDER

for sterile and aseptic filling, lyophilization and containment technology

GMP-COMPLIANT MACHINES AND SYSTEMS

including the newest technologies

MAXIMUM SECURITY AND HIGHEST SAFETY

with our machine solutions for highest purity levels.

EXPERTISE IN THE IMPLEMENTATION

of complex turnkey projects.

Design Your Own Washing Process

Optima Pharma washers are made of stainless steel, non-corrosive, pharma conform plastics. The washers are designed according to cGMP standards and have a wide variety of uses. Product contact parts are easy to clean and designed for easy access. All cleaning solutions that are customary to the pharmaceutical industry can be used for the cleaning and treatment of the containers.

VWM / WMR

Fully-automatic rotary washers are available for the treatment of vials and infusion bottles. Washers can be ordered with or without ultra-sonic pre-treatment and the connection to a sterilization tunnel can be performed with ease. The washer has an output of up to 24,000 containers/hour. The transport can either be cycled or continuous by means of one or several lanes of transport grippers.



Technical Data – Rotary Washer				
Type	VWM218	WMR600	WMR1800	WMR2400
Machine type	Fully-automatic intermittent	Fully automatic continuous		
Containers	Vials and infusion bottles			
Container size range: neck opening	> 7 mm	> 5 mm	> 5 mm	> 5 mm
Container size range: outer diameter	16-80 mm	7-52 mm	7-52 mm	7-42 mm
Max. height	up to 180 mm	up to 105 mm	up to 105 mm	up to 105 mm
Spray positions	1–3	1–4	1–6	1–8
Output	up to 7,200 pcs./h	up to 12,000 pcs./h	up to 18,000 pcs./h	up to 24,000 pcs./h
Processing sequences	8	7	6	
Ultrasonic infeed / siliconization	Optional			
Infeed of containers	Transport grippers			

For All Applications

SHT

Optima Pharma sterilization tunnels are part of a complete aseptic filling line designed to sterilize and to depyrogenate glass containers such as injection and infusion bottles and syringes. From cleaning to aseptic filling, our machines provide a continuous operation mode in a clean room environment. The tunnel program consists of Laminar-Flow (LF) hot air tunnels and infrared/hot air combination tunnels. Optima Pharma has the right tunnel for your needs.

The cleaned containers travel through the infeed, which is equipped with Laminar Flow, into the sterilization area – the heating zone. The containers are heated to a defined temperature to ensure secure sterilization and depyrogenation. Sterilization is performed using LF-hot air, or a combination of hot air and infrared quartz glass heaters. Both of the sterile systems are designed for specific applications. The tunnels are equipped with state-of-the-art automation and communication systems. This ensures detailed data recording and temperature tracing.



Sterilization Tunnel

Features

- Heat sterilization of the cooling zone
- Automatically lockable and heated gas-tight tunnel door with sealing at the outfeed of the tunnel
- Isolation of the cooling zone
- Special fans
- Separate closed cooling circuit with re-circulation pump and mixing valve for the sterilized cooling zone
- Program for implementing the sterilization process

Technical Data

Type	SHT
Conveyor belt width	450, 600, 800, 1,250
Transport height	900 mm +/- 25 mm
Filter system	HEPA Filter-H13/H14
Output	depending on format
Heating power	20 – 200 KW
Cooling power	0.3 – 15 m³/h
Options	- Sterilizable cooling zone - Infrared emitter





The Compact Line

VFVM2000

In laboratories and R&D, the demands on technical equipment for the manufacturing of sterile and aseptic products are continuously increasing. Optima Pharma has a leading position in the field of sterile filling technology.

To meet the market challenges, we provide a custom-made integral solution for the processing steps of:

- Washing
- Sterilizing
- Filling
- Stopper insertion
- Crimping

This state-of-the art compact concept meets all known requirements regarding technological design and the ever increasing cGMP regulations. The filling machine is also available as a stand-alone model.



Technical Data

Type	VFVM2000
Machine description	Compact laboratory machine
Objects	Injection bottles
Infeed	Manual on turntable From sterilizing tunnel on turntable
Filling volume	up to 100 ml
Container size range	up to 100 H
Output	up to 2,700 pcs./h
Operators	1
In-Process Control	100%

Features

- Intermittent operation
- 100% In-Process Control
- Appropriate for small batch production and laboratory applications
- Processing of highly potent and non highly potent products



FILLING AND CLOSING

Application Flexibility
with a Modular Design

VFVM7000/10000/18000/24000

A fully automatic filling and closing machine to process vials and infusion bottles ranging in size from 0.1 ml to 500 ml with an output up to 30,000 containers/h depending on product viscosity and fill volume.

Advantages of the rake transport system versus the alternative system for machines with a medium output include: the vials and infusion bottles are not processed or filled in a star wheel or on a conveyor belt. There is easy access to the individual station because of the narrow machine design. The vials/infusion bottles are continuously secured and centered during transport, ensuring that the vials or infusion bottles will not topple over or interchange. The linear transport system permits better accessibility for the cleaning and monitoring of processes. The absence of a transport star wheel allows for the faster and safer change of parts.



Filling and
Closing Machines

Technical Data

Type	VFVM7000 VFVM10000	VFVM18000	VFVM24000
Machine description	Filling and closing machine		
Containers	Vials and infusion bottles		
Infeed	Conveyor belt Turntable		
Filling volume	up to 500 ml	up to 500 ml	up to 100 ml
Container size range	up to 500 IL	up to 500 IL	up to 100 H
Output	up to 12,000 pcs./h	up to 27,000 pcs./h	up to 30,000 pcs./h
In-Process Control	100%	100%	statistic

Features

- 100% In-Process Control
- Constant final dosing (CFD)
- Redosing on request (ROR)
- Weigh dosing mode at production start and end
- Restoppering
- Stopper repressing
- Suitable for oRABS, cRABS and isolator
- Processing of highly potent and non highly potent products



Our Filling Systems at a Glance

In order to decide on the most suitable filling system for sterile pharmaceutical liquids and powders, different factors must be taken into consideration:

- Product characteristics
- Environmental conditions of the filling process
- Format diversities
- Desired output quantity



Rotary Piston Pumps

Self-priming rotary piston pumps can be used for a wide range of products.

Time Pressure

The time pressure dosing system is the most frequently installed system in pharmaceutical applications.



Powder Dosing

Auger filling for sterile filling of powdery products.



Peristaltic Pumps

Peristaltic pumps are highly preferable in biotechnological applications.



Mass Flow Meter

A mass flow meter is usually installed in applications where product viscosity is temperature sensitive.



LYOPHILIZATION

Maximum Process Safety

Freeze Dryer

Sensitive pharmaceutical products often need to be freeze dried to extend shelf life. The Optima Pharma brand provides solutions for all requirements with its broad range of machines. From high tech pilot plants up to high efficiency production plants for vials, syringes and ampoules as single units or in bulk.

Optima Pharma's modern manufacturing site is state-of-the-art. All the required media for the different processes are available: Clean steam, CIP water, liquid nitrogen. The construction, commissioning, and FAT of the freeze drying unit takes place in our split level facility. Freeze drying units can be installed, tested, and operated under real conditions, saving time and money for qualification (IQ/OQ) and the final site installation (SAT).

Optimized and standardized processes ensure professional project handling. As a technology leader, Optima Pharma uses the most modern simulation and calculation tools to optimally design and construct the units to your specific requirements. Respective tests are carried out by our technology department.



Freeze Dryer

Your Advantages

- Flexible and customer focused layout concepts
- Shelves with an extremely even temperature distribution
- Fully automatic filter test units (WIT)
- Steam sterilization at 1.5 bar
- H2O2 sterilization
- Clean in place (CIP)
- Modem support / remote control
- Processing of solvents in compliance with ATEX directive

Features

- Innovative solutions tailored to the customer's requirements, e.g. a movable loading cart
- Loading row by row, shelf by shelf, frame by frame
- Fully automatic handling of vials, ampoules, syringes and magazines



Technology Tailored to Your Product and Container Type

VVM

Machines designed to close a wide variety of containers for the pharmaceutical industry. Even in the basic machine, several design details are utilized, which sets us apart from the standard:

- Electronic and central height adjustment
- Selectable torque function
- PLC guided size part change



Technical Data				
Type	VVM211	VVM4020	VVM7020	VVM36000
Machine description	Fully automatic closing machine			
Objects	Vials and infusion bottles			
Container size range	Up to 100 H	Up to 500 IL	Up to 500 IL	Up to 500 IL
Output	up to 2,700 pcs./h	up to 4,000 pcs./h	up to 7,200 pcs./h	up to 36,000 pcs./h

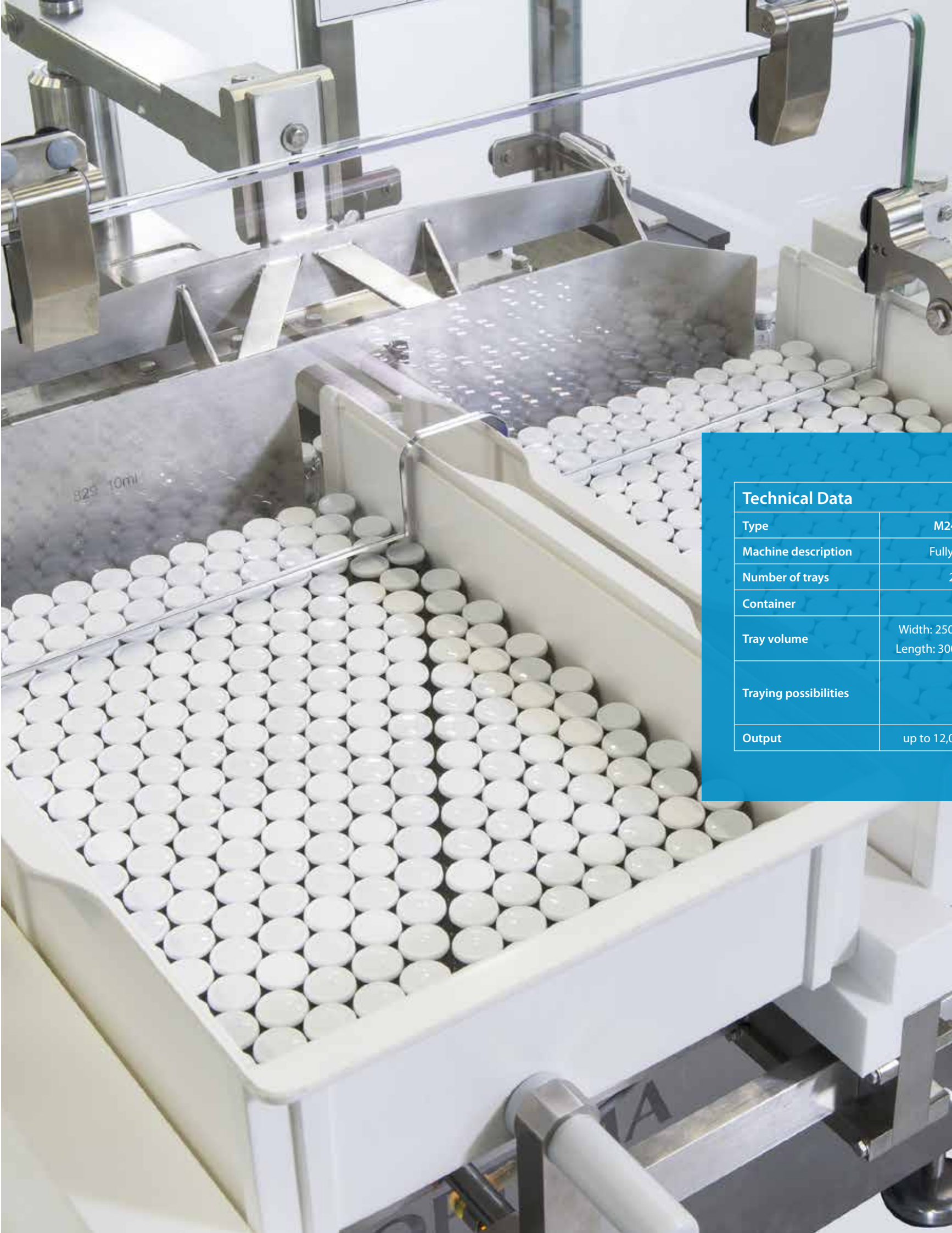


Tray Loading Machine for Perfect Vial Handling

M

An exact number of steady vials or bottles can be loaded with our fully automatic, high speed tray loader.

Between two and four trays are filled alternately, allowing tray swapping to occur without stopping the machine. A conveyor belt equipped with a minimum accumulation sensor feeds the vials/bottles into the infeed. Reciprocal interlocks at the infeed create an accumulation with the exact number of vials/bottles. The accumulated vials/bottles are transported in front of the pusher, where a stopping finger ensures the correct placement. To prevent the vials/bottles from tipping over, a mechanically driven pusher with a counter guide maintains their placement. The number of cross pushers are counted to ensure the exact amount of vials/bottles are in each tray. The trays are then secured to prevent an overload.



Tray Loader

Technical Data		
Type	M2412	M2424
Machine description	Fully automatic magazinging machine	
Number of trays	2	4
Container	14.5 - 78 mm	
Tray volume	Width: 250 - 500 mm Length: 300 - 600 mm	Width: 250 - 400 mm Length: 300 - 600 mm
Traying possibilities	No nesting Semi nesting Full nesting	
Output	up to 12,000 pcs./h	up to 24,000 pcs./h



ISOLATOR/RABS

Cleanroom Technology for the Highest Aseptic Quality

A leading global company for the development, manufacturing, installation, and validation of isolators. Metall+Plastic isolators can be installed on different pharmaceutical machinery and combined with various process functions, such as machines for the aseptic dosing of liquids and powder, epyrogenation tunnels, freeze dryers, autoclaving equipment, and aseptic transfer systems. Metall+Plastic also designs E-Beam tunnels and emitter, locks, gas tight doors, and glove testing systems.

Triple Protection

At first glance, all three systems work as a clean room micro plant. As far as technology and regulation are concerned, the differences are quite considerable and have to be assessed for each individual project. We would be happy to recommend the correct protection system that is suitable for your application.

To restrict the operator access to the process area, our filling machines can be provided with RABS equipment as an option. The restricted access is, in this case, achieved by glove systems and mock-up studies are used to determine the gloves' positions in advance.



Cleanroom Technology

METALL+PLASTIC

Cleanroom Technology

Isolator

- Possible operation parameters
- Air speed
- Pressure regulation (option)
- Air temperature controls (option)
- Humidity controls

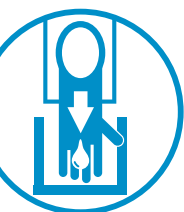
Restricted Access BarrierSystem (RABS)

The processed air is taken from the machine environment and filtered through a HEPA filter. Variable speed-controlled ventilators supply constant air volume to the unit. Airdistribution is achieved with a plastic diaphragm, which ensures uniform air distribution in the protected area with little turbulence.

Closed Restricted AccessBarrier System (C-RABS)

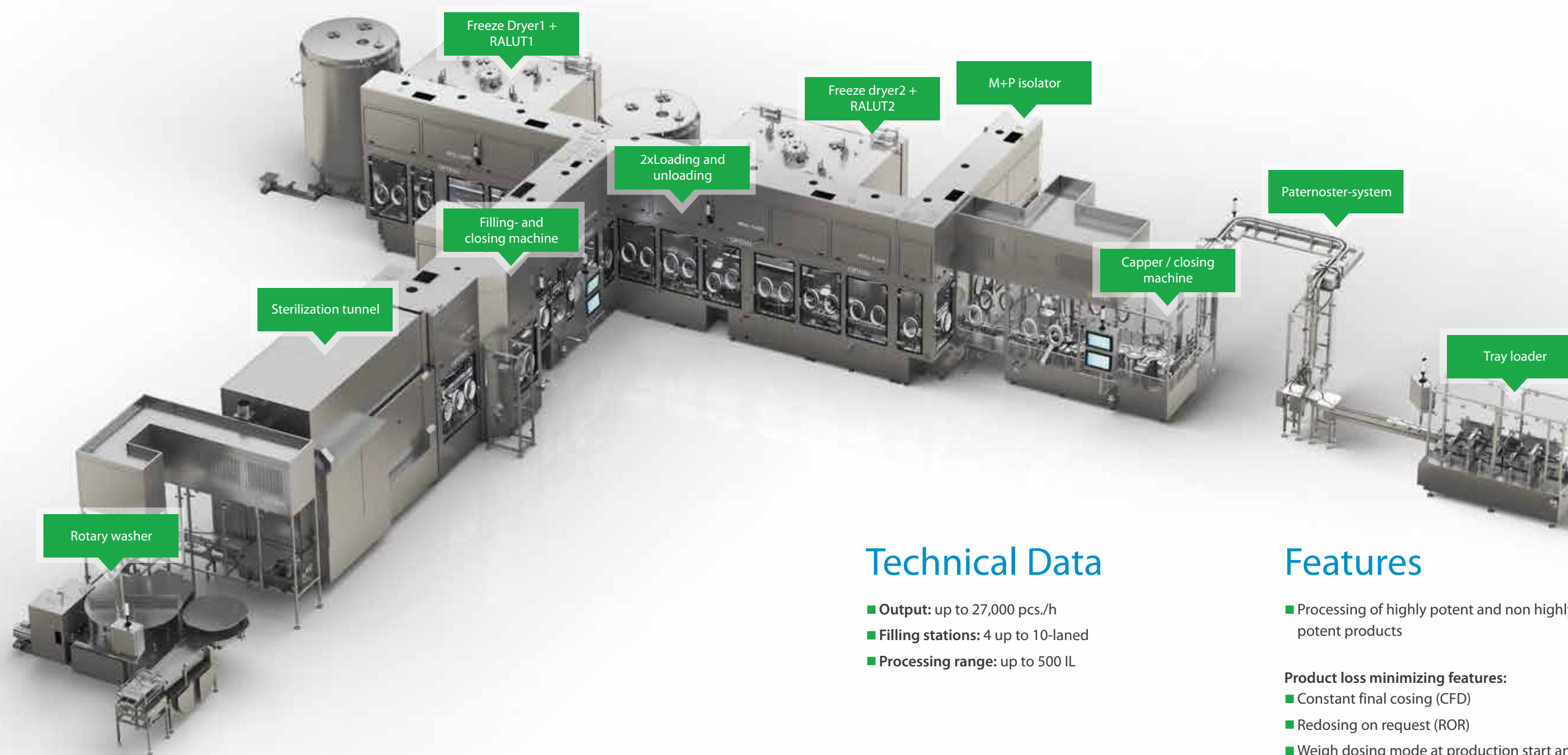
The technical module consists of high-quality stainless steel materials and is located above the protection module. It contains the complete technical air equipment, such as ventilators, filters, cleanroom illumination and air distribution diaphragm.

The protection module consists of high-quality stainless steel materials. Doors, windows and other functional elements are integrated into the modular sectional framework. Intervention in the protection module is achieved with glove accesses that are integrated into the glass doors (tempered safety glass (ESG).



Turnkey Line with Isolator and Freeze Dryer

WMR1800 | SHT9SKZ | VFVM18000 | 2xRALUT | 2xFreeze Dryer S-23 |
M+P Isolator | VVM2428 | M2424

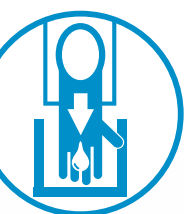


Technical Data

- **Output:** up to 27,000 pcs./h
- **Filling stations:** 4 up to 10-laned
- **Processing range:** up to 500 IL

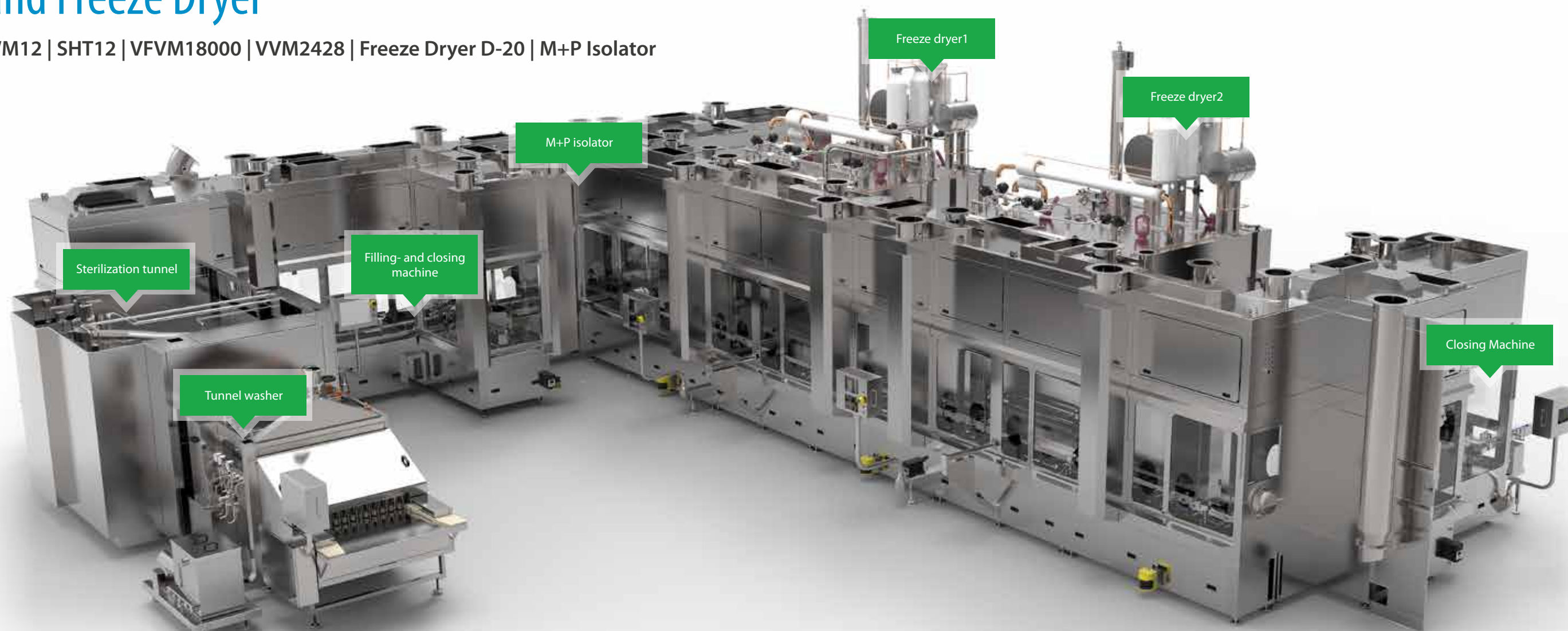
Features

- Processing of highly potent and non highly potent products
- Product loss minimizing features:**
 - Constant final cosing (CFD)
 - Redosing on request (ROR)
 - Weigh dosing mode at production start and end
 - Restoppering
 - Stopper repressing
 - 100% In-Process Control



Turnkey Line for Vials with Isolator and Freeze Dryer

WM12 | SHT12 | VFVM18000 | VVM2428 | Freeze Dryer D-20 | M+P Isolator



Technical Data

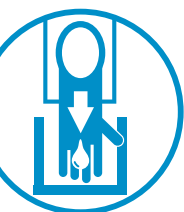
- Output: up to 27,000 pcs./h
- Filling stations: 4 up to 10-laned
- Processing range: up to max. 500 IL

Features

- Processing of highly potent and non highly potent products

Product loss minimizing features:

- Constant final dosing (CFD)
- Redosing on request (ROR)
- Weigh dosing mode at production start and end
- Restoppering
- Stopper repressing
- 100% In-Process Control



Turnkey Line for Vials with Isolator

WMR600 | SHT6 | VFVM18000 | M+P Isolator | VVM2428



Technical Data

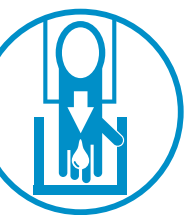
- **Output:** up to 27,000 pcs./h
- **Filling stations:** 4 up to 10-laned
- **Processing range:** up to max. 500 IL

Features

- Processing of highly potent and non highly potent products

Product loss minimizing features:

- Constant final dosing (CFD)
- Redosing on request (ROR)
- Weigh dosing mode at production start and end
- Restoppering
- Stopper repressing
- 100% In-Process Control



Turnkey-Line for Vials with Isolator

WMR2400 | SHT15SKZ | VFVM18000 | VVM2428 | M2424 | M+P Isolator



Technical Data

- **Output:** up to 27,000 pcs./h
- **Filling stations:** 4 up to 10-stellig
- **Processing range:** up to max. 500 IL

Features

- Processing of highly potent and non highly potent products

Product loss minimizing features:

- Constant final dosing (CFD)
- Redosing on request (ROR)
- Weigh dosing mode at production start and end
- Restoppering
- Stopper repressing
- 100% in-process control

Life Cycle Based Services

Packaging processes of the future will be more efficient, digitally interconnected and complex. We gladly support you with this process. Personal and individual customer service is the highest priority at Optima. Choose from our comprehensive "OPTIMA Total Care" portfolio to support your needs and to reach your objectives faster and more efficiently. Our consultants and experts will be at your side – at all times during the complete life cycle of your equipment. Our constant focus: Your needs, your objectives and your success. You can rely on us.



Smart Services

Our Smart Services are designed to effectively complement our Basic Services package. They include all of Optima's digital services, which you use to improve the efficiency of your production. These Services comprise Knowledge Transfer, Manufacturing Intelligence, Maintenance Support, and Smart Assistance. What you get is a powerful comprehensive package that can be tailored precisely to your requirements, including everything from OEE optimization to your desired maintenance mode and fast access to machine knowledge, as well as digital support when process issues or format changes occur. All services are available around the clock on the Optima central platform. In addition, they can also be tested live at the Digital Innovation Center in Schwäbisch Hall.



Basic Services

Our Basic Services offer you a wide range of services that are designed to support you in all phases of the machine life cycle. These services start up in the project phase, where we provide support during installation, commissioning, qualification, and user training. Integrated factory acceptance tests reduce your time-to-market. They continue in the ramp-up phase, where customized production support is offered. During the production phase, our Basic Services are there for you, providing a wide range of services around the clock – all the way up to retrofitting.



More Information:
www.optima-packaging.com/totalcare



Instruction & Training

Become an expert. Our specialists will convey their knowledge about Optima's equipment through virtual reality, at the machine at Optima's facility or at your production site. The easy and correct utilization of our machinery is our work guarantee. With each custom tailored machine, we offer individual training that is customized to your needs. A special emphasis is placed on complete documentation.

For basic or more extensive expert knowledge, you can choose from a variety of training units based on your requirements. After the training, you will be able to identify application opportunities, potential safety hazards, error sources and understand safety requirements.



Total Care

Your Advantages

- Training tailored to your requirements and designed for your machine needs
- Minimal downtime, high efficiency and minimal error rate
- User-oriented machine settings
- Knowledge transfer through experts
- Production safety for operators and machines

Services

- Virtual reality training
- Training units tailored to your needs
- Individual training documentation
- Various training medias as reference guides
- Basic and operator training
- Technician and expert training
- "Train-the-Trainer" education
- Safety training

More information:
www.optima-packaging.com/pharma