

# SMART SOLUTIONS FOR DIAGNOSTIC EXPERTS

Member of

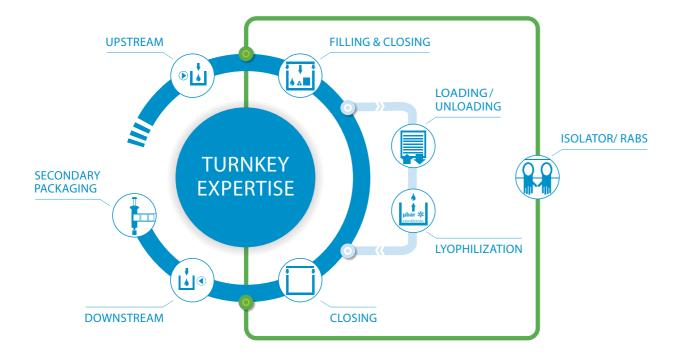


## **OPTIMA**

#### 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**







# DIAGNOSTIC FILLING SOLUTIONS

## Contents

Monoblock Machines	6
Flexofill Machines	10
Linoline Machines	16
Contiline Machines	22
Freeze Dryer	24
Turnkey Solutions	26
Total Care	32

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

# Diagnostic **Filling Solutions**

at the heart of our systems.

The extensive range is completed by process technology, freeze-drying systems, and automated loading and unloading as well as robot technology. This means that we are your partner for carrying out turnkey projects cost-effectively and with utmost precision. As experienced solution providers and customizers, we have a wide range of synergy effects within the Optima Group and we implement intelligent solutions for diagnostic experts or, in other words, we provide them with: Smart Solutions for Diagnostic Experts.

Filling of Diagnostic **Products** 

> LEADING ROLE AS A SOLUTION PROVIDER for filling and production systems in the Fill & Finish and freeze-drying sectors for the diagnostics and life science industries

**GMP-COMPLIANT MACHINES AND SYSTEMS** including the newest technologies

INDIVIDUAL CUSTOMER SOLUTIONS for a variety of investment scenarios

**EXPERTISE IN THE IMPLEMENTATION** of complex turnkey projects

In diagnostics, we focus on the specific manufacturer requirements in two sectors: Firstly, there are applications in human and veterinary diagnostics, and secondly, life science research. We focus on automatic monoblock systems and complete production lines for filling and processing liquid and powder products for in-vitro diagnostics. These include PCR test kits for SARS-CoV-2. Dosing and closing systems are



## Safe Filling of Highly **Sensitive and Potent** Products

The manufacturing of reagents often requires dealing with sensitive and/or aggressive liquids in different volumes, outputs and dosage forms. To meet the requirements for the liquids, gels and powders used in diagnostics, Optima Pharma designs and develops specialized equipment to coat micro titer plates or to fill bottles, vials, cartridges, cuvettes and other innovative and proprietary containers.

Optima Pharma specializes in fully automatic equipment to fill and close every type of bottle and container and reach an output of up to 21,600 units/h.

We make use of a wide range of dosing systems, such as peristaltic and rotary piston pumps ensuring that filling volumes in the  $\mu$ l range up to 1 IL is commonplace.



### **Monoblock Machines**

	Vials Micro V	Cartridges, Cuvettes
1	x	x
	x	x
	x	

g,	Closing Stand-Alone	Lyophilization
./h	up to 3,600 pcs./h Flexocap	1 – 7.9 m²
./h	up to 7,200 pcs./h Linocap	8 – 12 m²
s./h	up to 14,400 pcs./h Rotocap	12 – 43 m²
		1



## The Versatile Machine

#### **Monoblock Machines**

Monoblock machines provide filling and closing units that are integrated into one machine frame. Products travel short distances between the filling and closing steps and the machines offer particularly safe production with an extremely small footprint. This is especially ideal for diagnostics in small to medium sized companies.



- Process monitoring for microdosing
- In-Process Control
- ATEX execution for solvent-based products
- Modular construction

Technical Data						
	Flexofill	Linoline	Contiline			
Products	Liquid to viscous					
Container	100 mm/ 220 height	95 mm/ 220 height	95 mm/ 220 height			
Output	up to 4,200 pcs./h	up to 7,200 pcs./h	up to 21,600 pcs./h			
Filling volume	0.1 – 2,500 ml					
Closure types	Ø 50 mm For stoppers, droppers, screw caps, spray pumps, crimping caps, roll-on caps, PP-caps					
Closing stations	3	3	2			

### **Monoblock Machines**



- Excellent cleanability and accessiblity
- Variable use of different dosing systems
- Quick format changeovers
- cGMP conformity



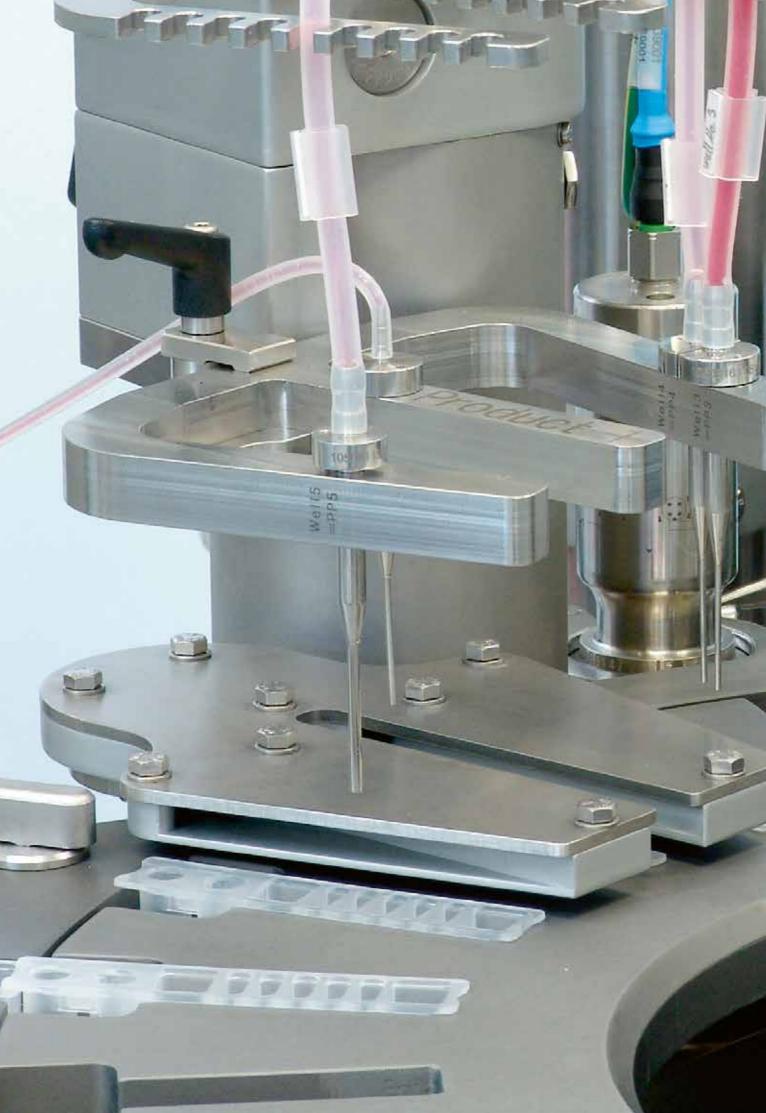


## Micro Dosing for Multi Cartridges

#### Flexofill

Our Flexofill machine platform fills various container types. With a vibrating sorting device and an infeed orientation device for the cartridges, the machines fill solvent-based products, accumulation solutions and magnetic beads in multi cartridges. Explosion proof design guarantees the process safety for micro dosing and a strict compliance with the ATEX-guidelines while maintaining a high-speed output: 1,800 multi cartridges are processed per hour.







### **Flexofill Machines**

#### Features

Container ■ Multi cartridge

Product
Solvent-based products
Buffer solutions
Magnetic beads

**Filling Quantity** ■ 40 – 2,000 µl

Output ■ up to 1,800 pcs./h

#### Functions & Equipment ■ Vibratory sorting and correctly positioned feeding of cartridges

- Unwinding and cutting device
- Hot sealing station
- ATEX version
- LF-design

## Micro Dosing for Micro Vials

#### Flexofill

The Optima Flexofill is the perfect solution for filling micro tubes. The machine can fill powder and liquid products. Our machines are equipped with a powder dosing system including a Piezo chute and a micro weighing scale. Liquid products are filled precisely using a micro dosing system. The pre- and post-screw-on station make the process very reliable and safe, ensuring that your product, after labeling, exits the machine in perfect condition.





### **Flexofill Machines**

#### Features

Container ■ Micro vials

Product ■ Powdery/Liquid

- Functions & Equipment ■ Sorting
- Powder dosing with piezo feed and micro weigh cell
- Liquid micro dosing
- Pre-torquing
- Cap verification and servo torquing
- Labeling
- Discharge



# Efficient Filling of Cartridges

#### Flexofill

Filling cartridges? Again, the Flexofill machine is the right machine for this application, equipped with the appropriate modules. This includes a 20-laned cartridge infeed magazine and a transport star wheel. A splicer guarantees the unwinding of the film without any loss. The machine also includes the following functions: film transfer, cutting and sealing. An OCR print control and a 100% In-Process Control inspect the integrity of the product after the discharge.





#### **Flexofill Machines**

#### Features

Container ■ Diagnostic cartridges

Product ■ Diagnostic screening product

Filling Range ■ 0.1– 2,500 ml

Output ■ up to 3,600 pcs./h

Functions & Equipment ■ 20-lane buffer round tower

- Cartridge buffer silo
- Destacking to transport star wheel

■ Servo controlled filling

- Loss-free foil unwinding with splicer and UV decontamination
- Foil transfer and clinching
- Final sealing
- Discharge and reject
- OCR print verification
- 100 % check weighing



## Filling of Diagnostic **Products in Plastic Bottles**

#### Linoline

The Linoline is filling diagnostic products at high outputs and volumes. The machine is designed to process plastic bottles with filling volumes up to 2,500 milliliters at high speed. The machine is equipped with a 100% In-process control, a screw-capping station and an 8-headed peristaltic pump dosing system. Other features include 100% torque-monitoring control and a cap placement control station ensuring the quality of your product.





#### **Linoline Machines**

#### Features

**Container** ■ Plastic bottles: 100 ml - 1,000 ml

Product Culture media

Filling Range ■ 0.1– 2,500 ml

The

Output ■ up to 6,600 pcs./h

- Functions & Equipment Bottle infeed for angled bottle
- Cap removal station
- Continuous filling with 8-lane peristaltic pump dosing system
- Intermittent transport 2-lane
- Servo cap transfer and pre-torquing
- Servo cap torquing
- Skewed cap detection
- Reject / discharge



## Filling, Closing and Accurate Weighing of Cartridges

#### Linoline

The Linoline is also the correct machine for protein solutions and micro-beads with different fill volumes. The machine fills plastic cartridges with five wells.

The Linoline provides flexibility due to its dosing range from 1.4 to 14 milliliters and high output of up to 3,000 cartridges per hour. The machine offers the possibility to print a code via laser printing. A particle suction device, camera inspection and a 100% in-process control ensure the process safety. A 5-headed peristaltic pump filling system gives the Linoline its flexibility, covering a large filling range without format change. The processed cartridges are sealed with film and are transported to the discharge or reject station.







#### **Linoline Machines**

#### **Features**

■ Cartridges made of plastic with 5 cavities each

#### Product

Liquid diagnostic (protein solutions and beads) with various volumes

Filling Range ■ 0.1– 2,500 ml

#### Output

■ up to 3,000 pcs./h

#### **Functions & Equipment**

- Laser code with batch code and data matrix
- Particle suction
- Vision system for data matrix code
- 100% In-process control
- 5-lane peristaltic filling system for a large filling range without the need to change formats
- Track & Trace
- Leak test
- Homogenization of suspensions
- Laser cutting of sealing films
- Discharge / reject





# Fill Volume Flexibility

#### Linoline

The Linoline is highly flexible. Liquid diagnostic reagents can be filled plastic container of various sizes, forms and with different closures. The machine also handles challenging products, like micro-suspensions, metal incompatible or aggressive liquids. Are you looking for flexible solutions? The fill volume of the Linoline can vary from 0.1 to 2,500 ml - this will not affect the output of up to 6,600 containers per hour.





### **Linoline Machines**

#### Features

#### Container

PET bottles in different sizes and formats with various closures

#### Product

- Liquid diagnostic reagents
- Various product characteristics: Micro suspensions Metal imcompatible products Aggressive liquids
- Filling range: 0.1– 2,500 ml

#### Output ■ up to 6,600 pcs./h

#### Functions & Equipment ■ Infeed turn table

- 4-lane rotary piston pumps
- 100% In-Process Controll
- Dropper insertion
- Pre- and final torquing
- Servo cap torquing with 100% IPC
- Discharge / reject



## Dynamic Bottle Heating in Combination with Hot Filling

#### Contiline

An output of 6,600 per hour is not sufficient? Then the Contiline from Optima Pharma is the correct solution for you. The machine fills up to 21,600 plastic bottles per hour with liquid diagnostic reagents. A special highlight of this filling machine is a transport conveyor with an infrared radiant heater that heats the bottles up to 70 to 80° C. A product temperature control with product drainage recognizes product with incorrect temperatures. A 16-headed ceramic rotary piston pump system ensures a quick filling process. Rely on our process safety: a CIP cleaning function for the pumps and the product paths ensures the necessary cleanliness level.





### **Contiline Machines**

#### **Features**

Container ■ PET bottle 80 ml

Product ■ Liquid diagnostic reagents

Filling range ■ 0.1– 2,500 ml

Output ■ Up to 21,600 pcs./h

#### Functions & Equipment

- Transport conveyor belt with radiant carbon heater to heat the bottles to 70-80 °C
- Container temperature monitoring with product drainage in case of incorrect temperature
- Continuous filling with 16 ceramic rotary piston pumps
- Product temperature monitoring
- Gas flushing during filling
- CIP cleaning for pumps and product path
- 10-headed crimping rotor for aluminium crimp caps with inlaid seal disk





LYOPHILIZATION

# Highest Security for Your Product

#### Freeze Dryer

Sensitive pharmaceutical products often need to be freeze dried to extend shelf life. Optima Pharma Mornshausen provides solutions for all requirements with its broad range of machines. From hightech pilot plants up to high efficiency production plants for vials 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 and 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.



# **Your Advantages** 1000 ■ 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 NI-NE ■ H<sub>2</sub>O<sub>2</sub> sterilization Clean In Place (CIP) ■ Modem support / remote control Processing of solvents in compliance with ATEX directive



#### Freeze Dryer

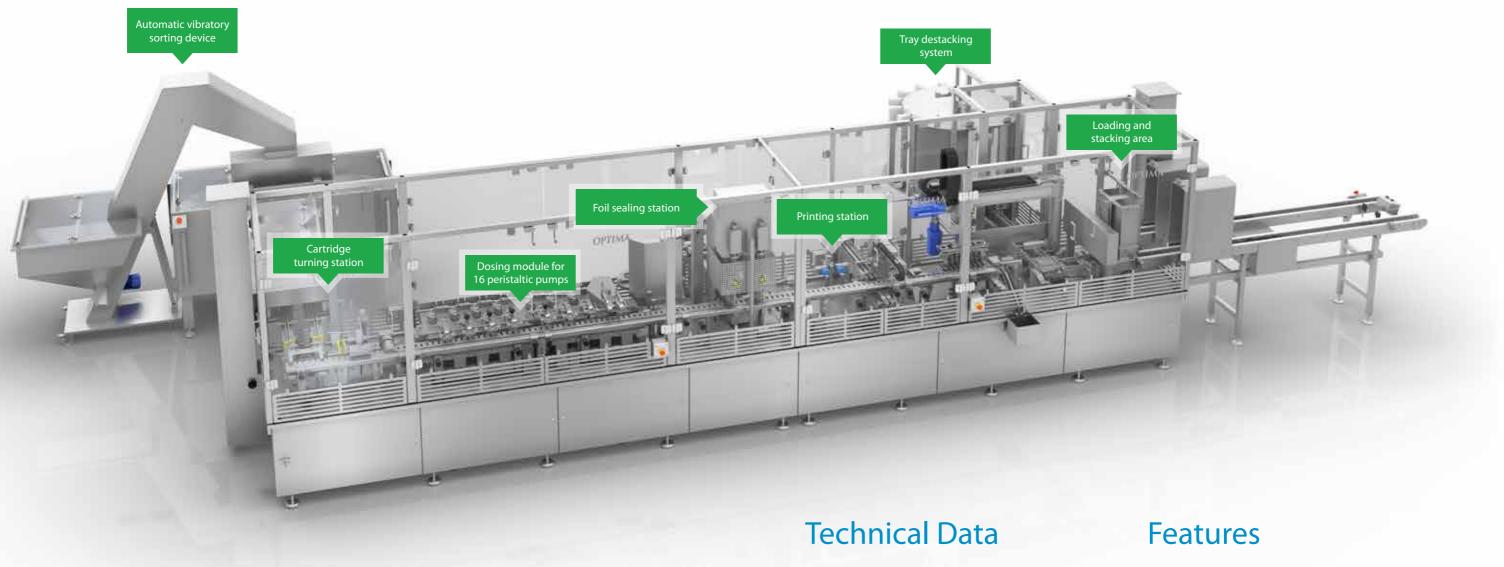
#### Features

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



# **Turnkey Line for Multi Cartridges**

Linoline120



- Output: up to 7,200 pcs./h
- Processing Range: 2-laned
- Object Diameter: between 30 mm and 95 mm
- Object Height: between 50 mm and 220 mm

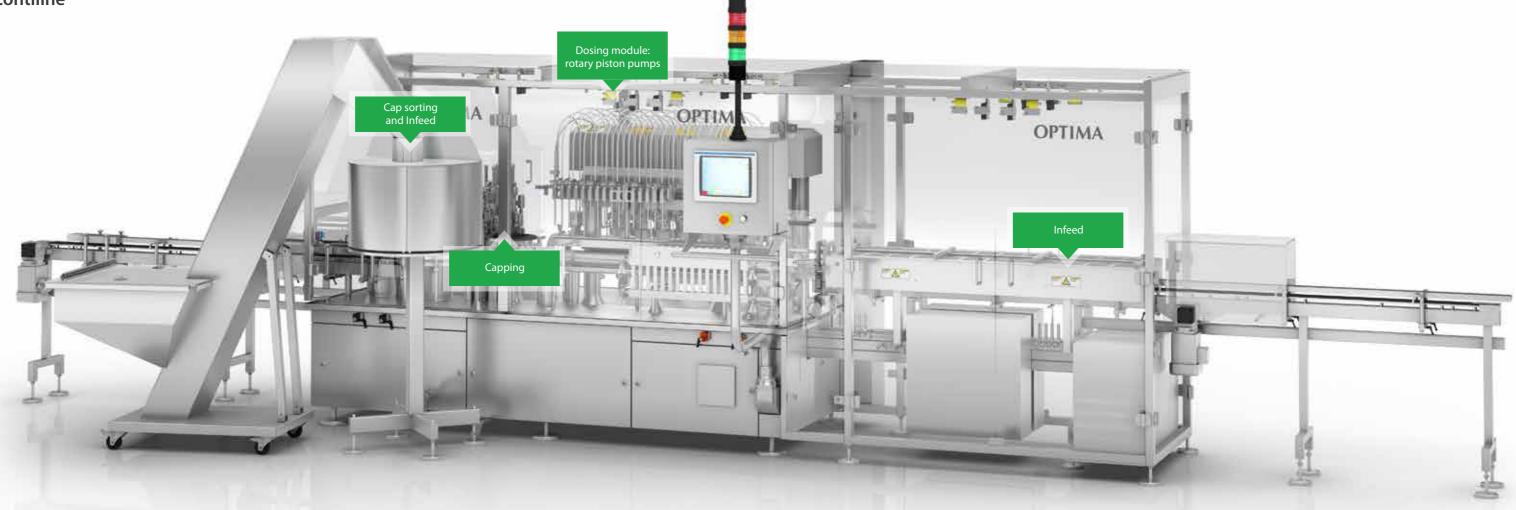
### **Turnkey Solutions**

- 100% In-Process Control
- ATEX model optional
- Intermittent operation



# Turnkey Line for Vials, Bottles and Similar Containers





# **Technical Data**

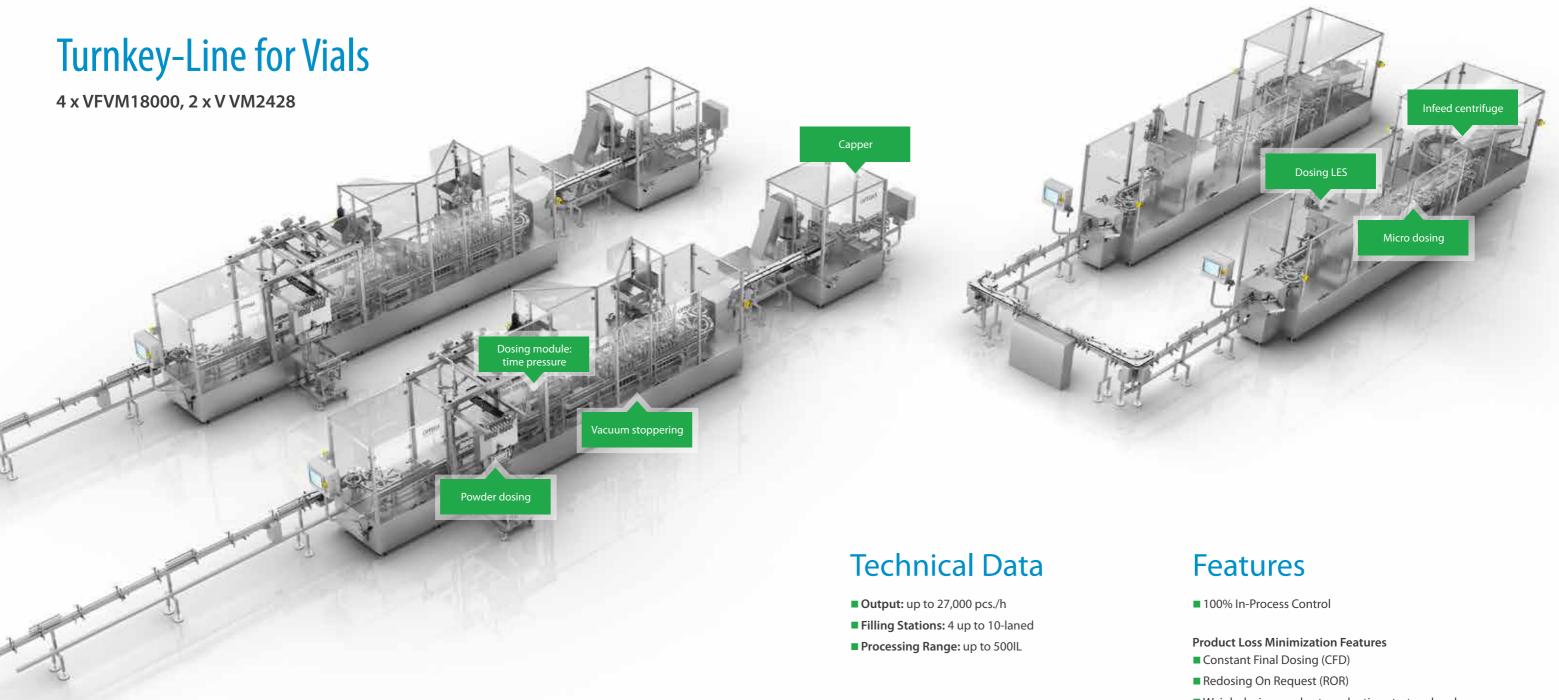
- Output: up to 21,600 pcs./h
- Processing sites: between 4- and 8-laned
- Object diameter: between 16 mm and 66 mm
- Object height: between 30 mm and 150 mm

#### **Turnkey Solutions**

### Features

- ATEX model optional
- 100% In-Process Control
- Continuous operation





### **Turnkey Solutions**

- Weigh dosing mode at production start and end
- Restoppering
- Stopper Repressing
- Processing of highly potent and non highly

# **OPTIMA**<br/> total care\*\*

# 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 Assistance

Tim



#### **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-tomarket. 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.

Smart Services





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

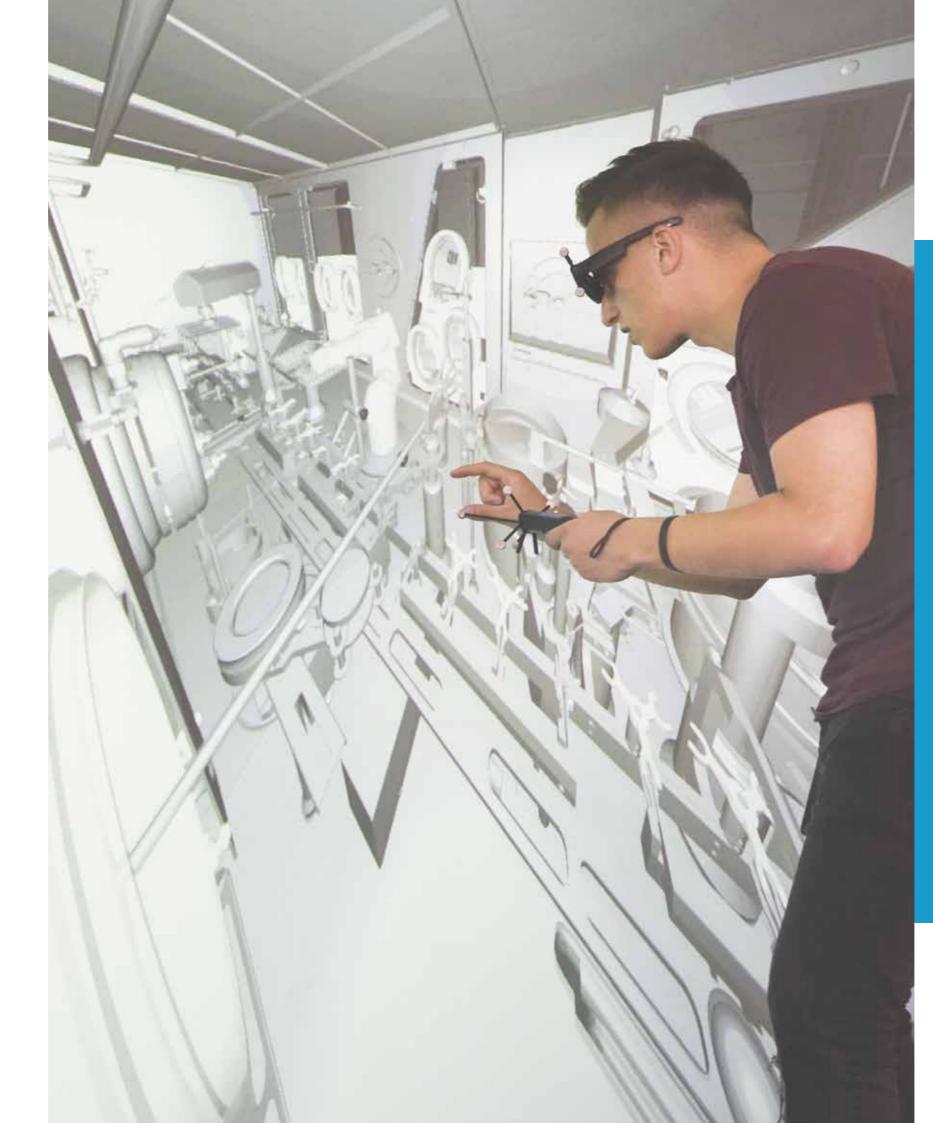
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# Instruction & Training

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 chose 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