VARIOSYS®

Flexible solutions for pharmaceutical processing

skan

BAUSCH+STRÖBEL

GEA

Harro Höfliger

CONTENT


VARIOSYS®

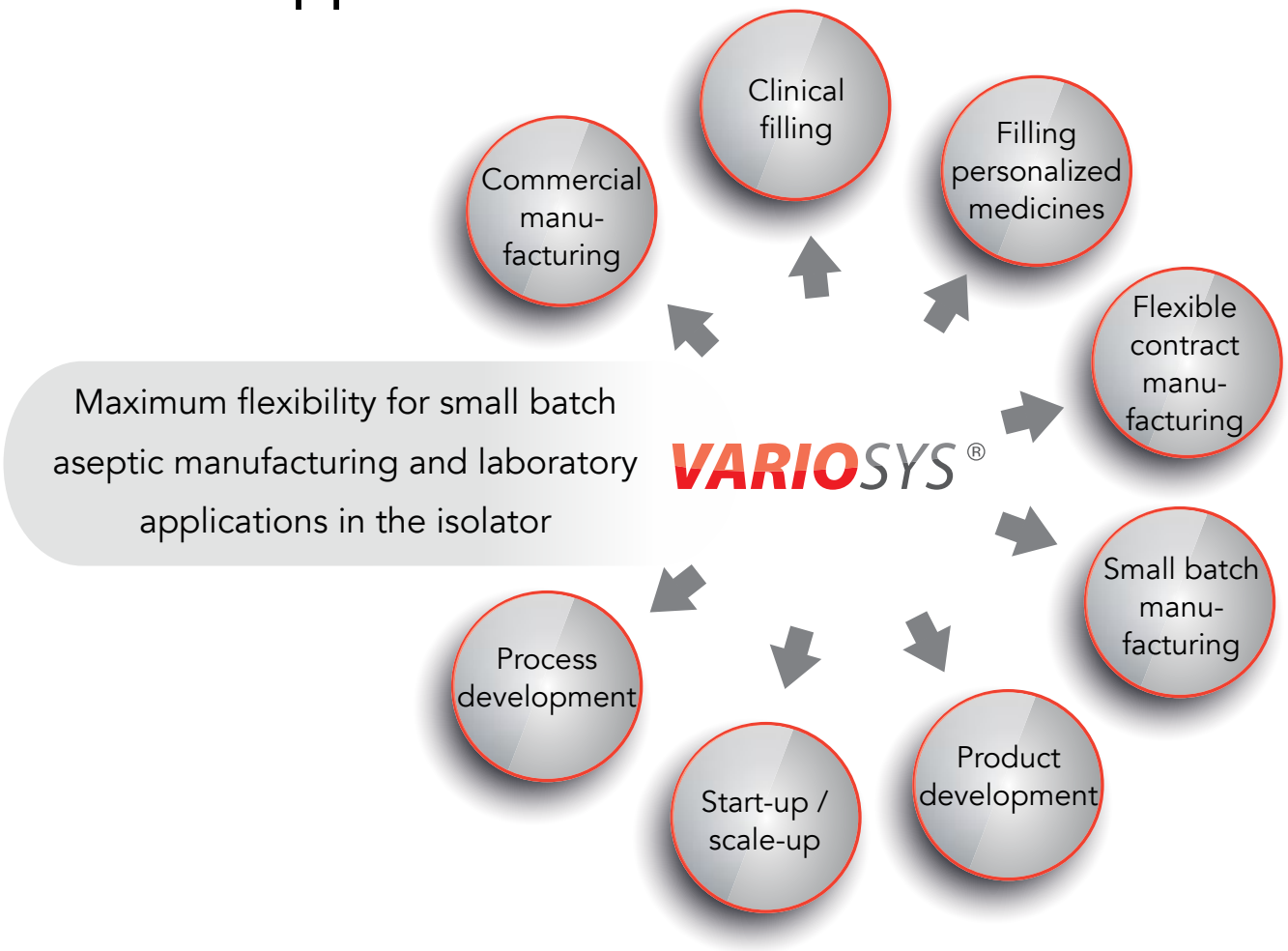
Discover VarioSys®

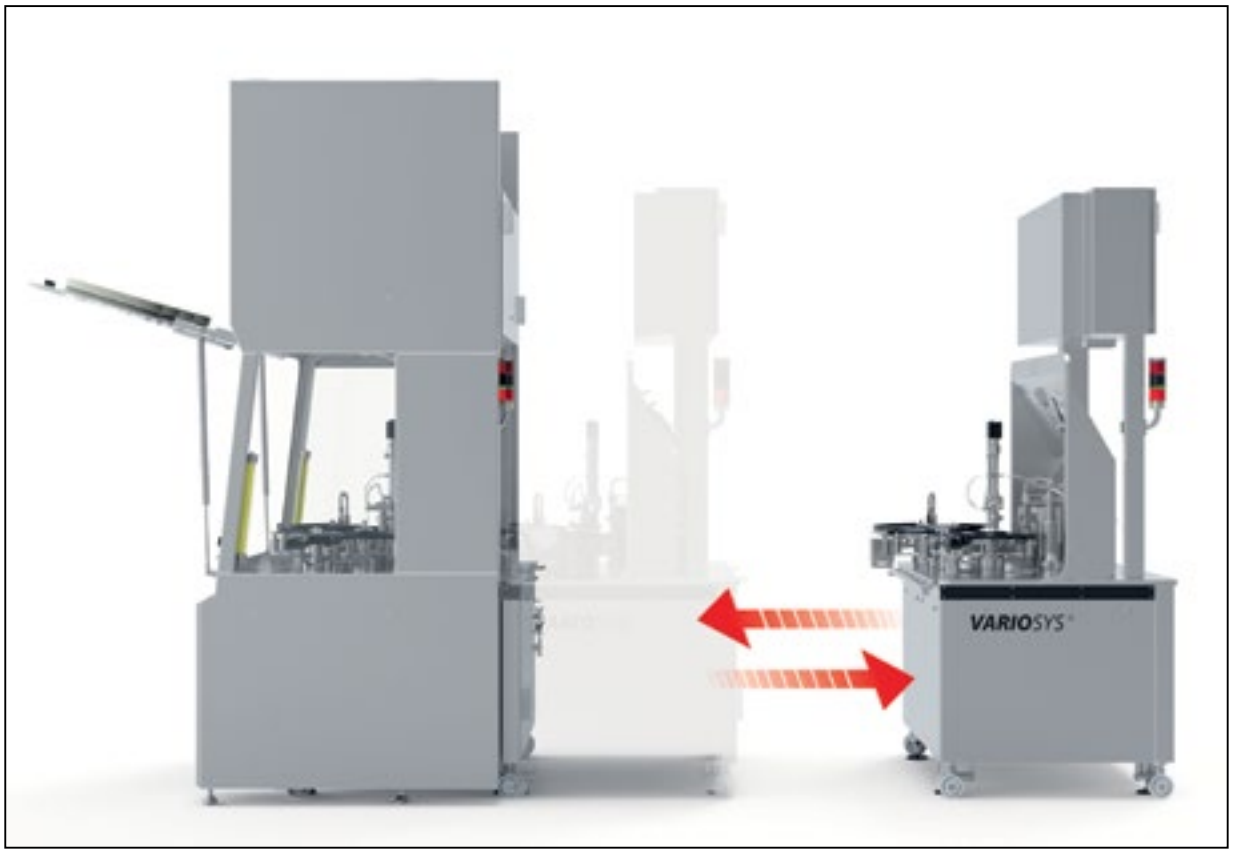
The innovative and highly flexible VarioSys® production system for biotech and pharmaceuticals is essentially a combination of two elements: an isolator made by SKAN and machine modules made by Bausch+Ströbel and Harro Höfliger. The system has been designed to provide utmost flexibility in the production of medications by exchanging modules. The machine modules are simply slotted into place on the "lock-and-key" principle and plugged in. Pharmaceutical production can be extended by adding a suitable freeze-dryer made by GEA.

VarioSys® is suitable for a wide range of applications that the manufacturing of clinical samples as well as the production of batches is possible in one installation. All FDA requirements for pharmaceutical production are met.

Discover more on our website
www.variosys.com

Fields of application





Benefits

Plug & Play

Adaptable to various packaging materials

Extendable modular design

Modular design of the processing line

Lock and key

Standardization of subassemblies

GMP and FDA conforming machine design

Processing toxic medications

Space saving

Time efficient

Four partners – one system

SKAN

Founded in 1968, SKAN AG today holds a leading position in the field of isolator technology for the pharmaceutical industry worldwide. Their major products include: various safety glove isolators and filling isolators for aseptic and/or highly active products, as well as complete validation/qualification documentation and service execution. For 20 years SKAN has been the leading manufacturer of isolator systems in the pharmaceutical sector.

HH Harro Höfliger

Harro Höfliger is specialized in the development of customer-oriented process and production solutions for pharmaceutical and medical applications as well as market-oriented consumer products.
With a team of experts the family run company offers extensive services related to product and process development and is globally recognized as a supplier of turnkey systems.

BAUSCH+STRÖBEL

Providing the best technical and economical answers to the challenges presented by the world market. With this clearly defined company goal in mind, Bausch+Ströbel designs, builds and sells packaging and production systems for the pharmaceutical and allied industries. From modest beginnings more than 55 years ago – with only four people – Bausch+Ströbel has developed into an international enterprise. It is now one of the leading manufacturers in pharmaceutical packaging.

GEA

GEA is an expert in freeze drying technology – a partner that knows the requirements of the pharmaceutical and biotech industries and builds them into every plant it creates. With over 75 years of experience, GEA is one of the leading manufacturers of freeze dryers worldwide. The product range includes pilot plants for R+D as well as production plants for industrial batches and complete production systems containing multiple freeze dryers and Automatic Loading and Unloading Systems (ALUS™).

SKAN VarioSys Isolator (PSI-L 2.0)

The isolator provides an aseptic environment for the VarioSys® system and thus reliably protects the operating personnel and the product. This solution is suitable for processing aseptic and/or highly active substances. The new version of the isolator impresses with the patented SKANFOG® Flow System, a cleaning-friendly design and a revised air processing concept. Highest process reliability is ensured by reliable cycles with lower consumption and, above all, a significantly reduced cycle time.

Great variety of possible combinations

The individual isolator modules can be combined as required depending on the process. Depending on the production process, the system can be loaded and unloaded via a mousehole, the SARA-XL fast airlock or a sterilization tunnel. For the connection to upstream and downstream machines, various interface modules are available to cover the entire process safely.

Efficient air-handling concept

The pre-filters, the HEPA filters of filter class H13 / H14 and the catalysts are components of the efficient air treatment concept. Different pressure cascades can also be implemented between the individual modules. The isolator can also be operated at overpressure or underpressure. The filtered air is returned via the catalysts and discharged into the room or can be exhausted externally.

Features

- Isolator with quick and easy interchangeable modules.
- Aseptic production due to H_2O_2 decontamination of the isolator
- Toxic processes can be realized as well
- Robot safety for risk minimization on the part of the operator and the process
- Fast H_2O_2 decontamination of the material lock with SKANFOG technology
- Excellent operator protection with safely replaceable FIPA return air filters
- Suitable for many different sizes and types of pre-sterilized (RTU) packaging materials

SARA-XL Airlock

The newly designed SARA-XL with integrated SKANFOG® Flow technology is a safe and fast airlock for a short and gentle bio-decontamination process. The upgraded stainless-steel construction is also easy to clean. Due to its modular design, the airlock can be attached to any isolator configuration. Even when loaded, very short cycle times are possible. In addition, the principle of the single flow chamber in conjunction with the double HEPA filtered exhaust air ensure the highest level of process reliability.

SKANFOG® H_2O_2 micro-nebulization

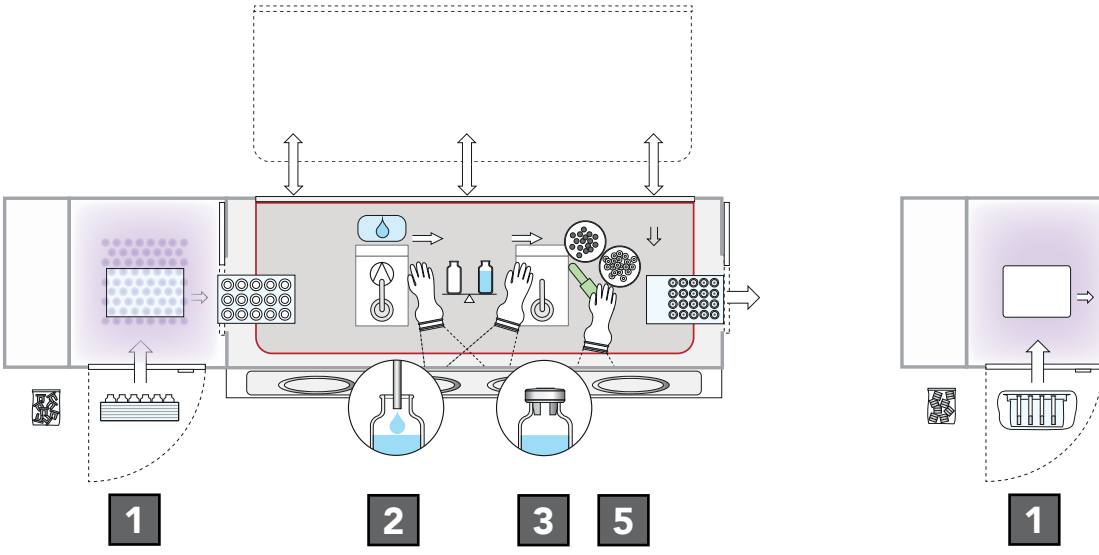
Controlling the microbial load within A/B cleanroom classes is a daily challenge. Surface decontamination of the equipment is a time-consuming procedure, and validation is often complex. SKANFOG® is a decontamination technology based on the micro-nebulization of hydrogen peroxide (H_2O_2). Compared with conventional decontamination, it simplifies and enhances both process flow and validation. Moreover, nebulized H_2O_2 in moderate concentrations can be used without concern for toxicity, corrosion and persistence. Scientific studies have shown that a total kill of a 10^6 population of the test organism Geobacillus stearothermophilus can be achieved and reproduced. SKAN are experts in H_2O_2 decontamination processes and provide support in all phases of cycle development and microbiological validation.

- Total kill of a 10^6 population of G. stearothermophilus
- Can be validated and is reproducible
- Once-through unidirectional airflow, integrated
- Catalytic converter and powerful fan for fast decontamination
- Ultra-short cycle times
- Suitable for H_2O_2 resistant and ready-to-use (RTU) packaging material

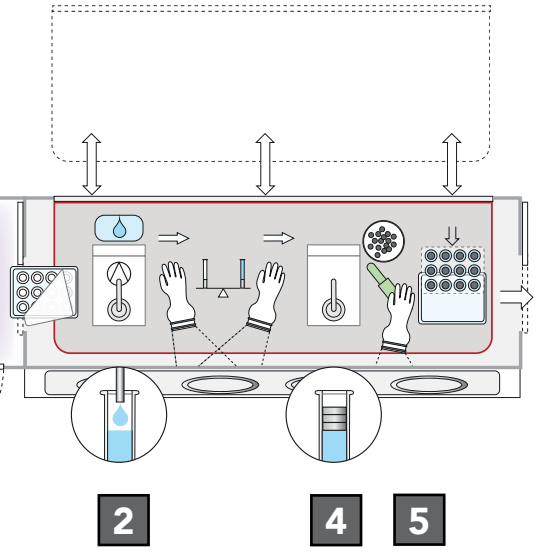
Semi-automatic processing

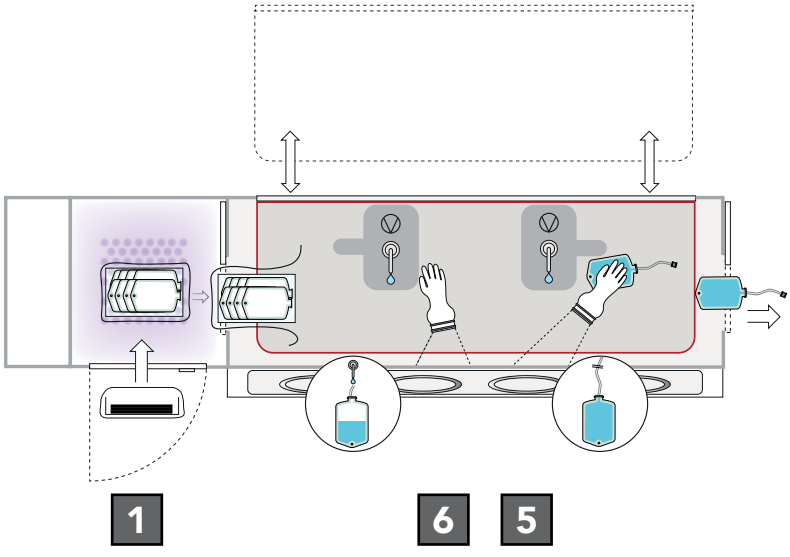
VarioSys® provides an ideal production environment – whether in galenics, in the lab or in small batch manufacturing. Equipped with semi-automatic machines, it can be used to fill a wide range of different containers with liquid and powder products very flexibly and efficiently. The system can easily be upgraded to a fully functional production line at any time.

1	Quick decontamination SARA for material transfer
2	Bench-top machine for simple and precise filling of all kinds of containers EDM
3	Bench-top machine for closing vials with crimp or screw caps HVM
4	Bench-top machine for closing cartridges and syringes SVP
5	Isolator PSI-L
6	Semi-automatic module for the aseptic filling of bags




skan
BAUSCH+STRÖBEL
VARIOSYS


2
4
5


1
6
5

Dosing machines EDM

Bench-top machines for simple and precise filling of all kinds of containers. Unstable containers such as cartridges, syringes barrels and test tubes can also be processed easily using transport stands.

Features:

- Rotary piston pump
- Patented single-hose peristaltic pump
- ViscoTec rotary displacement pump for dosing highly viscous (up to 5.000.000 mPas), shear sensitive and abrasive products
- Dosing with ADVANCEDfill technology
- Filling needle movement
- Vacuum-assisted dosing
- Automatic feedback adjustment of the dose
- In-process control 1 – 100 %

EDM with single-hose peristaltic pump

Technical Specifications	
Dosing range	> 0.02 ml
Vial, Syringe, Cartridge	Ø 6.85 – 68 mm h 35 – 160 mm

EDM with rotary piston pump

ADVANCEDFILL

With this self-priming and run empty function without product loss, only the last container may need to be rejected.

Closing machine SVP

Bench-top machine to close cartridges and syringes with plunger stoppers (type SVP). The stopper insertion depth and insertion speed can be freely selected.

Features:

- Gas-flushing during stopper insertion (option)
- Stopper insertion by vacuum (option)

Technical Specifications SVP	
Plunger stoppers	Ø 5 – 30 mm h 6 – 15 mm
Syringe	Ø 6.85 – 35 mm h 45 – 160 mm
Cartridge	Ø 8.55 – 35 mm h 35 – 106 mm

SVP for closing cartridges and syringes

Closing machine HVM

Bench-top machine for closing vials and cartridges with crimp caps or flip-off caps. Crimping speed and pressure as well as crimping tool lift are freely adjustable.

Features:

- Rotation of containers during closing
- Central crimping pressure adjustment
- Single crimping disc with servo controlled movement

HVM for closing vials

Technical Specifications HVM	
Crimp caps	Ø 7.5 – 34 mm h 4.8 – 19 mm
Flip-off caps	Ø 13.5 – 36.5 mm h 7 – 19 mm
Containers	Ø 8.55 – 68 mm h 35 – 136 mm

Closing vials with crimp caps

Aseptic filling module for IV bags

The system is suited for the dosing of liquids in a filling range from 50 to 2000 ml. The wide format range offers a great variety of applications. Infusion bags or larger containers as disposable product bags can be filled.

Features:

- Fully automatic filling process – mass flow system (Coriolis)
- Individual closing technology according to requirements (clamps, stoppers, welding)
- Completely integrated CIP/SIP (optional)
- Format independent (individual retrofitting)
- Nitrogen flushing (integrated)

Technical Specifications	
Working positions	1
Dosing range	50 – 2000 ml

Filling head with integrated media connections for nitrogen, vacuum evacuation and liquid product

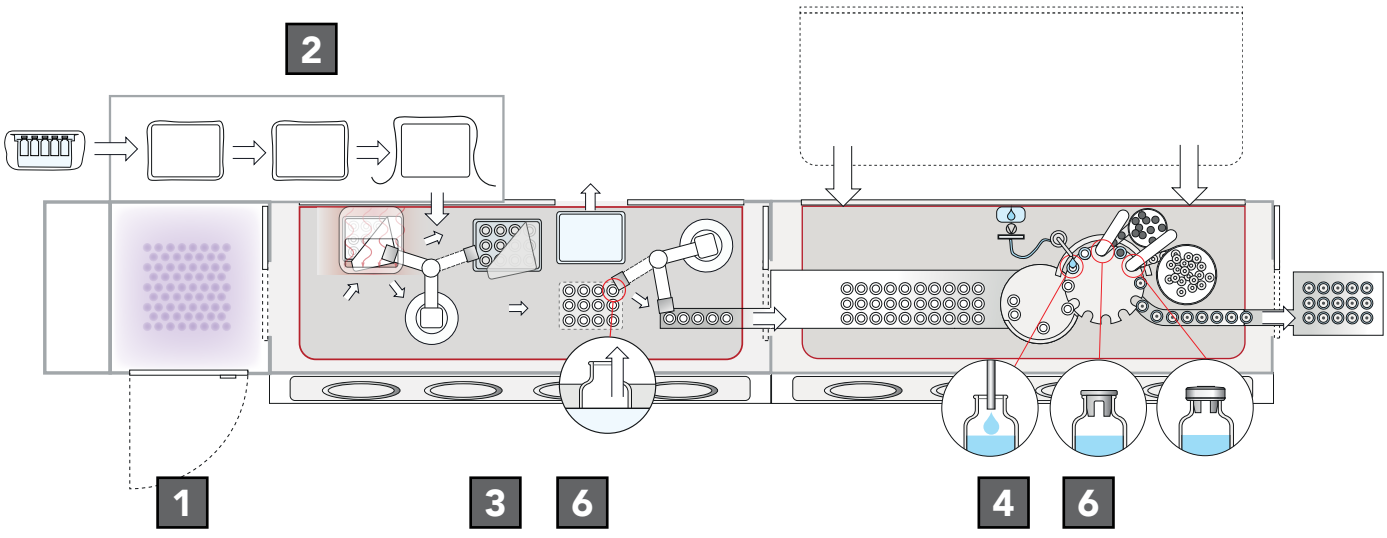
Nest processing

Pharmaceuticals manufacturers are increasingly using RTU containers, particularly in processes such as small batch manufacturing. This eliminates the need for cleaning and sterilizing syringes, vials and cartridges; the nested containers are delivered directly to the dosing process in special packaging. VarioSys® can be used in combination with handling, filling and closing modules to guarantee efficient processing and compliance with all regulations applicable to aseptic production.

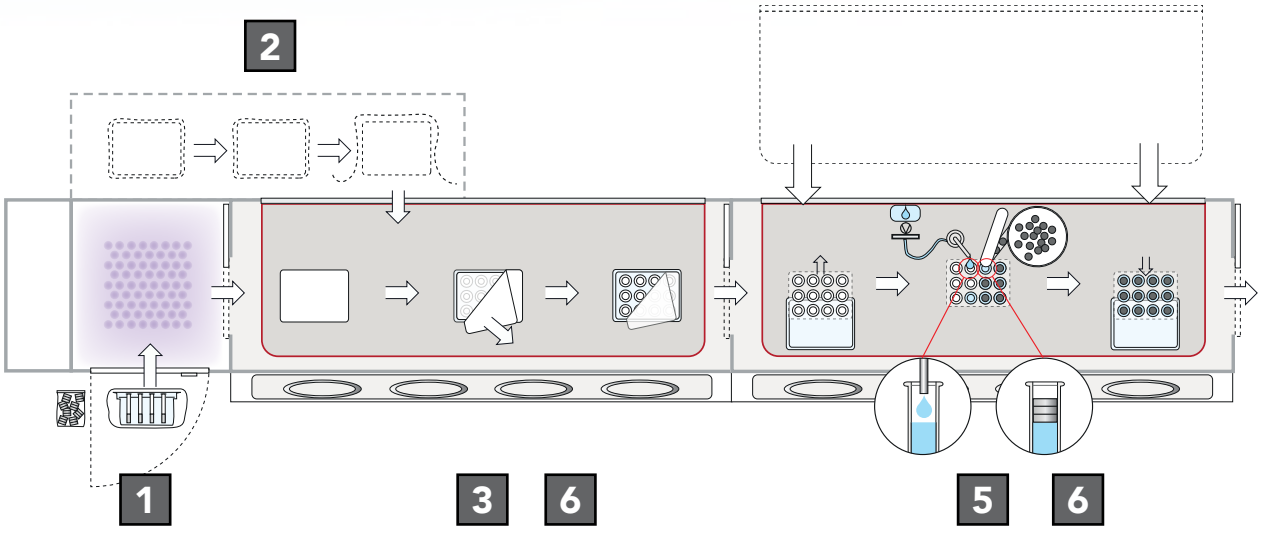
1	Quick decontamination SARA for material transfer
2	Tub debagging TUM 9030
3	VarioSys® module DDM 9105 for tub opening and denesting
4	VarioSys® module KSF 5105 for filling and stoppering vials
5	VarioSys® module SFM 5105 for filling and closing RTU containers
6	Isolator PSI-L

Photo: SCHOTT AG

Vial nest processing – filling in bulk



Syringe / Cartridge nest processing



Module for tray/tub opening and denesting TDM 9105 (manual/semi-automatic)

Tray processing

After loading, the tray is opened manually and then placed in the inversion unit. Once the tray is inverted, it is removed and the vials are transferred manually to the next module.

Tub processing

After the RTU tubs have been loaded, the foil and liner are removed. The next processing step depends on what downstream module is used. After opening, the tub is either transferred to the module downstream by a conveyor, or the nest is removed from the tub with a handling tool and positioned for automatic denesting of the containers.

Features:

- No movement above the open containers
- Simple and safe mode of operation
- Automatic denesting of the vials
- Denesting prior to filling allows the processing of potent/toxic products in bulk

Technical Specifications	
Output/h	60 trays/tubs

TDM 9105

TDM 9105 - semi automatic tub opening and vial denesting

Module for tub opening and denesting DDM 9105 (fully automatic)

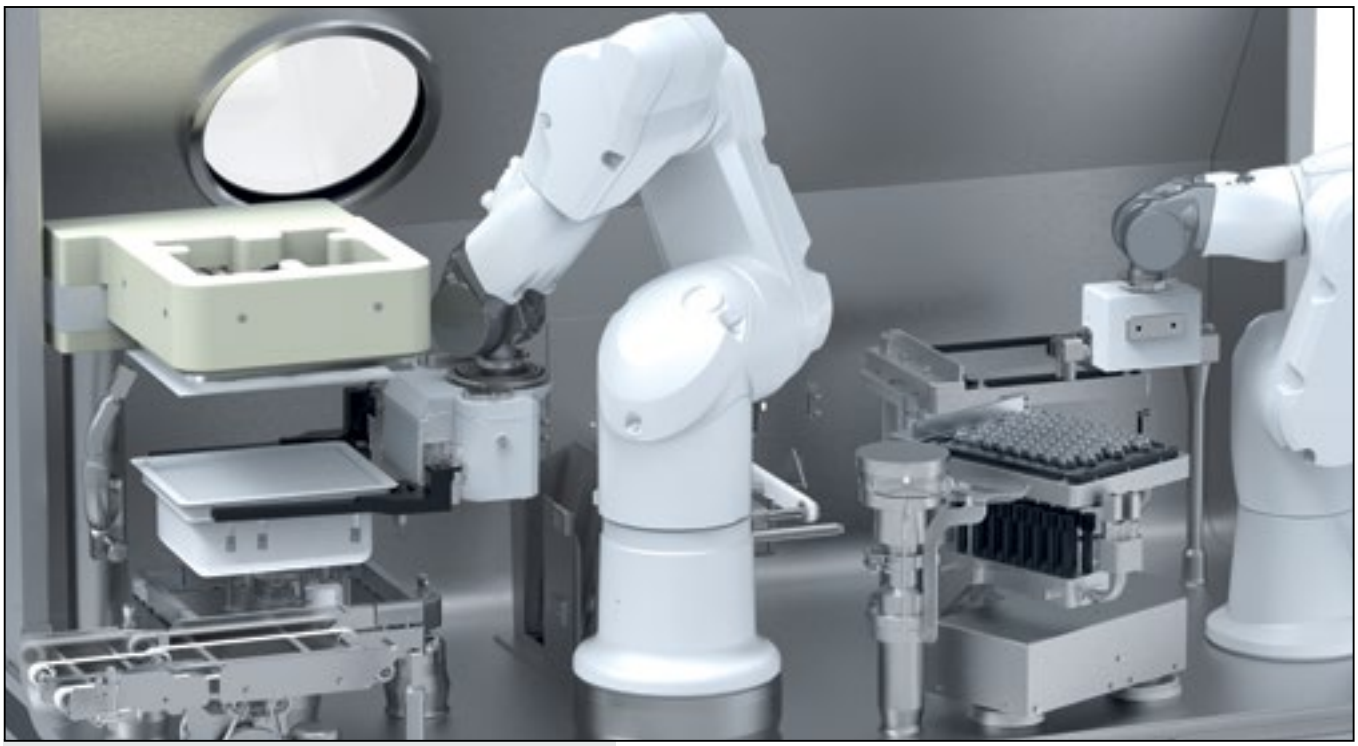
The tubs are opened fully automatically using a heating frame. For that purpose, they are transferred to the relevant positions by a clean room robot. After the tub has been opened, a second clean room robot removes the RTU vials from the nest and transfers them to the next module for further processing in bulk. For nested filling and closing of the RTU containers, the tub is placed on a transfer track after it has been opened.

Features:

- Nest transport by clean room robot
- Automatic opening of the tubs
- Automatic removal of the containers
- Particle generation is minimized through heating frame at lid removal
- Denesting prior to filling allows the processing of potent/toxic products in bulk

Technical Specifications	
Output/h	60 tubs

DDM 9105



DDM 9105 - Fully automatic tub opening and vial denesting

Module for RTU containers SFM 5105

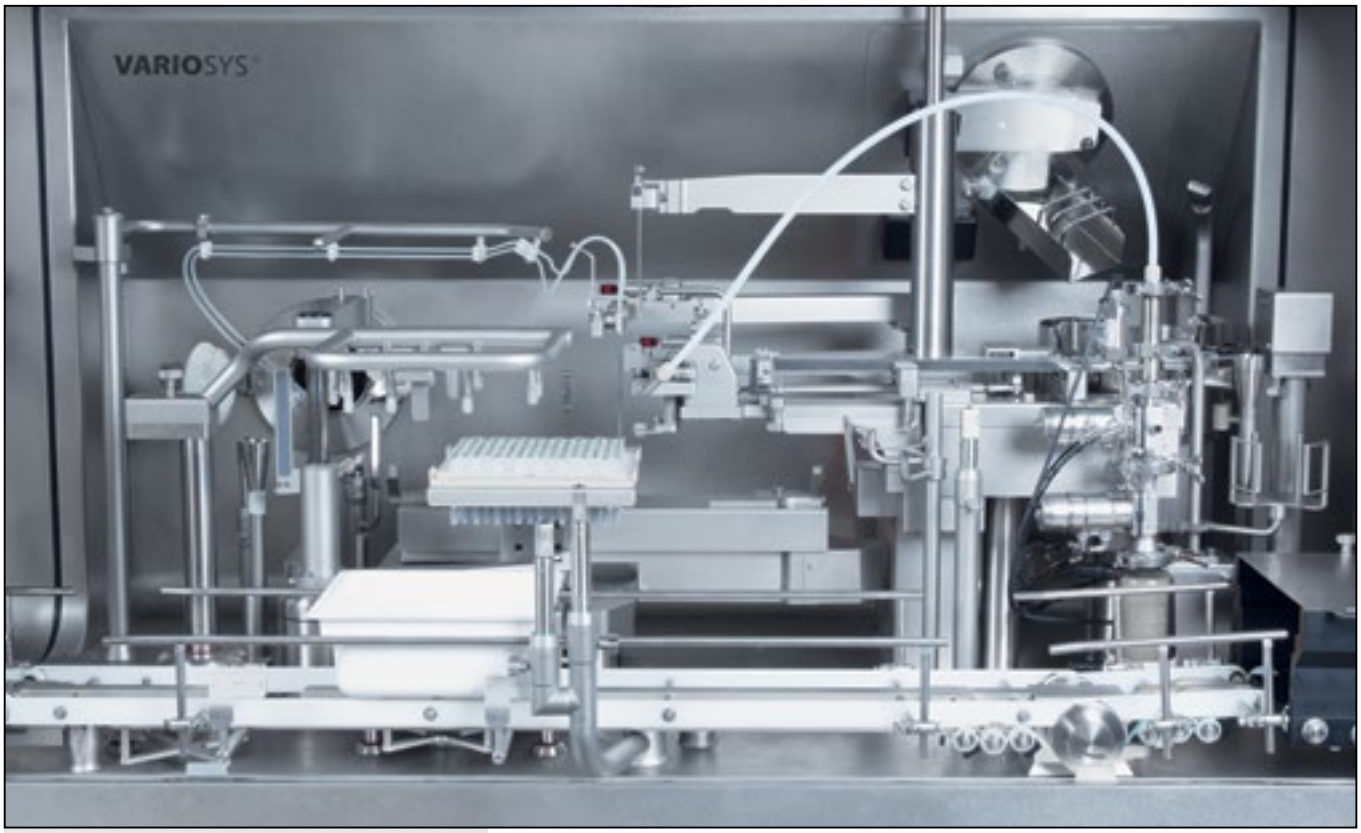
Fully automatic module for filling and closing RTU containers (syringes or cartridges with crimp caps) in the nest at an output of up to 4,300 containers/h.

Features:

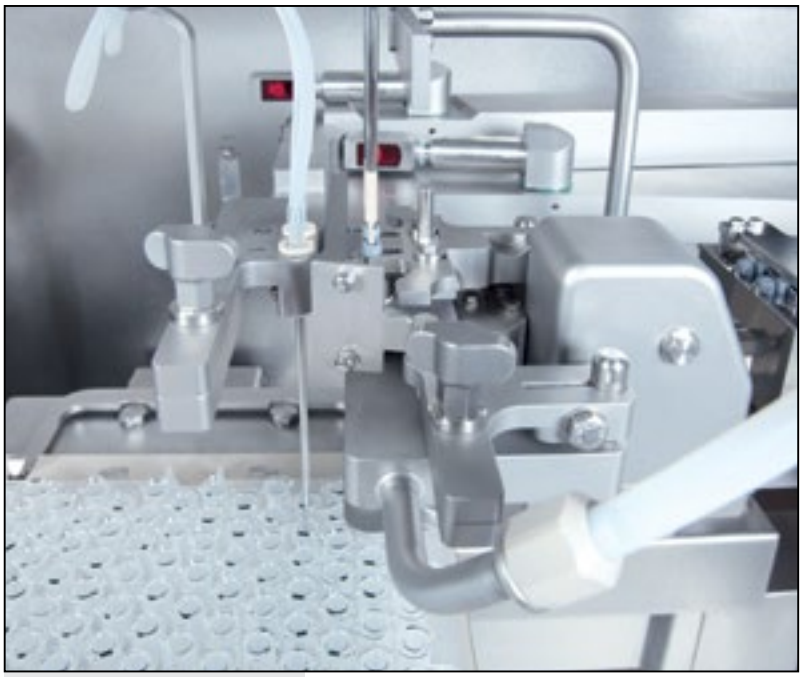
- Automatic nest handling
- Various dosing systems
- Vacuum-assisted dosing and closing of the containers
- In-process control 1 – 100 %
- Gas-flushing of the containers with a controlled amount of gas during filling and closing

SFM 5105

Technical Specifications	
Output/h	4,300
Dosing range	0.02 – 10 ml
Syringe size	0.5 – 10 ml
Cartridge size	1,8 – 3 ml



Fully automatic processing of RTU containers



Precise plunger placement

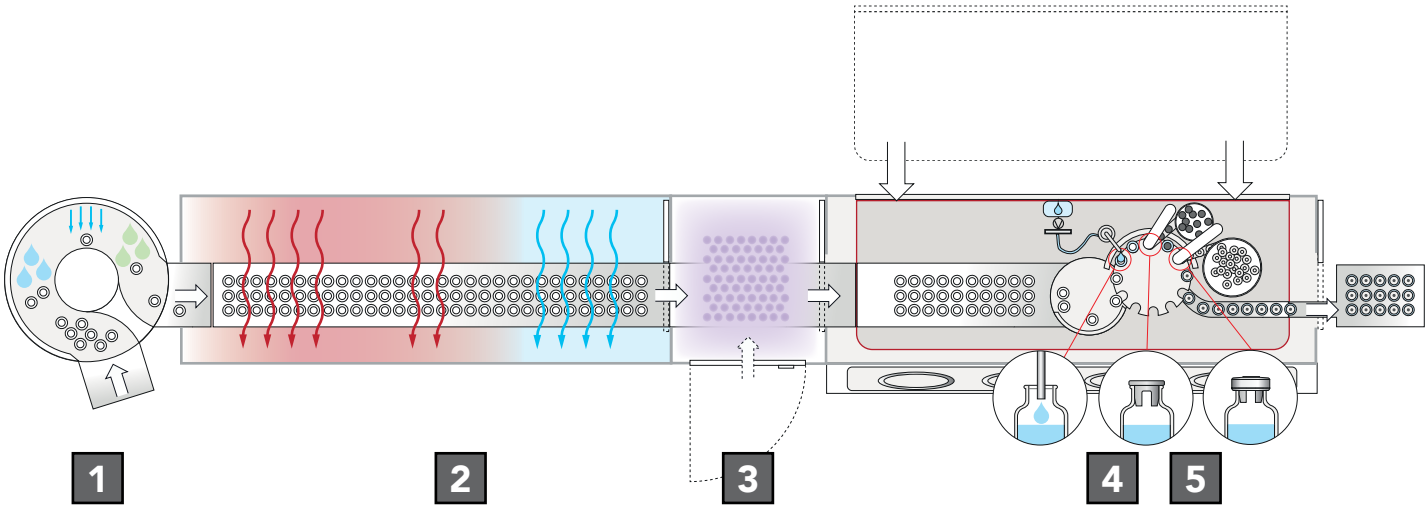
In-process control 1 – 100 %

Processing vials in bulk

VarioSys® reflects in its design the combined expertise and experience of our partners in the construction of machines for high-end pharmaceuticals production. The system is, as a result, an ideal solution for small-scale production runs with vials. Applications range from cleaning and sterilization, as well as gentle and precise dosing of liquid and powder products, to the closing of the containers.

1	Fully automatic cleaning machine for vials and bottles FAW 1005
2	Sterilizing tunnel DHT 2431
3	Quick decontamination SARA for material transfer
4	VarioSys® module KSF 5105 for filling and stoppering vials
5	Isolator PSI-L


skan


1
2
3
4
5

Module for filling and closing vials KSF 5105

Fully automatic module for filling and closing vials at an output of up to 3,600 containers/h.

Features:

- Various dosing systems for liquid and powder products with the ADVANDEDfill technology
- Gas flushing after filling and during closing
- 100 % in-process control at full speed
- Up to 2 closing stations – stoppers or similar inserts (e.g. press-fit caps), crimp caps
- Zero reject principle

KSF 5105

Technical Specifications	
Output/h	3,600
Dosing range (KSF 5105)	0.02 – 100 ml
Vial size	Ø 14.25 – 52 mm h 30 – 105 mm

ADVANCEDFILL

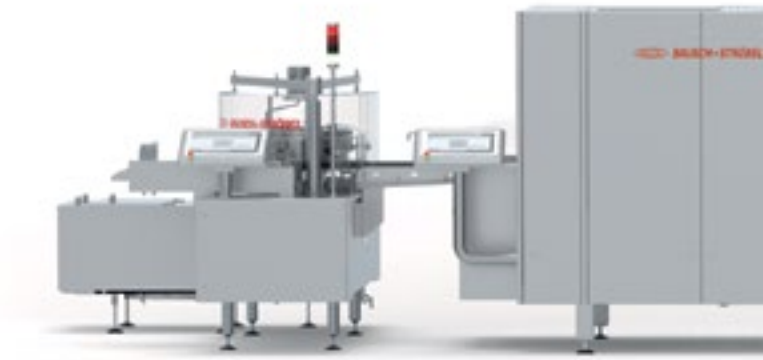
With this self-priming and run empty function without product loss, only the last container may need to be rejected.

Fully automatic vial filling and closing with press-fit caps

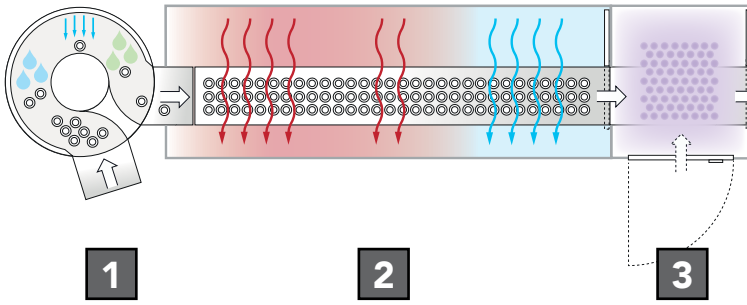
Filling and closing with stopper and crimp cap

Automatic vial processing with freeze drying

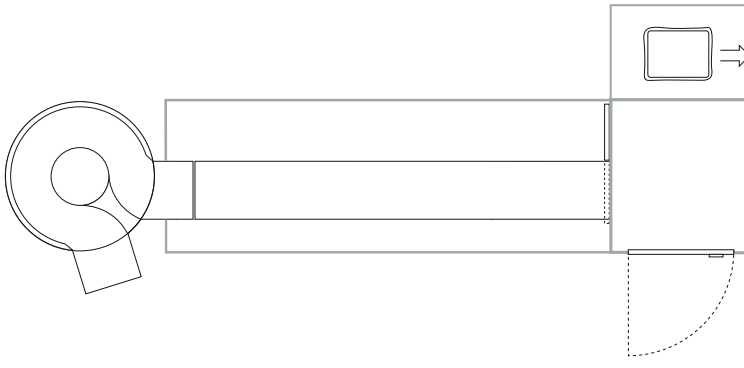
VarioSys® reflects in its design the combined expertise and experience of our partners in the construction of machines for high-end pharmaceuticals production. The system is, as a result, an ideal solution for small-scale production runs with vials and ampoules. Applications range from cleaning and sterilization, as well as gentle and precise dosing of liquid and powder products, to the closing of the containers. The concept also lends itself to processing complex and sensitive products such as bio-tech medicines.



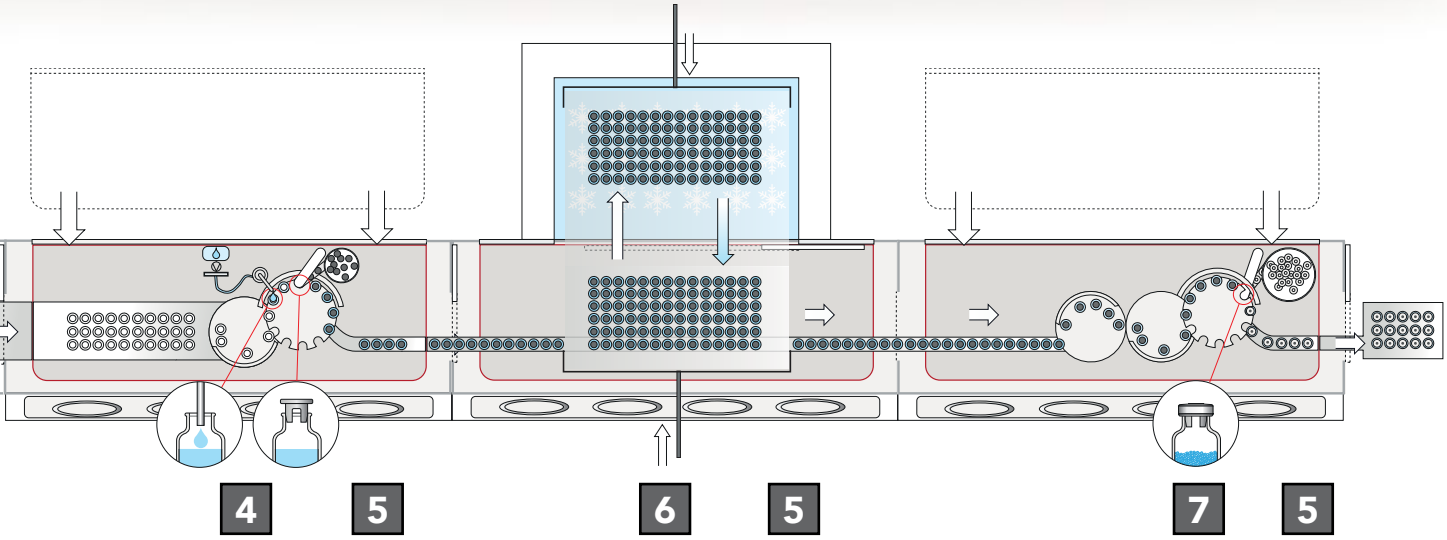
1	Fully automatic cleaning machine for vials and bottles FAW 1005
2	Sterilizing tunnel DHT 2431
3	Quick decontamination SARA for material transfer
4	VarioSys® module KSF 5105 for filling and stoppering vials
5	Isolator PSI-L
6	Freeze dryer for product lyophilization process
7	VarioSys® module KS 4105 for vial capping
8	Tub debagging TUM 9030
9	VarioSys® module DDM 9105 for removing lid and liner
10	VarioSys® module SFM 5105 for filling and closing RTU containers

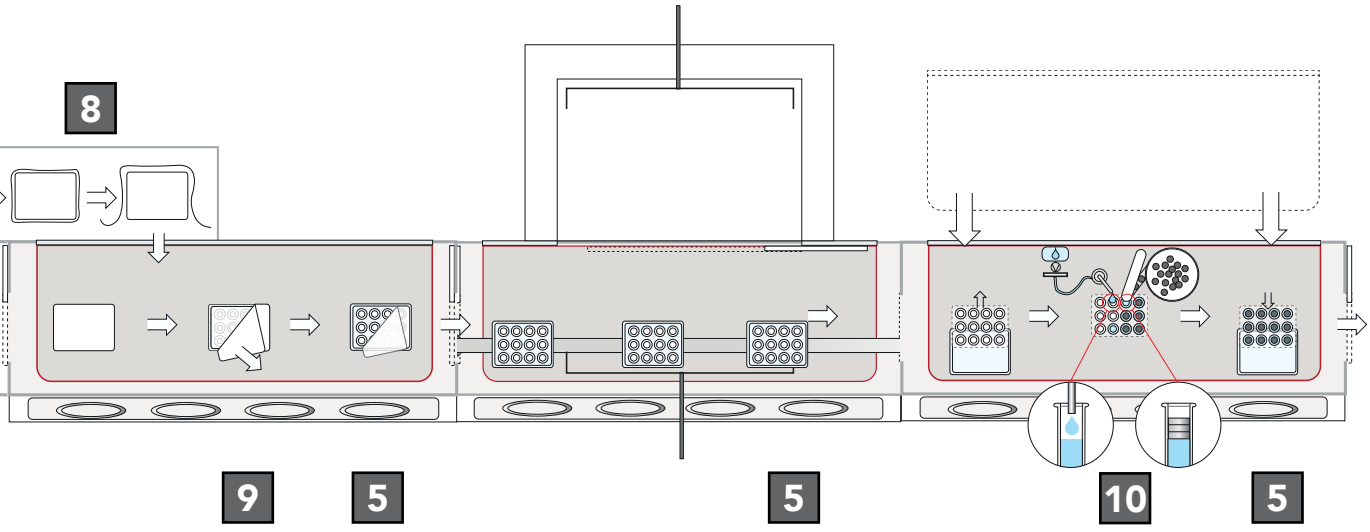


Easy change from bulk to nest processing




skan
GEA


4
5
6
5
7
5


8
9
5
5
10
5

Freeze dryer

If freeze drying is required, then the vials are transferred from the vial filler into the next isolator segment which contains a fully Automatic Loading and Unloading System ALUS™. Here the vials, without the frames, are fully automatically loaded into the freeze dryer. The bridge plate movement to dock onto the shelves, the shelf indexing and pizza door operation are all implemented in an automated sequence. When the freeze drying cycle is complete, the stoppered vials are then unloaded automatically and transferred into the following PSI-L isolator and onto the capper.

Ballroom design
The VarioSys® range of freeze dryers are available with a complete Grade C enclosure. You can walk right around the installation and never leave the cleanroom.

Features:

- Sizes to fit perfectly into the standardized isolator: FCM 75-I – 75 kg of ice capacity in 24 hours
- FCM 150-I – 150 kg of ice capacity in 24 hours (extended PSI-L)
- Compact footprint with a belly condenser design
- Grade C surround
- LYOSPARK™ controlled nucleation
- LYOPLUS™ mass spectrometer
- Potent/toxic product processing
- Redundancy of components
- Fast turnaround through defrost/CIP/SIP, also coordinated with the VHP cycle

Front view / Open door position

Shelf package

Technical Specifications:

FCM75-I 5+1 shelves @ 700 x 1350 mm 4.7 m² / 50 ft² Shelf interdistance = 120 mm		
Vial size	Diameter (mm)	Total vials
2/4R	16	20,039
6/8R	22	10,506
10/15R	24	8,802
20/30R	30	5,583
50R	40	3,094

FCM150-I 7+1 shelves @ 1050 x 1350 mm 9.9 m² / 106 ft² Shelf interdistance = 120 mm		
Vial size	Diameter (mm)	Total vials
2/4R	16	42,406
6/8R	22	22,295
10/15R	24	18,697
20/25/30R	30	11,900
50R	40	6,622

Module for closing vials KS 4105

Fully automatic module for closing vials at an output of up to 3,600 containers/h.

Features:

- Gas flushing during closing
- Stopper gap detection
- Closing station for crimp caps
- Check station „no container - no closure“
- Zero reject principle

Technical Specifications	
Output/h	3,600
Vial size	Ø 14.25 – 52 mm h 30 – 105 mm

KS 4105

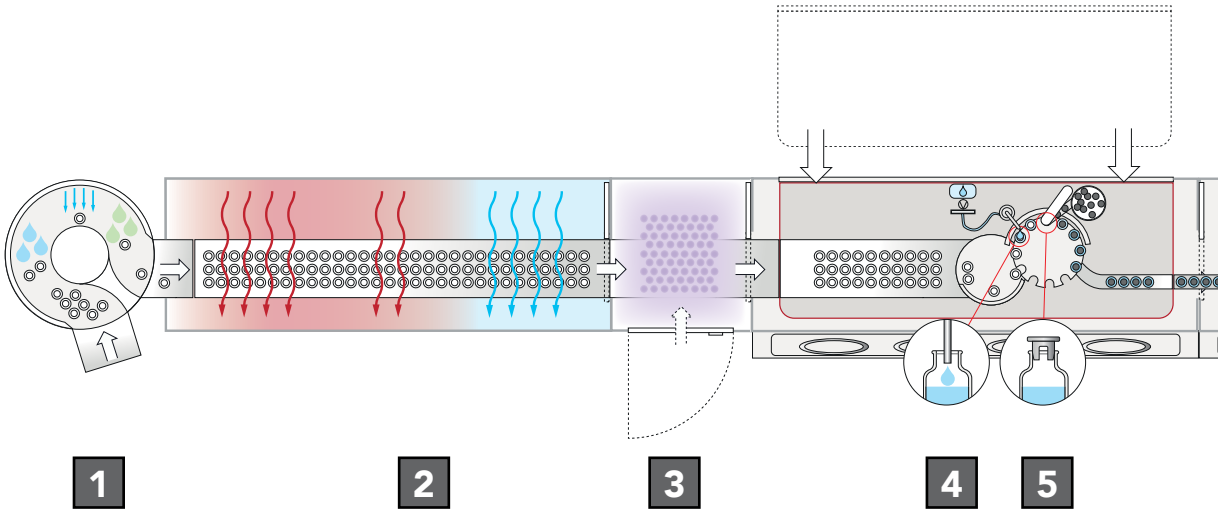
Fully automatic closing vials

Stopper gap detection

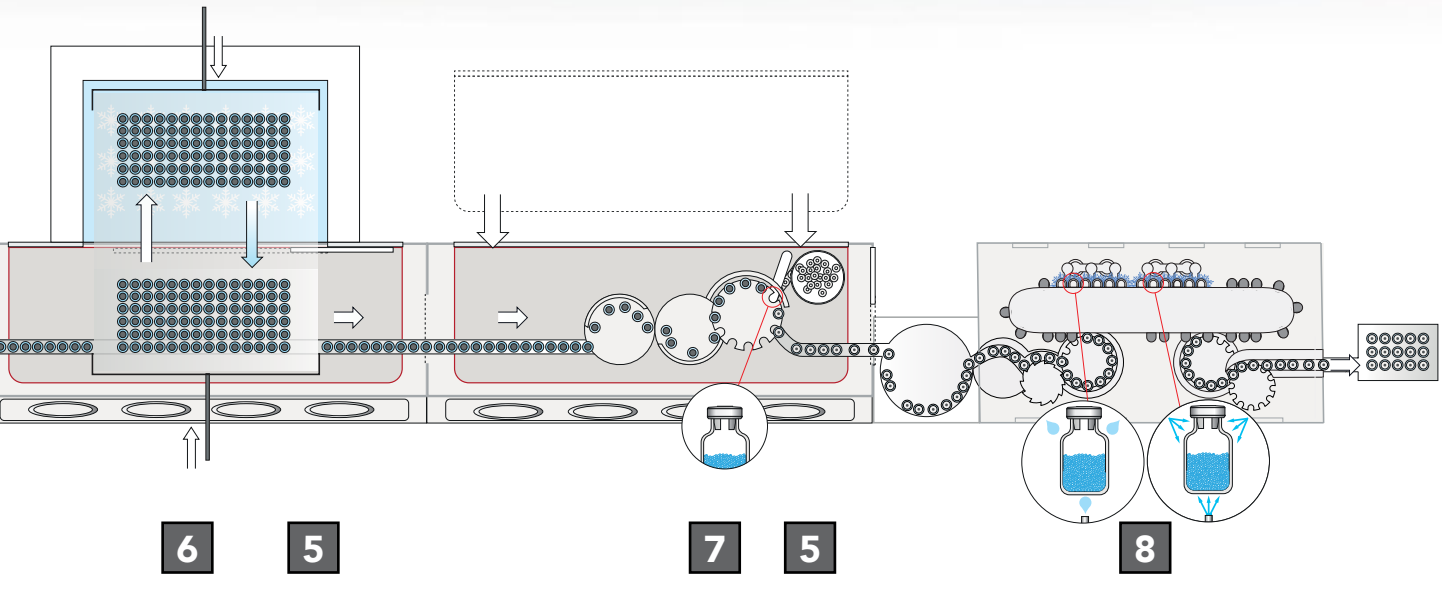
Closing station for crimp caps

Processing vials containing highly potent and toxic substances

VarioSys® was designed and developed drawing on the expertise and practical experience of all partners in the high-end production of drugs. This means that this system is also able to process toxic and/or highly active substances (OEB5/BSL2) safely and efficiently. VarioSys® modules can be used to build a complete production line with applications from cleaning and sterilization to the exact dosing of liquids and powders, freeze-drying, sealing and comprehensive external cleaning containers. VarioSys® includes a host of features to enhance operator and product safety.



1	Fully automatic cleaning machine for vials and bottles FAW 1005
2	Sterilizing tunnel DHT 2431
3	SARA rapid airlock for material transfer
4	VarioSys® module KSF 5105 for filling and closing vials
5	Isolator PSI-L
6	Freeze-dryer for product lyophilization
7	VarioSys® module KS 4105 for closing vials
8	External cleaning machine ARM 10600



External cleaning machine ARM 10600

The exterior cleaning and drying machine is designed for gentle and thorough cleaning of vials. This guarantees the safety of operators and users as well as trouble-free processing of filled and sealed containers.

Features:

- 360° cleaning thanks to special ring jets
- High-precision adjustment of cleaning parameters
- Low or high pressure cleaning
- Sealing or shielding of the crimp cap
- Integrated drying process
- Validated cleaning results
- Hygienic design
- Magnetic transport system
- Easy size changes

ARM 10600

360° cleaning thanks to special ring jets

Infeed and transfer to magnetic transport system

Discharge

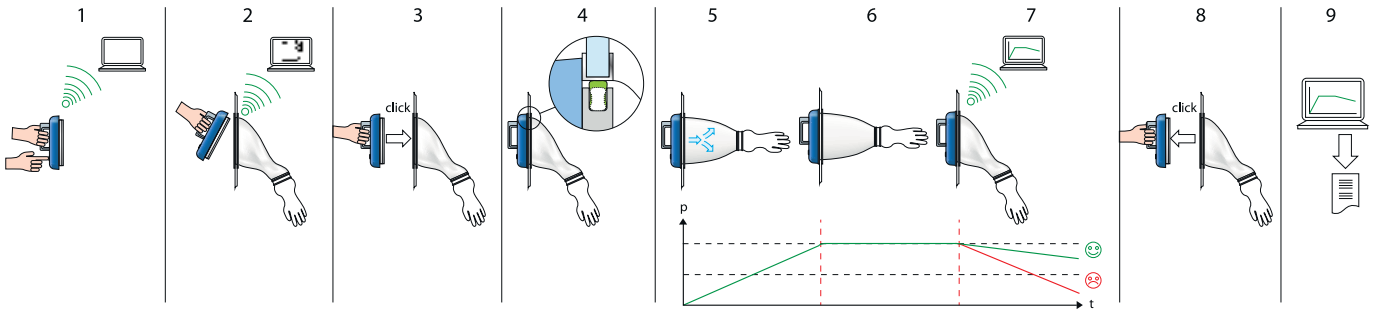
Basic L-flange

Flexible use of the empty flange

The L-flange can be supplied without fittings for flexible use or fully adapted for customer processes. The back wall, base frame and work bench can be fitted with laboratory equipment such as scales, incubators, mixers, sensors, piping, WFI and electrical connections. Large items of process equipment - such as vessels, RTP ports and hot air ovens - can be interfaced with pressure-tight flanges.

WirelessGT

WirelessGT is the most advanced and fully automated GAMP-compliant glove leak testing system with pressure decay measurement for isolators and RABS in the pharmaceutical industry. Operation is simple and fast, without tubes and wires. All the necessary functions for performing a reliable glove test are integrated in the battery-powered test cover. The test monitors the pressure loss of the glove/sleeve assembly over a defined period of time.

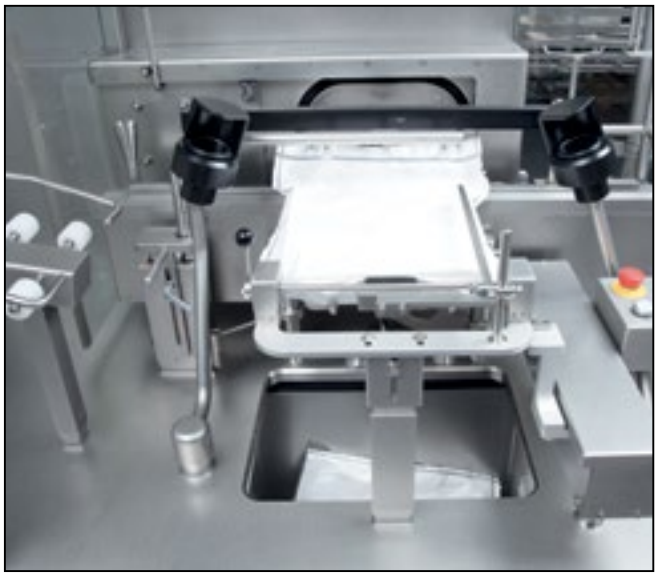


- Wireless transmission to PC
- Specific test recipes for different types of gloves
- Safe recognition of the tested glove port by RFID
- Detects holes larger than 100 µm
- Cleanroom compliant
- Test pressure up to 3000 Pa
- In situ testing without removal of the gloves
- Reduced turnaround time
- Reliable test results on a scientific basis

Tub/Tray handling (semi-automatic)

Debagging machines for tubs and trays TUM 9030 and TUM 90100

Built for absolute reliability and compliance with pharmaceutical industry standards, this system makes sterile and ready-to-fill nests available for further processing. The bags are opened inside the unit and the tubs are transferred through an airlock to the unit downstream without any direct contact.



TUM 9030 / TUM 90100

- Pharmaceutical transfer of tubs/trays
- Automatic bag opening and discharge of tubs/trays

Tub/Tray handling (manual)

Debagging machine for tubs and trays ATT 9000

The ATT opens the bags for the removal of tubs and trays in accordance with pharmaceutical standards. The tub or tray is debagged contactlessly and transferred to the machine downstream for further processing.

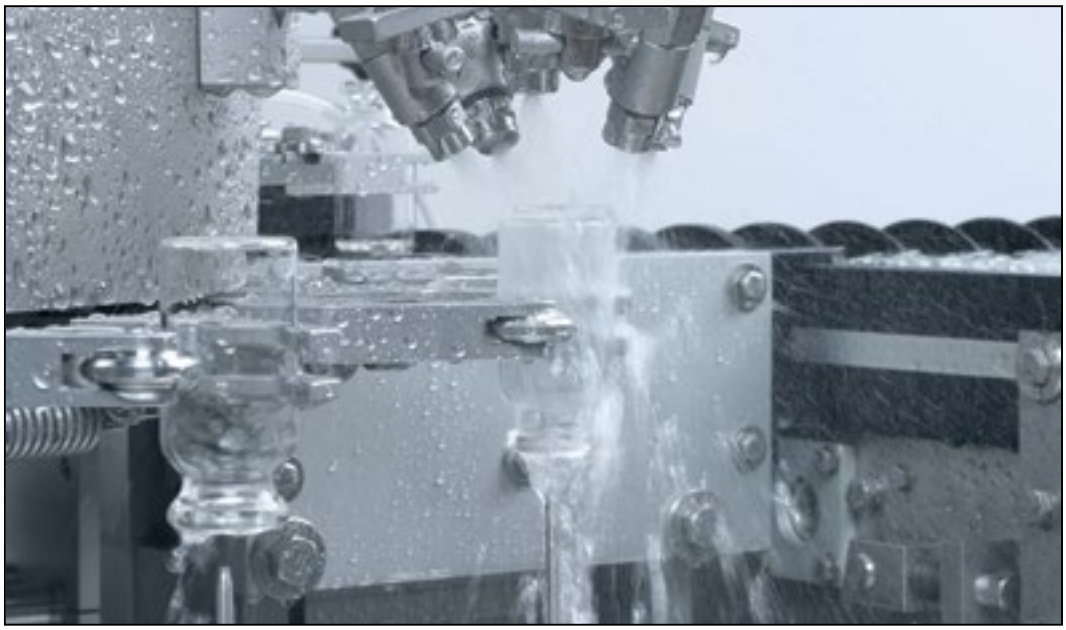
ATT 9000

- Pharmaceutical bag opening and discharge of tubs/trays
- Simple and safe mode of operation

Cleaning machine

Cleaning machine FAW 1005

The first step in the industrial processing of the containers for pharmaceutical purposes is to rinse the containers thoroughly. They can then proceed through further automated processing steps

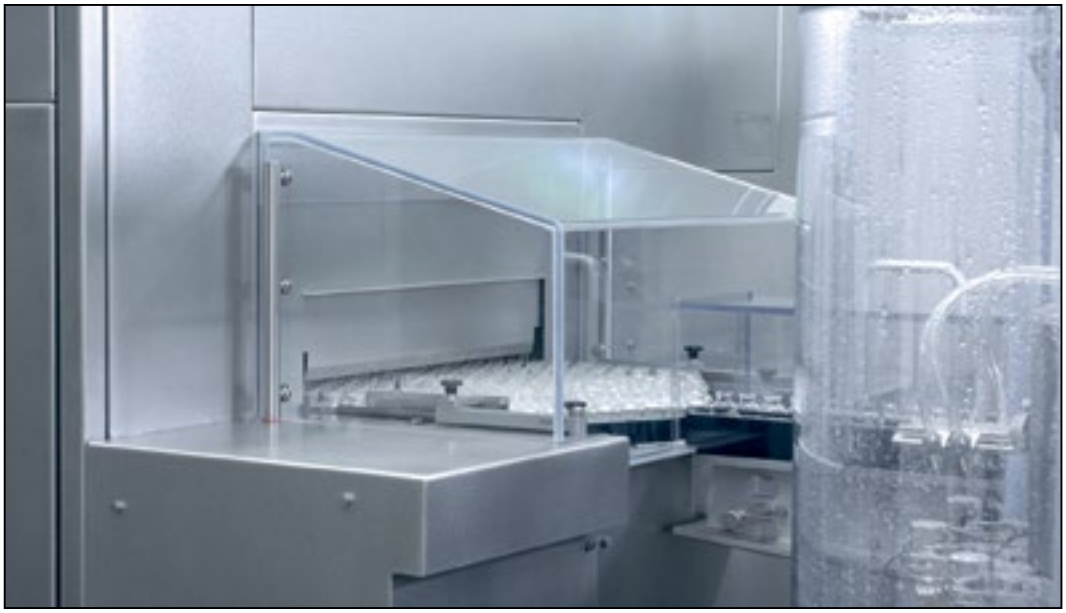


- **ECO**WASH
  an ideal and cost-efficient solution for cleaning containers of any type
- Washing inside and outside by intensive rinsing and spraying
- Blow-drying inside and outside
- Silicone coating of the inner glass wall
- Processing of vials

Sterilizing tunnel

Sterilizing tunnel DHT 2431

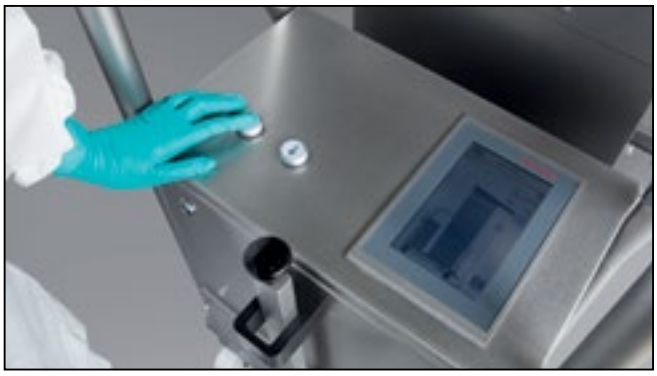
Sterile glass containers free of pyrogens are a prerequisite for industrial pharmaceutical production A low-turbulence vertical air flow is used for drying, sterilization and depyrogenation of glass containers. The controlled flow of ultra-pure air allows optimal heat transfer and temperature distribution.



- No seals are required for the HEPA filters
- B+S stainless steel filters
- High energy efficiency
- Processing vials

Sterile closure transfer BZV

The BZV 8110 hopper system automates the feeding of pre-sterilized components via a Rapid Transfer Port (RTP). The bin and feed unit is a portable system designed to store and supply ready-to-use or ready-to-sterilize component bags. It is automated by using a vibrating system to dispense the components into the bowls for processing. This prevents machine stoppages at the VarioSys® module due to a shortage of closures. The supply bin is mounted on an electrically controlled telescopic column which can be lowered for filling.

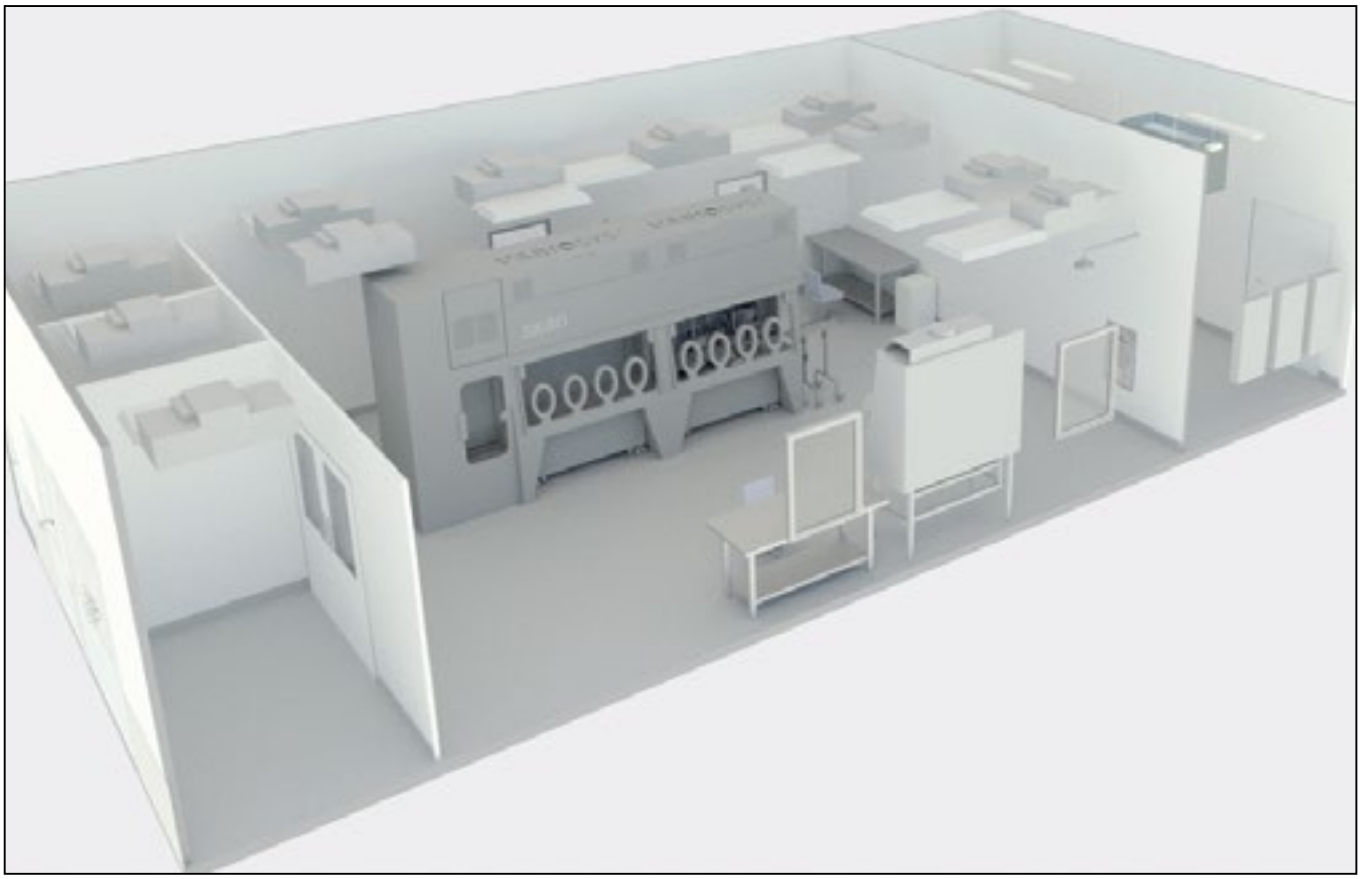


- No glove intervention with RTP with outside operation
- Highest process reliability with loading on demand
- Eliminates process risk of operator overfilling bowl
- Reduces number of operators (cost savings!)
- Fewer parts need to be sterilized
- Fully automatic closure bag unloading
- Electrical telescopic column for ergonomic handling
- Low particle generation for ISO 6/7 compliance
- Touch screen HMI with memory buttons
- Two BZV units cover all VarioSys® flexible filling line applications

Cleanroom

G-Con PODs®
Unique cleanroom infrastructures

The standard POD cleanroom unit is comprised of classified space (shown center), personnel and material airlocks (left) and a mechanical space (right). The mechanical space typically contains an air handling unit, the fire suppression system, and control/access points for utilities. Ductwork from the air handler to the clean space, integrated process piping, and fire suppression piping is contained inside the POD ceiling plenum for efficiency and compactness.



- Robust containment due to segregated air
- Clonable, facilitating duplicate installations
- Fast lead times, easily installed, relocatable

VarioSys® in the world –
Be the next one!

www.variosys.com

SKAN AG
Kreuzstrasse 5
4123 Allschwil
Switzerland
T +41 61 485 44 44
F +41 61 485 44 45
info@skan.com
www.skan.com

Bausch + Ströbel SE + Co. KG
Parkstraße 1
74532 Ilshofen
Germany
T +49 7904 701-0
F +49 7904 701-222
info@bausch-stroebel.de
www.bausch-stroebel.com

GEA Lyophil GmbH
Kalscheurenerstrasse 92
50354 Hürth
Germany
T +49 2233 6999 0
glde_empfang@gea.com
www.gea.com

Harro Höfliger Verpackungsmaschinen GmbH
Helmholtzstraße 4
71573 Allmersbach im Tal
Germany
T +49 7191 501 0
F +49 7191 501 5244
info@hoefliger.com
www.hoefliger.com

Please contact:

V1 / 2023_EN