



**Weiss Pharmatechnik GmbH**

## SCHUNK AT A GLANCE

- Ludwig Schunk
- Milestones
- Schunk in figures
- Schunk worldwide
- Awards



# Since our founding, we have been leading our markets technologically

## Starting points of our business units

1913

Foundation of Schunk & Ebe  
with production of carbon  
brushes  
*BU Industry*



1932

Sintered bearing production  
*BU Sinter Metals*



1970

Supplier for the  
semiconductor industry  
*BU Microelectronics*



1985

Entry into technical ceramics  
*BU Technical Ceramics*



2018

Entry into optical machines  
*BU OptoTech*



1928

Entry into automotive  
industry  
*BU Mobility Carbon*



1933

Production of carbon  
sliding strips  
*BU Transit Systems*



1978

Entry into environmental simulation and  
air conditioning technology  
*BU Environmental Simulation*  
*BU Air Solutions*



1990

Entry into ultrasonic welding  
*BU Sonosystems*



**26** COUNTRIES

**67** LOCATIONS

**9.000** EMPLOYEES



## WEISS PHARMATECHNIK

- Containment
- Stability Testing
- Service



- **1979:** Foundation of **GWE GmbH**  
Company for water treatment and energy recovery in Hude.
- Managing director and company founder Manfred Wiechmann and technical manager Wolfgang Bornhold jointly develop the WIBO systems
- **2001:** Purchase by Weiss Klimatechnik GmbH, Reiskirchen (100% subsidiary)  
Renaming to **Weiss GWE GmbH**. Since then, affiliation to the Weiss Group of the Schunk Group of Companies, Heuchelheim.
- **2015:** Merger of Weiss GWE GmbH with the sister company BDK Luft- und Reinraumtechnik GmbH in Sonnenbühl-Genkingen, Baden-Württemberg.  
Renaming to **Weiss Pharmatechnik GmbH**
- **2018:** Move to Oldenburg in the industrial area Tweelbäke



## Pharmatechnik locations



WEISS PHARMATECHNIK, OLDENBURG



WEISS TECHNIK, LINDENSTRUTH



WEISS TECHNIK, BALINGEN



WEISS TECHNIK, MARTILLAC AT BORDEAUX

# Oldenburg in Lower Saxony

## Production location Containment



# Reiskirchen-Lindenstruth in Hessen

## Production location special systems and walk-in climatic chambers



# Balingen in Baden-Württemberg

## Production location for standard equipment climatic test chambers



# Martillac at Bordeaux in France

## Production location for standard equipment stability test chambers



## STABILITY TESTING

- Standard Test Chambers –
- Walk-in climate chambers –
- Test Container –



## CONTAINMENT

- Isolators
- High Containment
- Safety Cabinet



## COMPLETE SOLUTION FOR THE PHARMACEUTICAL INDUSTRY

Consulting, Project planning, Standard and special solutions

Production, Assembly and Commissioning

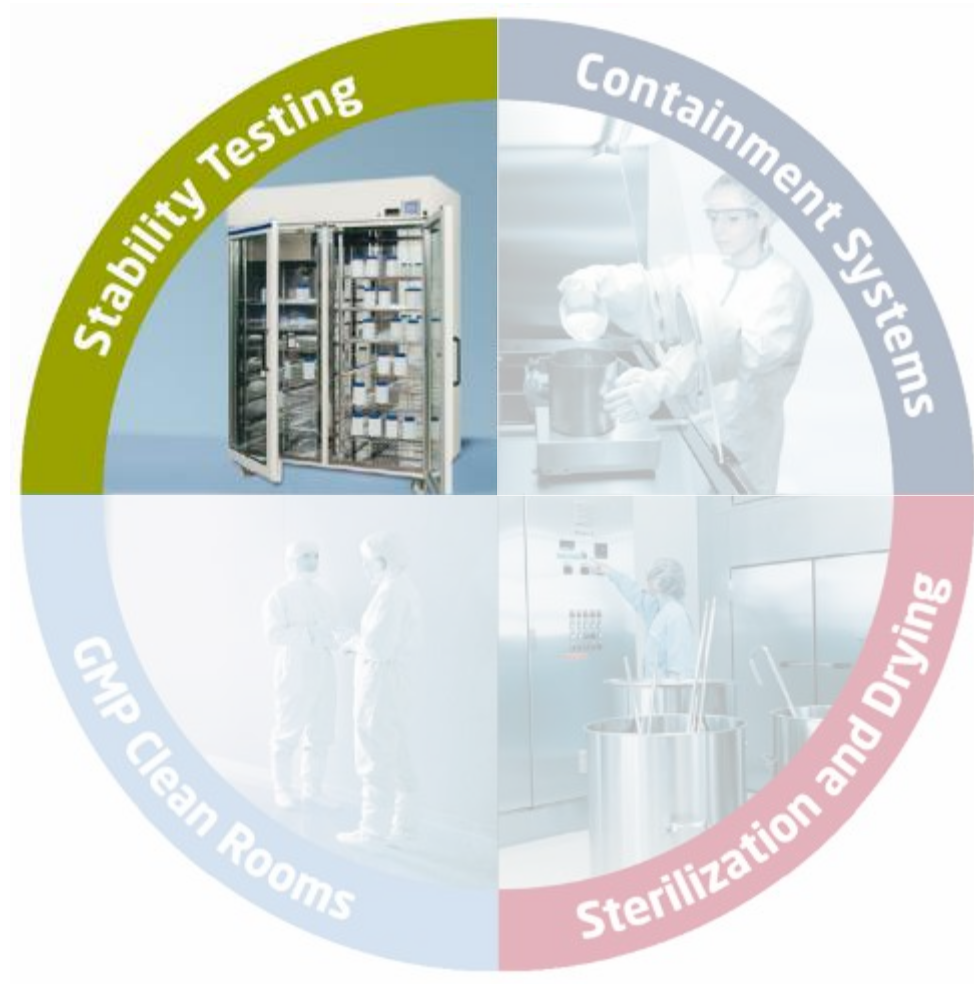
Documentation und Qualification

Calibration, Maintenance and Service

RetroFit and Modifications

Training





## Climate and stability tests

Safe. Compliant. PharmaEvent.

Test chambers from 34 to 2,000 l to walk-in stability test chambers from 10 to 300 m³ for optimal long-term testing. We offer a complete package with:

- Monitoring, documentation, qualification and training options.
- Comprehensive services including DAkkS calibration by Weiss Technik.



### Highlights

- ✓ Safe stability testing according to ICH guidelines Q1A or Q1B
- ✓ Documentation options according to FDA 21 CFR Part 11 and EU GMP Annex 11
- ✓ Monitoring and control S!MPAC® with 7" multi-user interface WEBSeason® and Audit Trail

## Stability Test Chamber PharmaEvent

Test technology you can rely on.

Stability tests according to ICH guideline Q1A



ICH-GUIDELINE Q1A  
FDA 21 CFR PART 11  
EU GMP ANNEX 11



### Highlights

- ✓ Climate storage at constant climate or climate cycles
- ✓ Stress tests and transport simulations
- ✓ Temperature range +2 to +70 °C
- ✓ Humidity range 20 to 90 % r.H.
- ✓ Available in the following sizes:  
280 l, 600 l, 1.300 l, 2.000 l

## Photostability Test Chamber PharmaEvent

Photostability test in less than 100 hours

Photostability Test according to ICH guideline Q1B



ICH GUIDELINE Q1B  
FDA 21 CFR PART 11  
EU GMP ANNEX 11



### Highlights

- ✓ Ideal distribution of light, UV, temperature and humidity
- ✓ Homogeneous irradiation due to special light and UV filter system
- ✓ Temperature range +10 to +50 °C  
(+5 to +50 °C for 250 l)
- ✓ Humidity range 20 to 90 % R.H.
- ✓ Light intensity up to 25000 Lux
- ✓ Available in the following sizes: 250 l und 500 l

## Walk-In Stability Test Chambers PharmaEvent

Customer-specific solutions.

Stability tests according to ICH guideline Q1A



ICH GUIDELINE Q1A  
FDA 21 CFR PART 11  
EU GMP ANNEX 11



### Highlights

- ✓ Temperature range +20 to +45 °C
- ✓ Humidity range 20 to 80 % R.H.
- ✓ Test sample protection, tmin./tmax.
- ✓ Protection against excessive humidity
- ✓ Qualification documentation according to GAMP
- ✓ Alarm system according to GAMP
- ✓ Test room door with multiple glazed observation window and emergency opening device
- ✓ The test room volumes range from 10 to 1.000 m<sup>3</sup>

## Mobile Stability Test Container PharmaEvent

Safe storage – reliable testing.

Stability tests according to ICH guideline Q1A



ICH GUIDELINE Q1A  
FDA 21 CFR PART 11  
EU GMP ANNEX 11



### Highlights

- ✓ Flexible and safe solution for drug testing
- ✓ Plug-and-play: only footprint and power connection required
- ✓ Temperature range +20 to +45 °C
- ✓ Humidity range 20 to 80 % R.H.
- ✓ Test product protection, tmin./tmax.
- ✓ Protection against excessive humidity
- ✓ Qualification documentation according to GAMP
- ✓ Alarm management according to GAMP risk analysis
- ✓ Test chamber door with multiple glazed observation window and emergency opening device
- ✓ Available with test chamber volumes of 18 and 47 m<sup>3</sup>



## Rental Units – PharmaEvent

Expand your capacities at short notice!

As a globally operating group of companies, weisstechnik has an extensive equipment pool of stock and rental equipment.



### Highlights

- ✓ The PharmaEvent stability testing systems are also available as rental equipment
- ✓ Optional financing through installment plan
- ✓ Latest testing technology at manageable monthly rental costs
- ✓ Flexible and economical solution

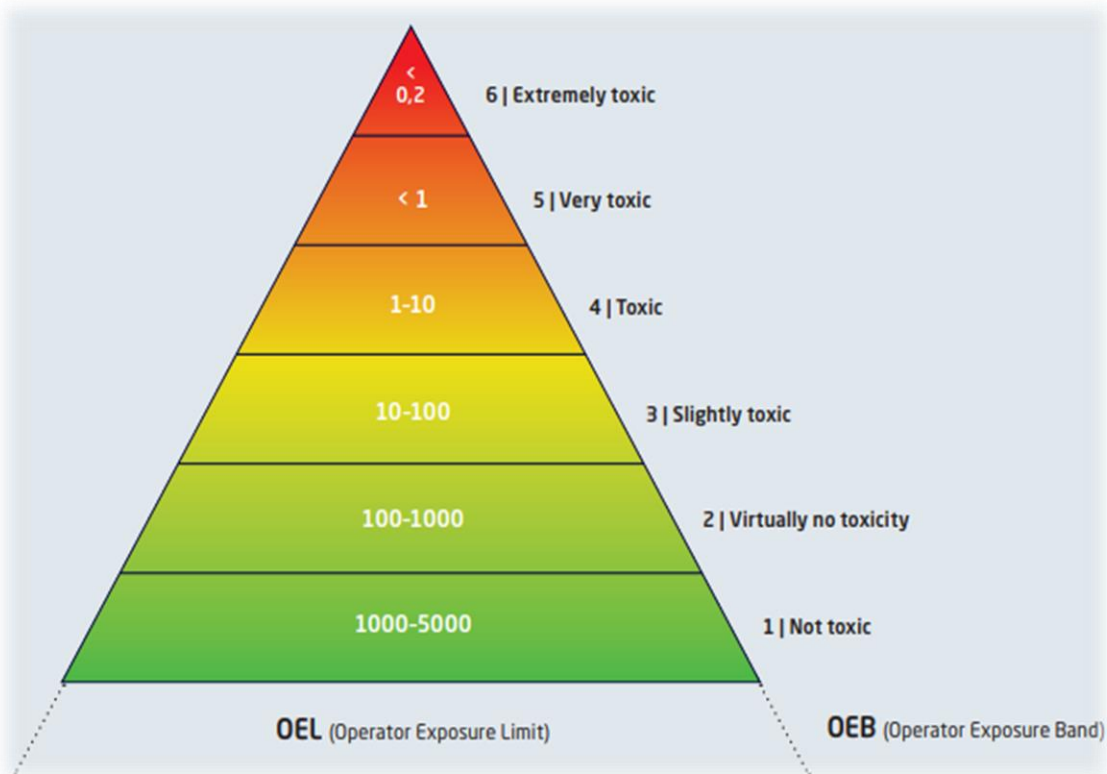
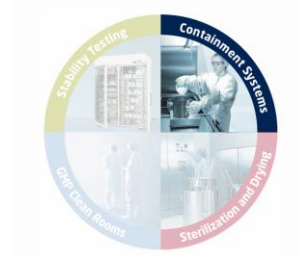


## OUR SOLUTIONS

- Isolators
- Weighing and sampling units
- Cleanrooms systems
- Personnel protection workplaces
- Chemical refilling workplaces
- Laminar-Flow workbenches
- Microbiological safety workbenches
- Material and personnel air locks

## Containment Classification

Highest safety for personnel and products.



OEB 1 - 6



### Highlights

- ✓ **OEL – Operator Exposure Limit** describes the average concentration of the active substance in  $\mu\text{g}/\text{m}^3$  within the breathing zone of the operating personnel over a period of eight hours.
- ✓ **OEB – Operator Exposure Band** characterizes the extent of the toxicity of the substance on a containment scale from 1 to 6.

## Product overview

Highest safety for personnel and products.



**WIBO® Safe Isolators**



**WIBObarrier® Safety Workplaces**



**WIBOjekt® Safety Workplaces**



**Laminar-Flow Systems, BSC**



**WIBOclean® Lock systems, House in House**



## WIBO® Safe Isolators

Highest safety for personnel and products.



OEB 5



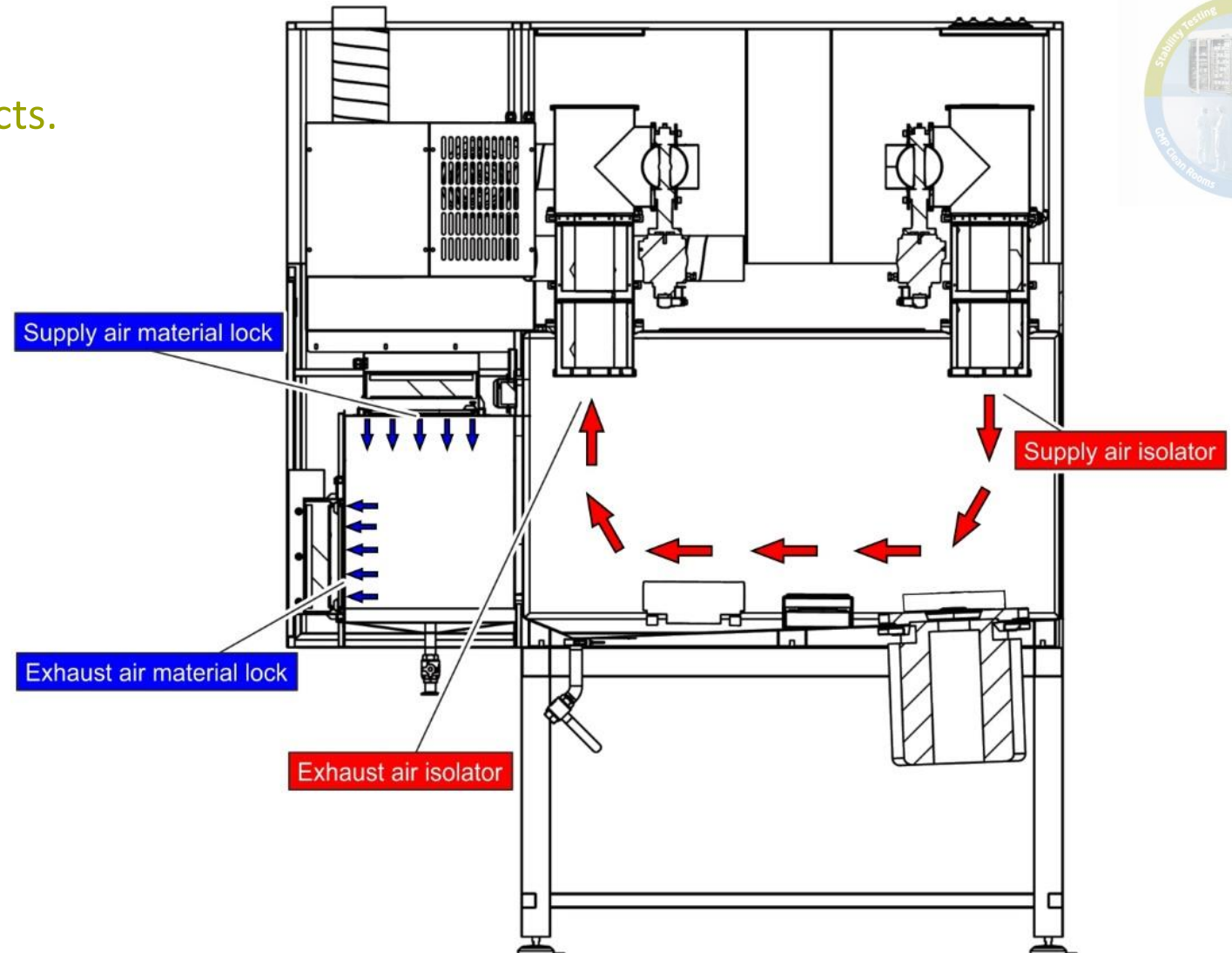
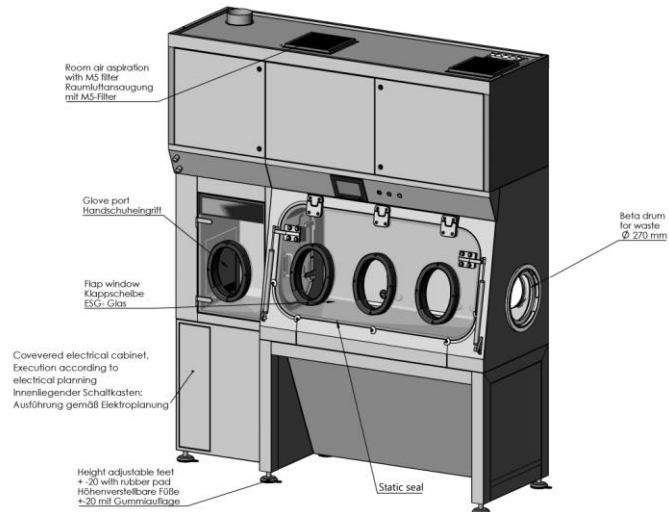
### Highlights

- ✓ Applications: Dispensing, weighing and sampling of pharmaceutical substances
- ✓ Customized solutions for research, development, laboratory and production
- ✓ Highest safety when handling critical substances up to OEB level 5
- ✓ Primary protection: personal and room protection
- ✓ Self-sufficient supply and exhaust air system
- ✓ Optional: Integration of WIP\*/CIP\*\* systems and H<sub>2</sub>O<sub>2</sub> decontamination

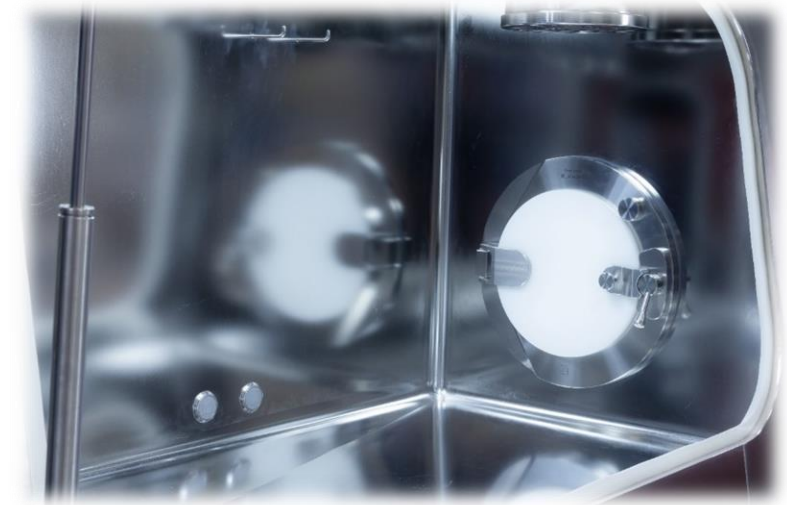
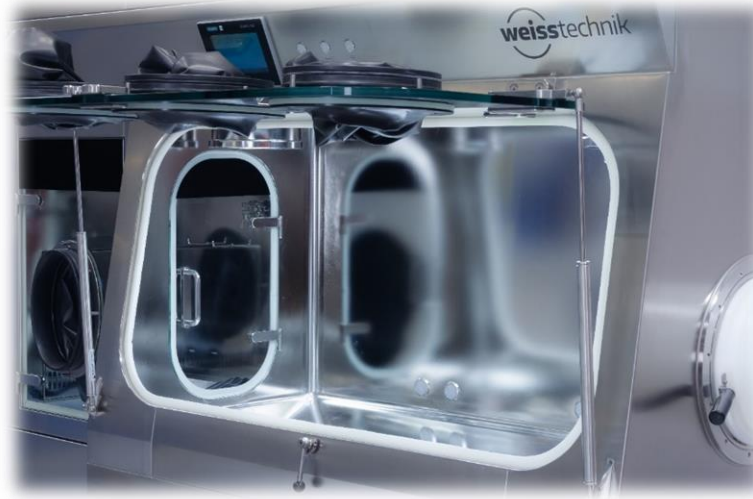
## WIBO® Safe Isolators

Highest safety for personnel and products.

P&ID



## WIBO® Safe Isolators

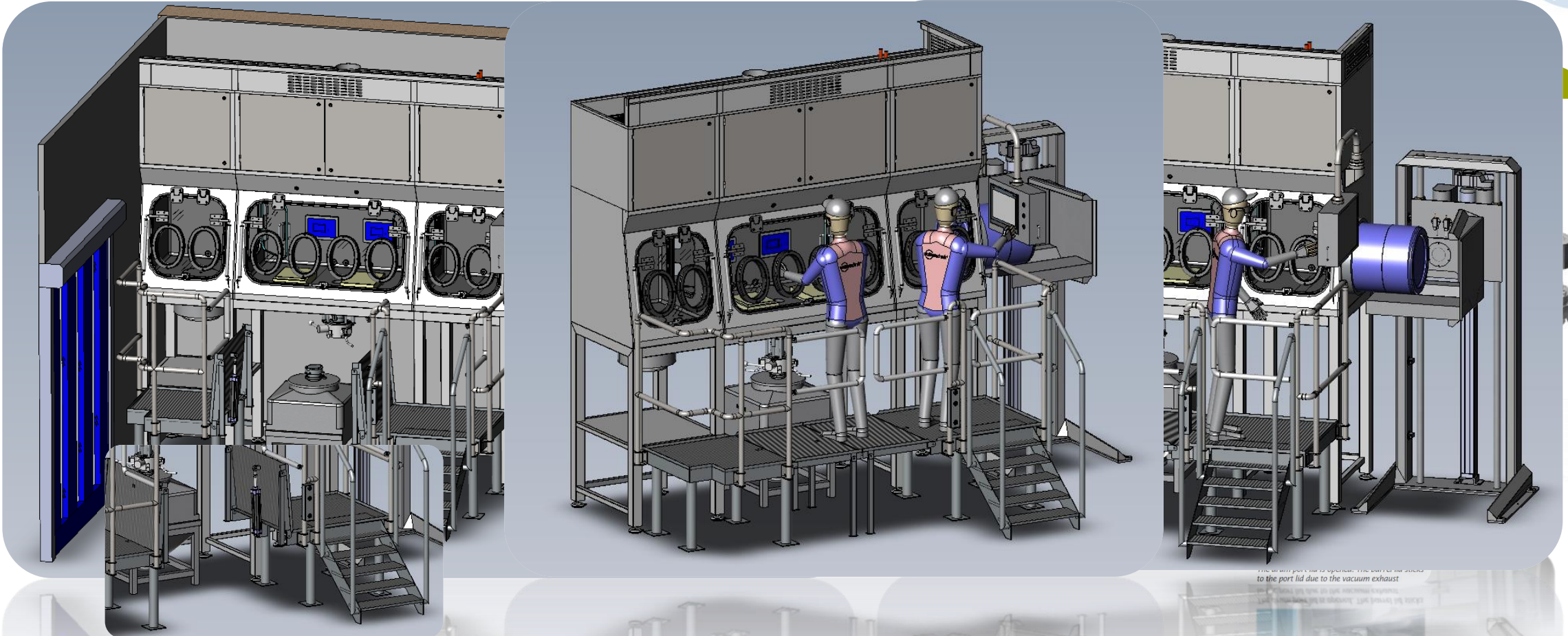


**Material Inside AISI 316L / 1.4404**  
**Surface treatment: Electro polished**  
**Optional: Mirror polished**

## WIBO® Safe Isolators

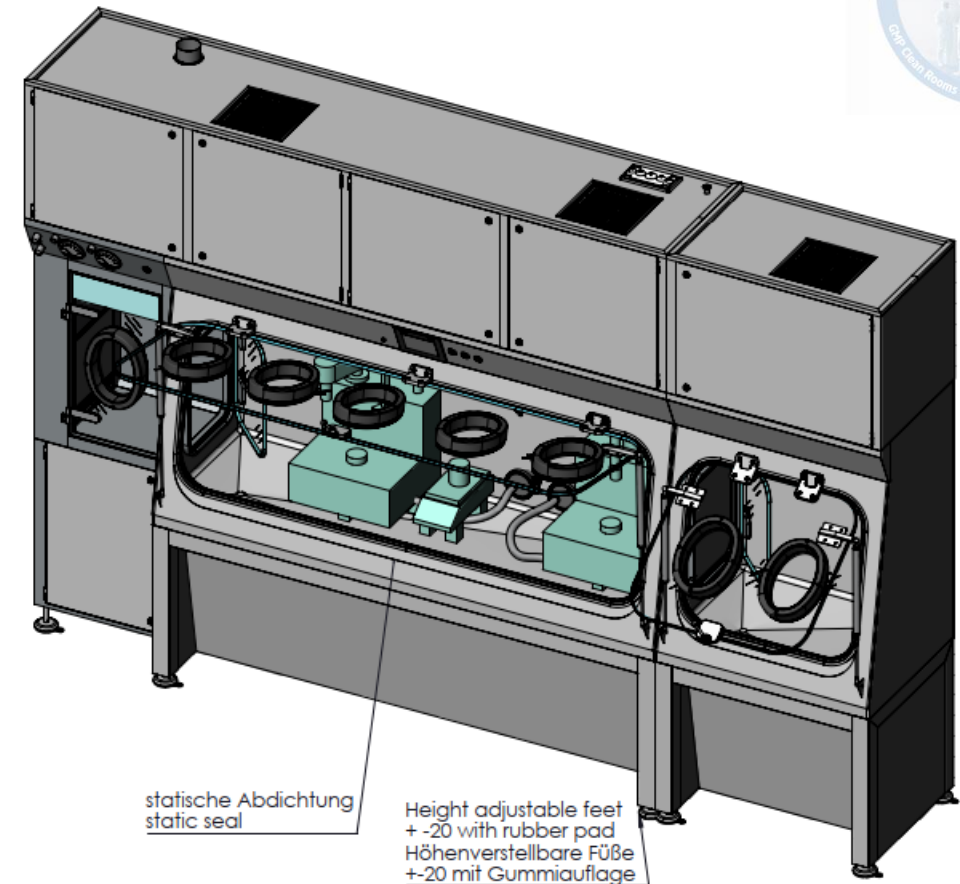
Highest safety for personnel and products.

Material handling by  
a lifting and tilting  
device incl. WIBO-  
Drum-Port System



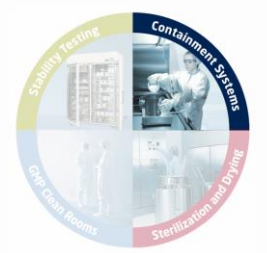
## WIBO® Safe Isolators for aseptic processing

Customized solutions.



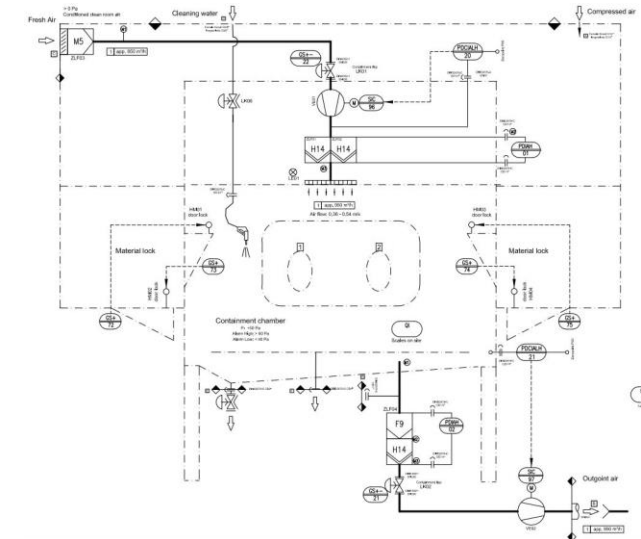
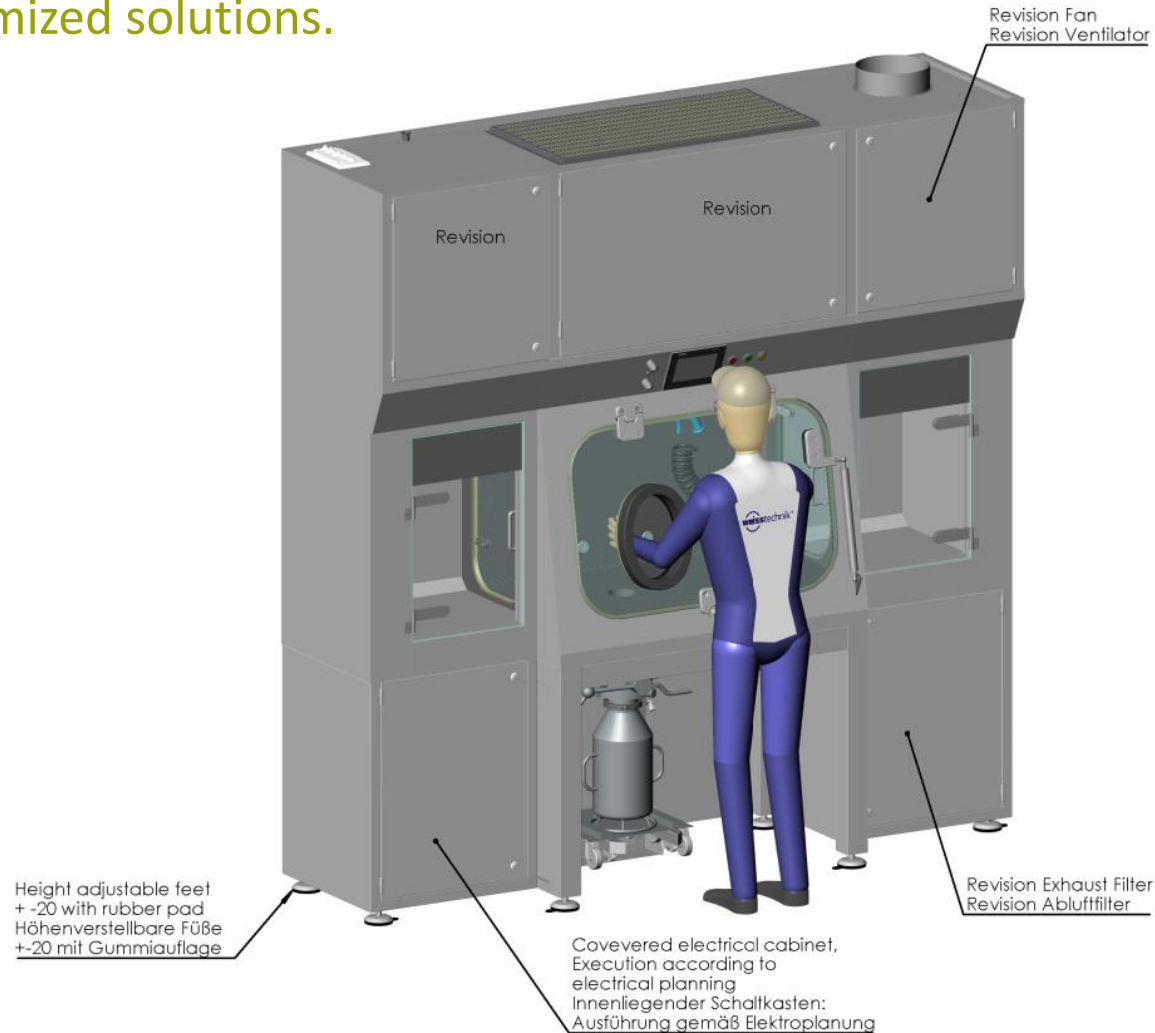
statische Abdichtung  
static seal

Height adjustable feet  
+ -20 with rubber pad  
Höhenverstellbare Füße  
+ -20 mit Gummiauflage



## WIBO® Safe Isolators for aseptic processing

Customized solutions.



## WIBO® Safe Isolators + Climate Chamber

Conditioning highly toxic APIs under clean room conditions.



OEB 5



### Highlights

- ✓ Reproducible production conditions in the climate chamber
- ✓ Closed containment system
- ✓ Climate chamber and periphery in the technical area
- ✓ Access from the protected area of the isolator
- ✓ CIP for isolator and climate chamber
- ✓ Jacket temperature control to prevent condensation
- ✓ Contamination-free filter change in the isolator (push push)
- ✓ BIBO (Bag in-Bag out)
- ✓ EU GMP and FDA compliant

## WIBObarrier® Safety Workbenches

ISO 5 purity class in the product area.

Safe product, personal and room protection.

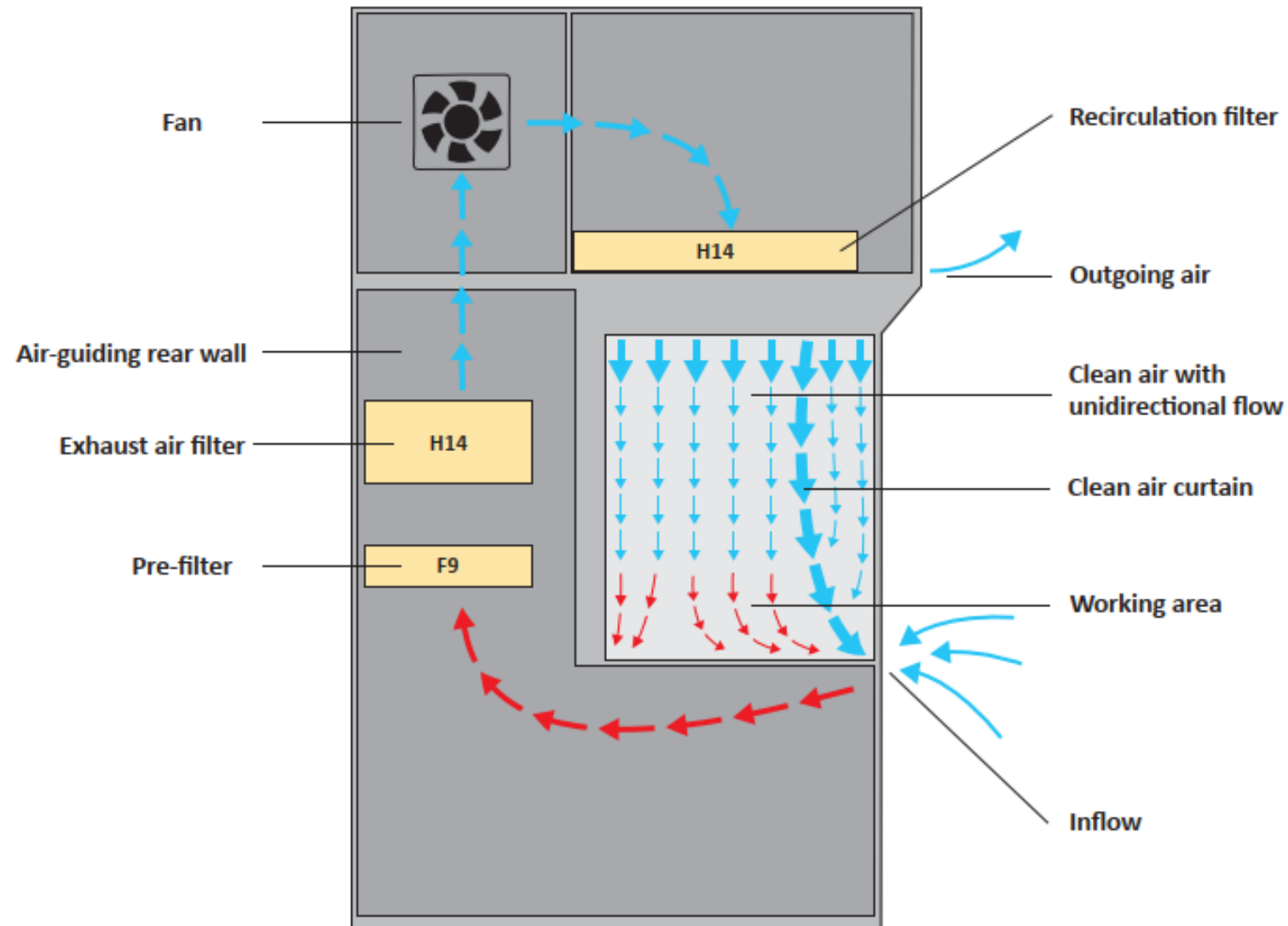


OEB 1 - 5



### Highlights

- ✓ Product protection of purity class ISO 5 according to ISO 14644-1
- ✓ Robust retention capacity according to ISPE-SMEPAC
- ✓ 3-zone-principle by separating WIBObarrier® clean air curtain
- ✓ Customized design, as open system up to closed containment system in isolator quality
- ✓ GMP-compliant, easy to clean



## WIBObarrier® Safety Workbenches

One system. Three solutions.



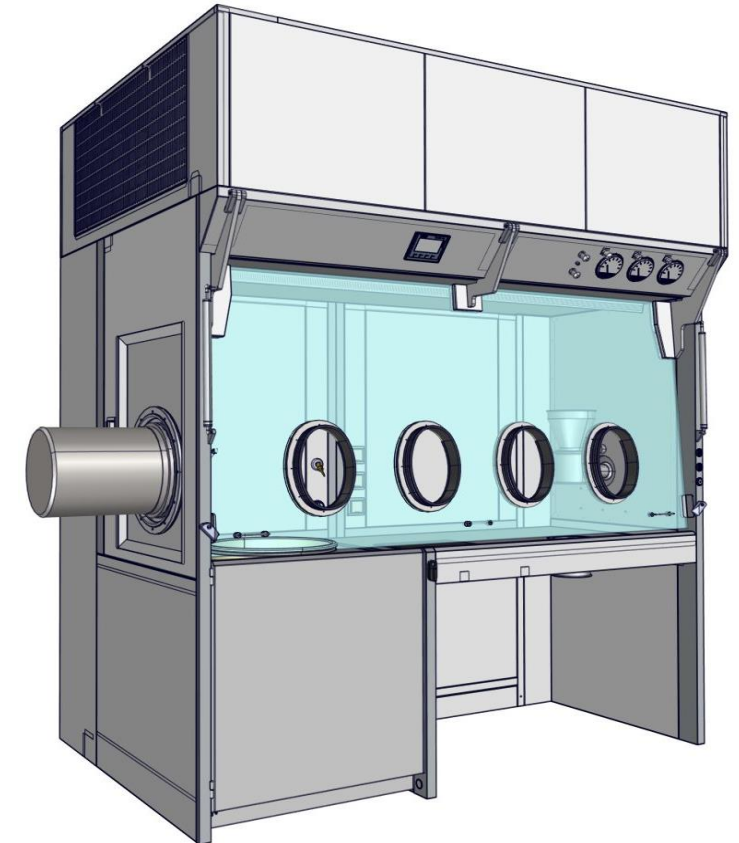
OEB 3

Open Containment System (OCS)

Open Containment System with  
sliding pane (OCS<sup>+</sup>)



OEB 4



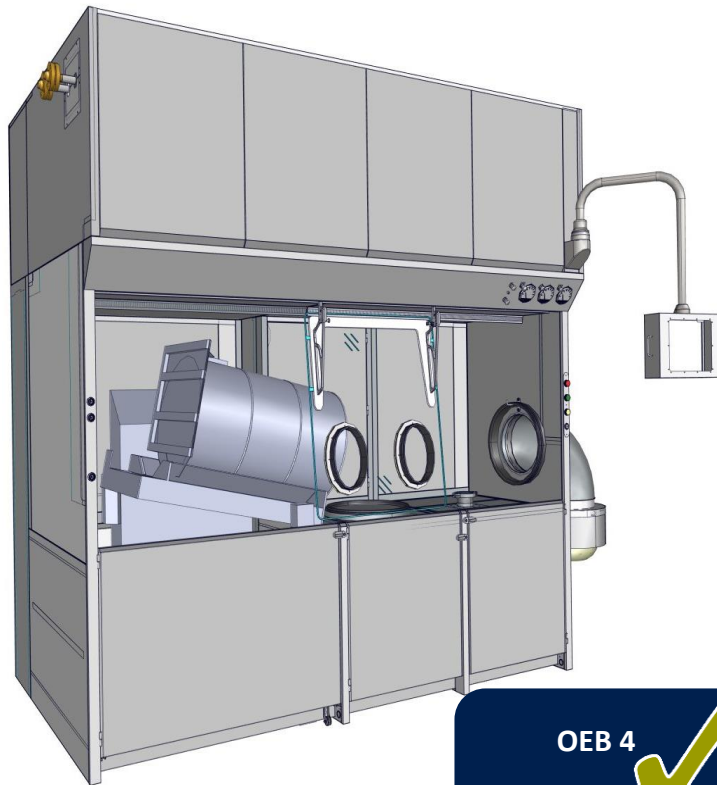
Closed Containment System (CCS)

OEB 5

## WIBObarrier® Safety Workplaces

Customized solutions.

WIBObarrier® CCS Transfer  
workstation for APIs with WIBO Drum  
Port



OEB 4

WIBObarrier® OCS<sup>+</sup> with  
integrated lifting device

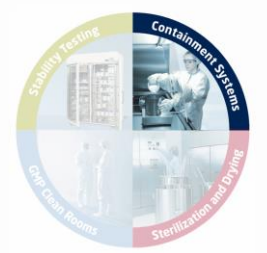


OEB 5

WIBObarrier® CCS  
Weighing workstation

## WIBObarrier® Safety Workplaces

Customized solutions.



OEB 4 - 5



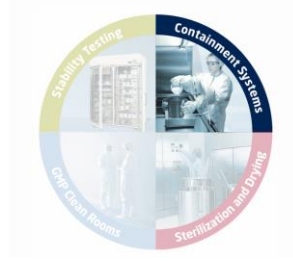
WIBObarrier® Lab Containment as open and closed system, with integrated laboratory equipment and mobile worktable

## WIBObarrier® Safety Workplaces

Customized solutions.



Refilling Station for half-automated (re-)filling of pharmaceutical substances up to OEB5



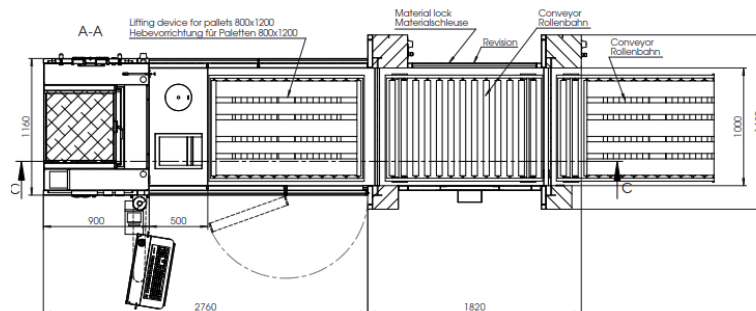
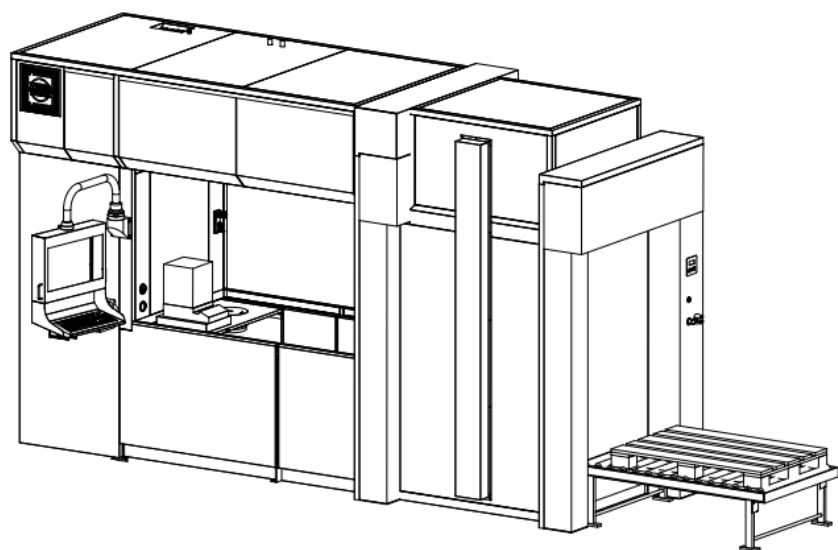
OEB 5

### Highlights

- ✓ For personnel and product protection
- ✓ Powder transfer system by vacuum conveyance
- ✓ Docked container station
- ✓ Filling via GMP-complaint double valve system
- ✓ Material air lock with roller conveyor system

## WIBObarrier® Safety Workplaces

Customized solutions.



## WIBObarrier® Flow Free Workstation

Optimal free space - with safety.

Reliable personal and product protection with free accessibility in the product area.



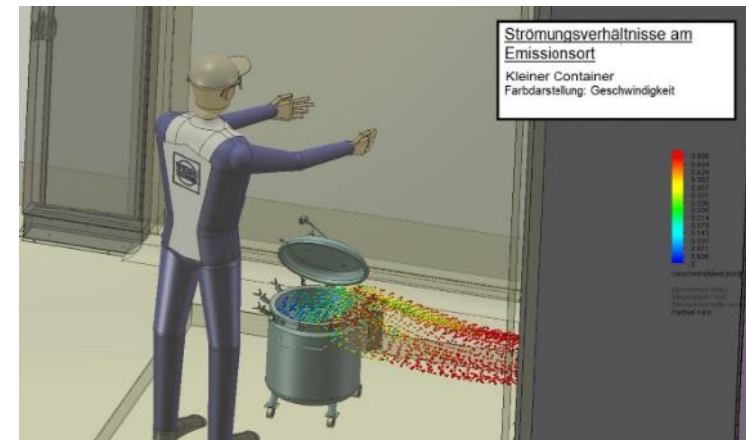
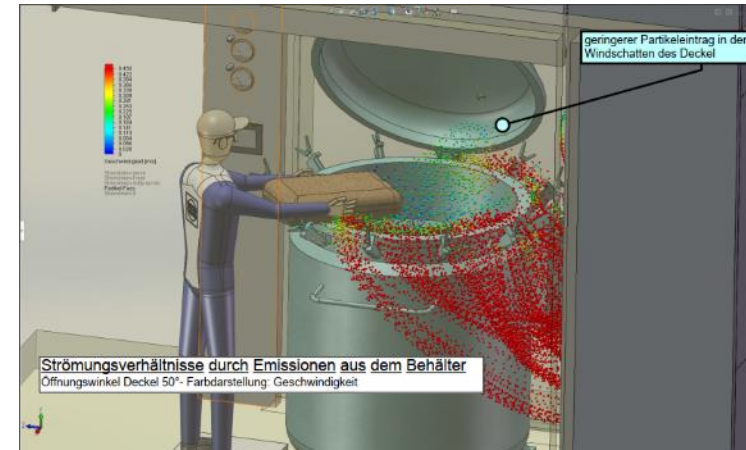
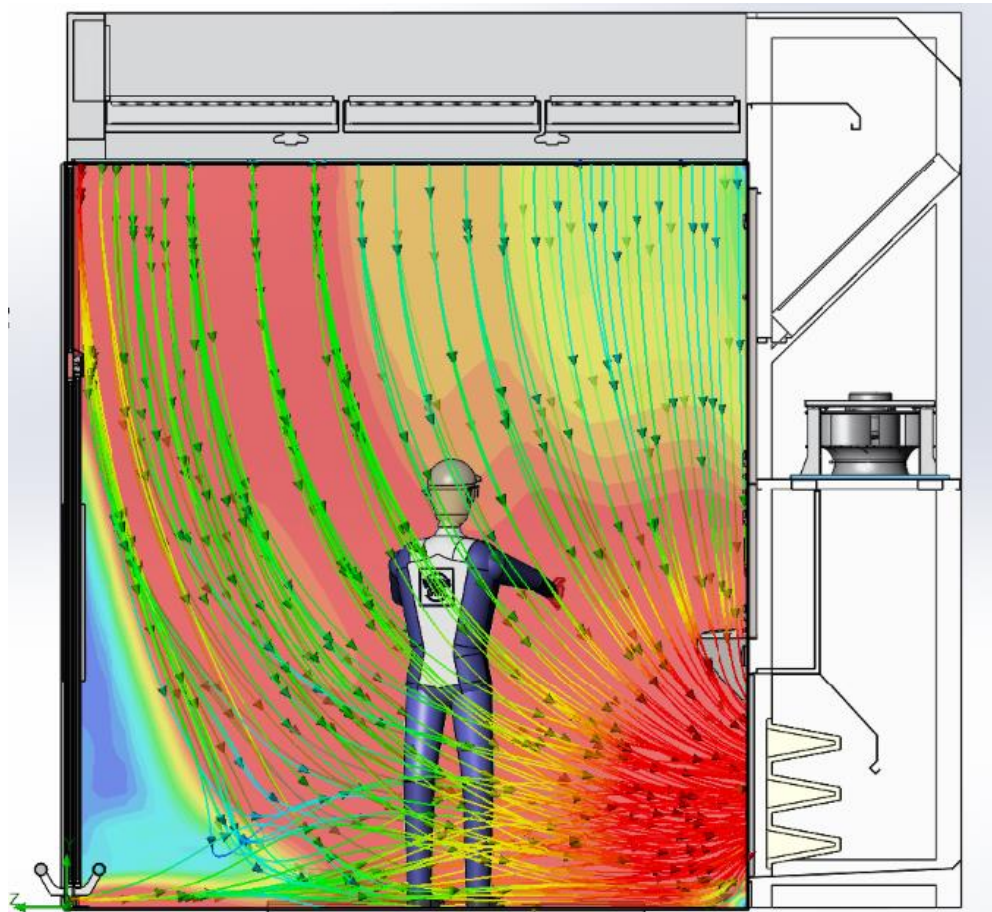
OEB 4



### Highlights

- ✓ Application: Refilling , weighing and test train of pharmaceutical substances
- ✓ The front-side, vertically directed barrier separating curtain reliably shields the work area from the surrounding area without strip curtains
- ✓ Reduced turbulent zone in the front area compared to conventional LF systems
- ✓ Suitable for hazardous substances of OEB 1-4
- ✓ Cleanroom class 5 acc. to ISO 14644-1

## WIBObarrier® Flow Ventilation System



## WIBObarrier® Flow Safety Workplaces

Customized solutions.

OEB 4



WIBObarrier® Flow Weighing workstation

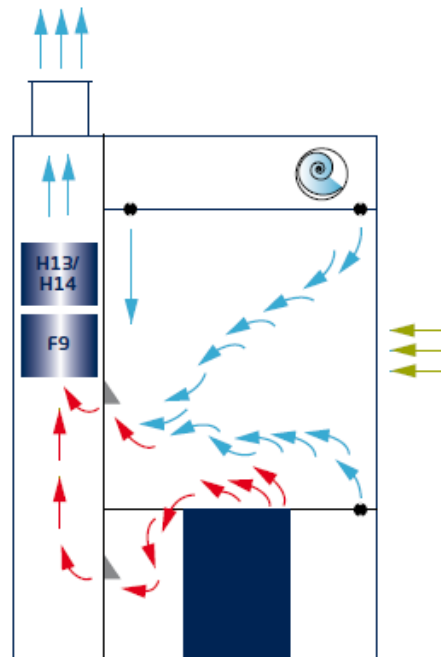


WIBObarrier® Flow for sample drawing in the clean room

## WIBOjekt® Safety Workplaces

efficient and economical.

For personal and environmental protection.



Robust retention



### Highlights

- ✓ Enables safe working with hazardous substances
- ✓ Reliable personal and environmental protection due to the stable clean air curtain and the targeted pollutant extraction
- ✓ Robust retention in accordance with DIN EN 14175-3
- ✓ In industrial standard with and without ATEX protection as well as GMP-compliant executable
- ✓ Low noise and economical

## WIBOjekt® Safety Workplaces

Customized solutions.

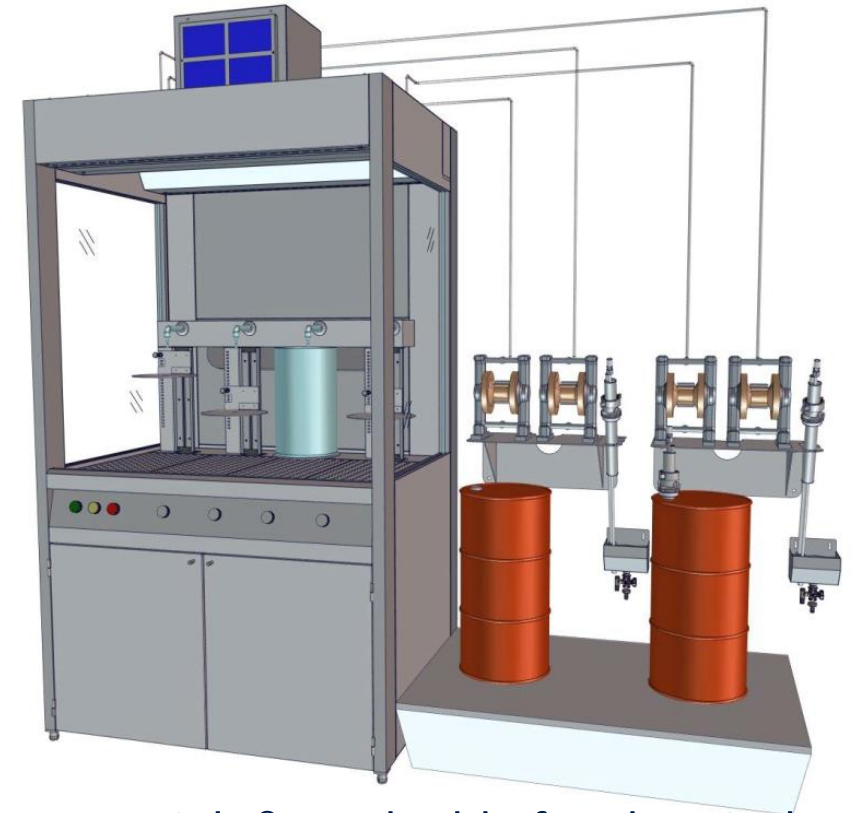


WIBOjekt® Worktable  
Classic for industry

WIBOjekt® Washing workstation  
in GMP-compliant design



GMP



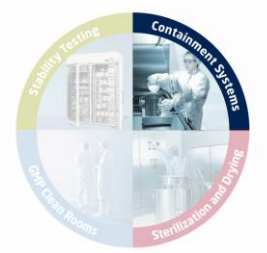
WIBOjekt® Worktable for chemical  
filling

ATEX



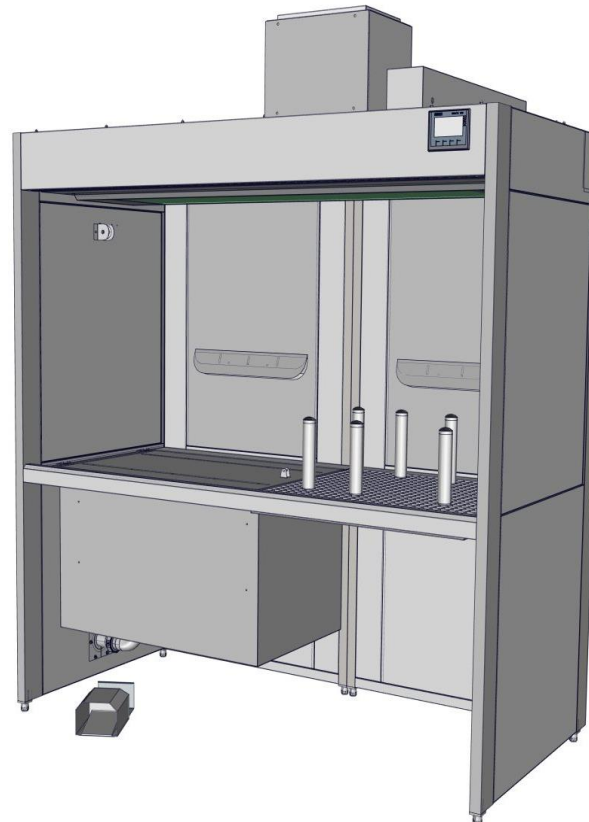
## WIBOjekt® Safety Workplaces

Customized solutions.



WIBOjekt® worktable for  
weighing activities

WIBOjekt® Washing workstation



WIBOjekt® FAP  
walk-in free workstation

## Laminar-Flow Systems

Typ BDK® safety cabinets and clean air modules

Protection for personal, product and environment.



ISO 5 - 8

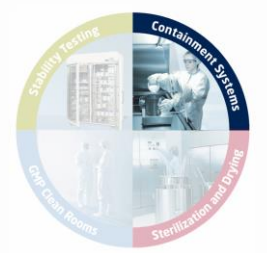


### Highlights

- ✓ Meet the requirements of class A according to EU GMP or purity class 5 according to cleanliness ISO 14644-1
- ✓ Reliable product protection and/or personal and environmental protection
- ✓ Customized solutions, with vertical or horizontal, low-turbulence displacement flow, depending on requirements

## Laminar-Flow Systems

Customized solutions.



ISO 5



Microbiological Safety  
Cabinet UVF-S

Product protection cover  
Clean Air Module MVF



ISO 7



ISO 5

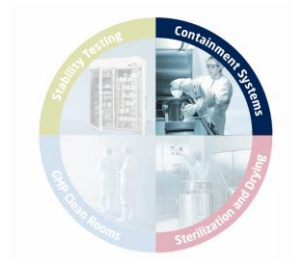
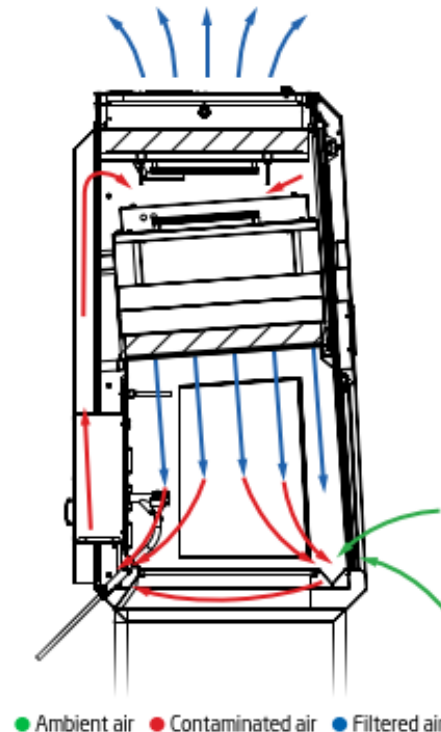


Clean Air Workbench  
FFM

## Microbiological Safety Cabinets of the class II

Typ KTB-NS according to DIN EN 12469.

Safe protection for people, product and environment



DIN EN 12469



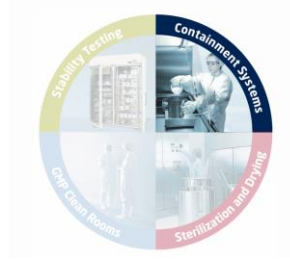
### Highlights

- ✓ TÜV-tested safety
- ✓ Meets the requirements of class A according to EU GMP guidelines or ISO 5 according to DIN EN ISO 14644-1
- ✓ Designed for safety level S1 and S2/Biosafety level BSL 1 and 2
- ✓ Glare-free LED illumination
- ✓ User-friendly TFT touch display
- ✓ Optimal armrest solution due to recessed intake grille
- ✓ Quiet, ergonomic and highly efficient

## House-in-House Systems

Turnkey solutions for sampling system.

- Modular, stable and self-supporting wall panels and ceiling systems
- Integrated ventilation components and airlock systems



## Highlights

- ✓ Everything from a single source
- ✓ Including measurements, qualifications and re-qualifications
- ✓ Service and maintenance

## House-in-House Systems

### GMP sampling system

For GMP sampling of active pharmaceutical ingredients and excipients

- Integrated WIBObarrier® Flow sampling booth with point suction system
- With pallet conveyor system and GMP roll-up doors incl. control and ventilation technology



## Our services

- Assembly and commissioning
- Maintenance, repairs, conversions and modifications of equipment
- All qualification and re-qualification : DQ, IQ, OQ, FAT, SAT
- DAkkS-Calibration according to DIN EN ISO / IEC 17025 through Weiss Technik GmbH
- Tests according to DGUV Regel 109-002 (BGR 121)
- Spare parts management



## Highlights

- ✓ Global service network
- ✓ Wide range of preventive maintenance
- ✓ Secure spare parts supply
- ✓ Fast response in the event of a malfunction global service-network

## Air Conditioning Technology – Cleanroom Solutions Pharma

- Turnkey cleanrooms
- Compounding laboratories
- Monitoring and GMP qualification



## Turnkey Cleanrooms



### Highlights

- ✓ Complete cleanroom services
- ✓ From consulting, project planning, installation to after-sales service - all from a single source
- ✓ Customized cleanrooms
- ✓ Equipment with personnel and material locks, workbenches and isolators

## Monitoring and GMP Qualification



### Highlights

- ✓ In compliance with applicable guidelines such as EC-GMP, FDA and DIN EN ISO 14644
- ✓ Innovative measurement technology for recording, monitoring and documentation
- ✓ Monitoring of all critical parameters
- ✓ Competent qualification team

## Compounding Laboratories



### Highlights

- ✓ Individual planning
- ✓ Consideration of production capacities
- ✓ Concept for the standard-compliant clean room or laboratory area



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