weisstechnik®
a schunk company

Vindur® Turn-Key Clean Rooms for pharmacies. Safe complete solutions from a single source.

www.weiss-technik.com

Highest competence for uncompromising safety.

Forward. Conscientious. Standard-compliant.

High quality-related demands are made on clean rooms in pharmacies and laboratories in accordance with the current ApBetrO (German Ordinance on the Operation of Pharmacies). Just like manufacturers of pharmaceutical products, officine pharmacies and hospital pharmacies as well as compounding centres are subject to numerous regulations and guidelines. For this reason, the forward planning and conscientious implementation of clean rooms require comprehensive special know-how.

Benefit from our know-how.

We are perfectly familiar with the special regulatory requirements regarding the planning, implementation and, above all, operation of clean rooms. They mainly apply to the preparation and production of parenteral nutrition, cytostatic drugs and other medicinal products like CMR substances (cancerogen mutagen reprotoxic) as well as for packaging as blister solution. Other sterile preparations such as ophthalmics, antibiotics and painkiller cassette reservoirs as well as parenteral mixed infusions are also subject to these regulations.

Make the most of our long years of experience for top-level patient, personnel and product safety in accordance with DIN EN ISO 14644, EU GMP Guideline and VDI 2083. With our clean room solutions, you are ideally equipped for this.

In addition, we support you in terms of the necessary certification and coordination with the responsible authorities.

Long-term partner to the pharmaceutical industry.

As experienced specialists in clean room technology, we have already been serving pharmacies and pharmaceutical production facilities as well as laboratories for many years. We exactly know the legal requirements, practical necessities and economic aspects. This enables us to classify these three criteria, integrate them and implement them in a needs- and process-based manner. Functional, economic and GMP-compliant: that is our understanding of a successful solution.

Our turn-key solutions:

- Complete clean room new builds
- Conversions and upgrade of existing systems
- Concepts with workbenches
- Solutions with isolators

Complete concepts for new build, conversion and modernisation.

Weiss Klimatechnik is your one-stop supplier of turn-key solutions. For every task of our customers, we develop an individual concept – regardless whether new build, conversion or modernisation.

Our range covers systems for complete clean rooms as well as components: functional and convenient clean room cabins, class 2 safety workbenches, laminar flow workbenches and isolators. The scope of delivery ranges from room concept through technology to monitoring and beyond.

Here, we accompany the entire project from the planning phase through to day-to-day practice: with consultation, planning, qualification, implementation and after-sales service. We are sure to have the ideal solution for you, too.

Our services:

- Clean room and specialist laboratory planning
- Risk analysis, qualification master plan
- Support with approval procedures
- Functional Design Specification (FDS)
- Clean room acceptance measurement in accordance with DIN EN ISO 14644, EU GMP and VDI 2083
- Analyses, measurements and calibrations
- GMP personnel training
- Implementation and start-up
- Qualification and re-qualification
- Maintenance and service

Our GMP-compatible products:

- Cytostatic drug workbenches and isolators
- Microbiological workbenches
- Clean room personnel and material airlocks
- Clean room wall, ceiling and floor systems incl. lighting suitable for clean rooms
- Air-conditioning units and refrigeration technology
- Laminar flow systems
- Clean room monitoring systems

Strict requirements. Reliable implementation.

Every task requires individual planning. We analyse your wishes and requirements and design the suitable solution. Therefore, you can concentrate on the essentials in peace.

Optimal room layout.

The first important planning variable are the spatial conditions on site. Taking the required production capacities and the product portfolio into consideration, we work together with our customers to develop a concept for future standard-compliant laboratory or clean room areas.

Initially, a room layout is prepared. This covers the areas personnel and material airlocks, preparation, processing and production. These are matched to the personnel and material flow, subject to the clean room classes and pressure levels.

Next, the locations of safety workbenches, laminar flow systems or isolators, airlocks as well as laboratory furniture and equipment are defined.

Exemplary implementation.

We regard the whole room – floor, walls and ceilings – and pay attention to all important details for you. This includes encapsulation areas in accordance with the EU GMP Guideline, for example, which must be easy to clean, disinfect, smooth and crack-free. Access to supply technology is knowingly planned outside the clean zones. The advantages: checks, maintenance and repairs are partly possible without suspending the clean room status.

Intelligent ventilation technology.

Ventilation suitable for clean rooms is a matter of technology. Our air-conditioning units and ventilation technology offer, besides safe and effective operation, a system matched to the overall installation concept in terms of energy. You save energy and costs.

Planning example (total area 300 m²)

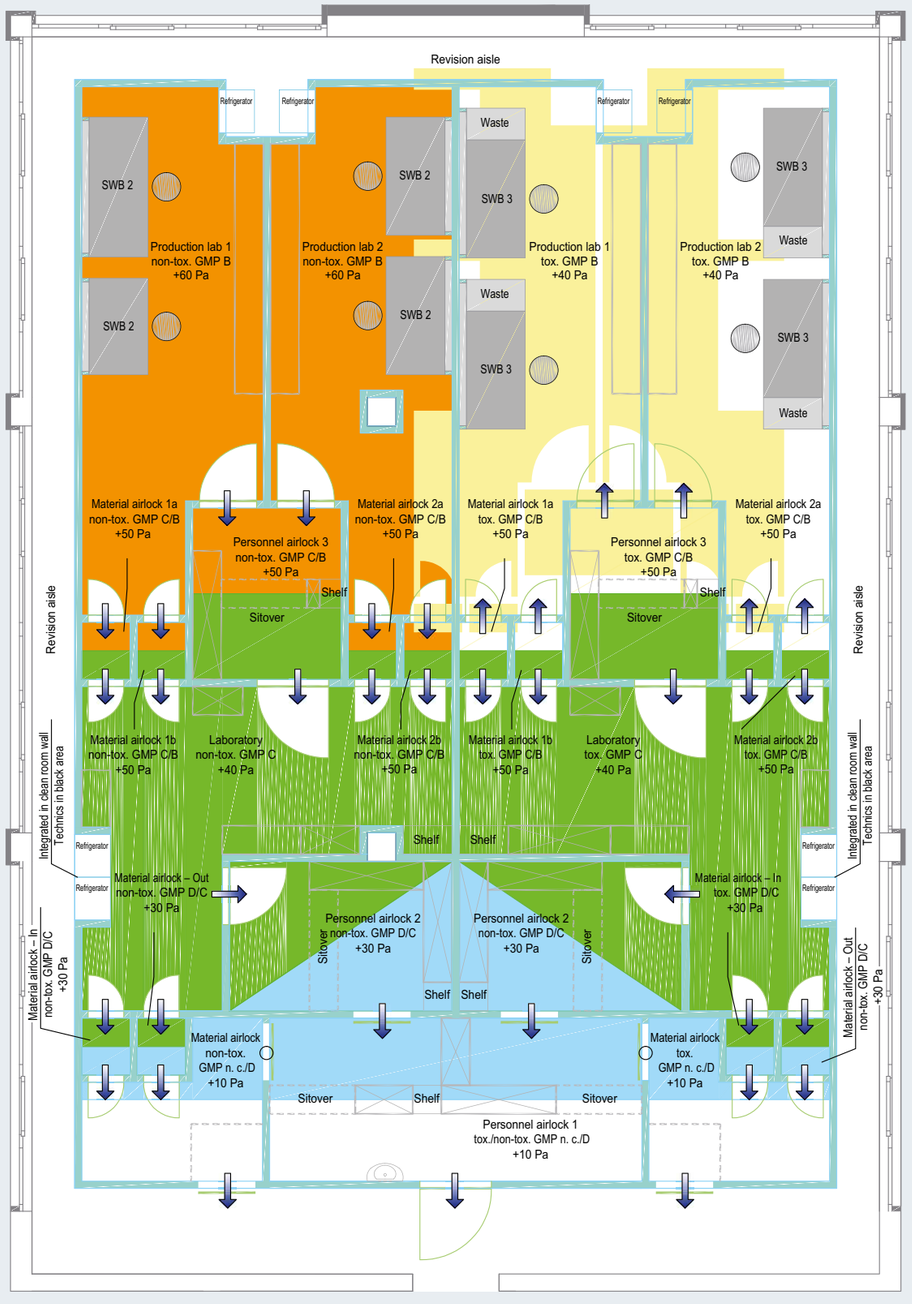
Directed air flow
No directed air flow

GMP-compatible work rooms under clean room classes:

Clean room class GMP A
Clean room class GMP B, toxic
Clean room class GMP B, non-toxic
Clean room class GMP C
Clean room class GMP D
n. c. = not classified

Safety workbenches (SWB):

SWB 2 (2 filters)
SWB 3 (exhaust air, 3 filters)



Safe solutions from a single source.

Ideal room climate.

As specialist for climate technology, we co-ordinate all areas of room air-conditioning optimally to achieve the required room climate. The system is usually connected to the general power supply. However, connection to an existing safety power supply provides more safety for an orderly shutdown in the event of an emergency.

Everything under control.

An intelligent, reliable monitoring system is one of the main elements of quality assurance. It records, monitors and documents all the operating parameters critical for clean room operation via measuring sensors. Deviations in the important physical parameters are signalled by alarm limits being exceeded.

These are:
- Particle concentration
- Room pressure
- Relative air humidity
- Room air temperature
- Air speed

Our clean room solutions fulfil these standards and guidelines:

- EU GMP Guideline
- DIN EN ISO 14644: Clean rooms and associated areas
- VDI 2083: Clean room technology
- DIN 1946: Clean room technology
- DIN EN 13779: Ventilation in non-residential buildings
- DIN 12980: Safety workbenches for cytostatic drugs
- VDI 6022: Clean air quality

Individual clean room equipment with safety workbench, isolator technology and personnel airlocks

Clean room classes as per EU GMP, VDI and DIN EN ISO:

Operating state	Clean room classes as per EU GMP	A	B	C	D
At rest	Clean room classes as per DIN EN ISO 14644/VDI 2083	5	5	7	8
In operation	Clean room classes as per DIN EN ISO 14644/VDI 2083	5	7	8	n. d.
Type of air flow		**LTDF**	**TMA**	**TMA**	**TMA**
At rest	Max. number of particles/m^3 ≥ 0,5 µm	3,520	3,520	352,000	3,520,000
In operation	Max. number of particles/m^3 ≥ 0,5 µm	3,520	352,000	3,520,000	n. d.
In operation	Max. number of colony-forming units in the airflow CFU/m^3	<1	10	100	200
In operation	Max. number of colony-forming units on sediment plates ø 90 mm CFU/4 h	<1	5	50	100
In operation	Max. number of colony-forming units on agar plates or contact plates ø 55 mm CFU/plate	<1	5	25	50

LTDF = Low turbulence displacement flow TMA = Turbulent mixed airflow At rest = Idling In operation = Running n. d. = not defined

Precise guidelines. Standard-compliant design.

As a partner to pharmacies we also offer you a complete solution for blistering in the clean room: planning, implementation, re-qualification and a comprehensive after-sales service. We implement the clean room according to your individual requirements and support you in terms of the necessary certification and coordination with the responsible authorities.

Model with perspective.

There are good reasons why the mechanical, patient-specific blistering of medicinal products is becoming more and more accepted: automated processes save time and costs, prescriptions can be checked better and the supply of medicines becomes more reliable. Finally, the blister service increases the trust of patients and care homes and thus boosts customer loyalty.

Reliable complete solution.

The clean room guidelines for blistering medicines correspond to those for the production of solid medicinal forms. They are applicable for manufacturing companies as well as for patient-specific pharmacy operation.

We implement these strict requirements within the context of the overall clean room concept unexceptionally in accordance with the applicable regulations. Hereby, we advise and accompany you throughout the course of the project and offer turn-key solutions. You can certainly rely on that.

GMP clean room with blister automat and deblistering workstation

Design of operating rooms.

During planning and implementation we particularly consider the deblistering and blistering areas, but also quality assurance as well as storage and dispatch of the ready-made blisters. To fulfil the requirements for handling open products in clean room conditions, walls must always be smooth, easy to clean and disinfect. In addition, a pressure level concept and suitable personnel and material airlocks must be provided.

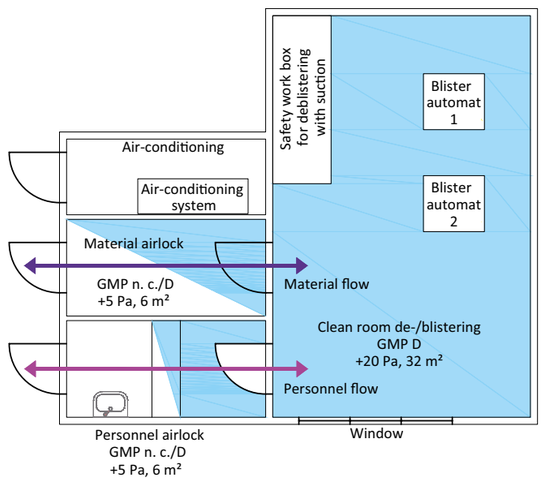
The technical clean room-related requirements:

- Active ventilation
- Filtered air
- Room temperature 20 °C/±2 K
- Relative humidity 40–65 %
- Defined room pressure between blister area and surrounding area
- Active or passive ventilation of airlocks

Planning example

The layout of the rooms and areas should comply with the working processes logically following one another:

- Room/area for storing medical products ready for blistering and packaging materials
- Deblistering
- Interim storage after deblistering
- Blistering
- Inspection area
- Storage of the ready-made blisters
- Dispatch



There for you, 365 days a year, 24 hours a day.

We measure ourselves by our service.

We think and act service-oriented, our customers consider us partners. With our specialised service teams, we offer them sustainable solutions for a long-term successful cooperation.

Nobody is faster.

Our comprehensive service network is ready for you: in Germany alone, a service organisation with more than 280 service employees is at your disposal. A specialist is always within reach. In this way, we reduce the reaction time to a minimum and increase the availability to the maximum.

Expertise and know-how.

Our service technicians are trained and certified by independent bodies. They are excellently trained specialists in the fields of electrical engineering/electronics, refrigeration technology, regulator and control technology, mechanics and software.

Professional consulting.

Our service experts support you with advice and assistance from the first idea to after-sales service in every step of your project. We help with approval procedures so that the overall solution can be quickly accepted and implemented. In addition, we offer professional start-up.

Maintenance and service.

Our comprehensive portfolio also includes services during operation. We reliably carry out all the necessary measurements, maintenance as well as any repairs. Thus you receive the regularly required verifications of the regulation-compliant operation.

Education and training.

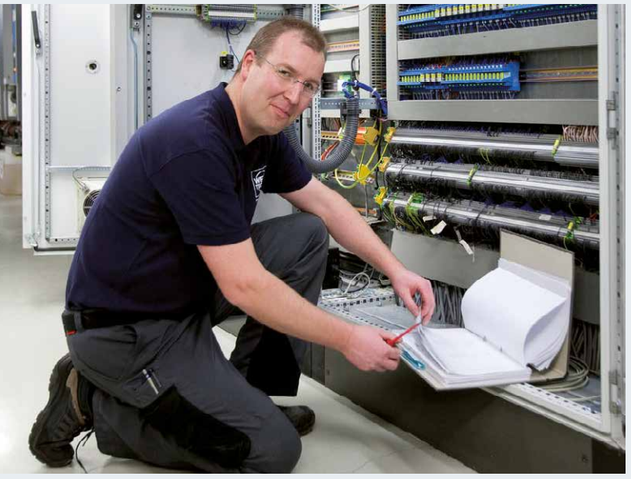
Our clean room solutions also include numerous qualification processes and training, including personnel instruction and special GMP personnel training.

Safe spare parts management.

Thanks to our extensive stock keeping and provisioning in our service vehicles, many spare and wearing parts are available reliably and promptly.

Qualification and re-qualification.

We provide our customers with all qualifications and re-qualifications necessary for the reliable operation of an installation. These include DQ, FAT, OQ, SAT, IQ and GMP.



Our comprehensive range of services:

- Custom consulting
- Assembly/start-up
- Maintenance/inspection/service
- Spare parts supply
- Clean room qualification/re-qualification
- Energy optimisation
- EnEV (Energy Saving Ordinance)
- Equipment and system monitoring
- Hygiene inspections as per VDI 6022/DIN 1946 part 4
- Training/workshops

Start-up, maintenance and qualification measurements, core competencies for safe clean room operation

Passionately innovative.

We work in partnership to support companies in research, development, production and quality assurance. With 22 companies in 15 countries at 40 locations.

weisstechnik
For a safe future.

Environmental Simulation

The first choice for engineers and researchers for innovative, safe environmental simulation facilities. In fast motion, our test systems can simulate all the influences in the world as well as for instance in space. In temperature, climate, corrosion, dust or combined stress tests. With a very high degree of reproducibility and precision.

Air Solutions

As the leading provider of clean rooms, climate technology and air dehumidification, we consistently ensure optimal climatic conditions for people and machines. For industrial production processes, in hospitals, mobile operation tents or in the field of information and telecommunications technology. From project planning to implementation.

Heat Technology

Experienced engineers and designers develop, plan and produce high-quality, reliable heat technology systems for a broad range of applications from heating and drying cabinets to microwave systems and industrial furnaces.

Pharmaceutical Technology

With decades of experience and know-how, we guarantee the most sophisticated clean air and containment solutions. Our comprehensive and innovative range of products includes barrier systems, laminar flow systems, safety workbenches, isolators, airlocks and stability test systems.

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Passion for Climate.

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