
weisstechnik®
a schunk company
Clean Room Technology.
Complete Solutions
for Pharmacies.
www.weiss-technik.com

Highest competence for optimum safety.

Clean rooms in pharmacies and laboratories must comply with stringent quality requirements. Officines and hospital pharmacies as well as compounding centres are as a rule subject to numerous regulations and guidelines as are the manufacturers of pharmaceutical products. The anticipatory planning and conscientious realisation of clean rooms therefore requires extensive expert knowledge.

Special regulatory requirements for the planning, building and above all the operation of clean rooms apply among other things to the manufacture of cytostatic drugs, antiviral drugs and blister solutions. Other sterile compounds e.g. ophthalmic agents, antibiotics and analgesic cassettes as well as parenteral mixed infusions also underlie these regulations.

With our clean room solutions, you are optimally organised and equipped to comply with these regulations.

Weiss Technik is the long-standing partner of the pharmaceutical industry. As experienced specialists for clean room technology, we advise not only pharmacies and pharmaceutical productions but also laboratories. We are familiar with both the legal and practical requirements and also the economical aspects that are involved. This know-how enables us to define and incorporate all three criteria to the satisfaction of our customers. Practical, economical and GMP-conform: this is our understanding of a successful solution.

For new buildings, conversions and modernisation purposes.

With its complete packages from one source, Weiss Technik offers pharmacies, laboratories and manufacturers customer-specific turn-key solutions. In other words, we develop the appropriate solution for every customer's application irrespective of whether they are to be installed in a new building, a conversion or in already existing buildings that are undergoing modernisation.

Our offer comprises systems for both complete clean rooms and components. We can integrate clean room cabinets that are convenient to use in existing buildings in the form of a comprehensive overall concept. We develop special solutions with workbenches and insulators to meet the specific requirements of the customer. The scope of performance ranges from the room concept to technology and monitoring.

We monitor the entire project from the planning phase through to daily practice: with consultation, planning and realisation. With products and components. With services.

Our services:
- Consultation and planning
- Qualification services
- Commissioning and maintenance services
- GMP training courses

Our turn-key solutions:
- Complete clean rooms for new buildings
- Conversions and upgrading of existing units
- Concepts with workbenches
- Solutions with insulators

Our GMP-conform products:
- Cytostatic safety cabinets and insulators
- Microbiological safety cabinets
- Clean room personnel and material airlocks
- Clean room wall, ceiling and floor systems including lighting that conforms with clean room specifications
- Air-conditioning systems and refrigeration technology
- Laminar flow systems
- Clean room monitoring systems

The compounding laboratory.

Specific requirements necessitate specific planning. We meet these requirements for you to the extent possible and design the appropriate solution so that you can concentrate on the essentials.

The existing building or those yet to be built are the initial planning factor and represent the cornerstones of the clean room.

Taking into consideration the desired production capacities, the product portfolio and the spatial conditions, we develop together with our customer a concept for the future clean room or laboratory that conforms to the relevant standards.

First of all, we design a layout of the room which includes the areas for preparation, manufacture, personnel and material air locks. These are adapted to the personnel and material flow.

The locations for e.g. cytostatic safety cabinets, laboratory furniture and equipment are then established.

Exemplary in every respect.

We consider the entire room: the floor, walls and ceilings and pay attention to all important details. These include for example encapsulation areas that are easy to clean, can be disinfected and that are smooth and without cracks. Furthermore, we also ensure that windows and doors are flush-mounted and that the floor and ceiling connection can be easily cleaned. As a rule, we plan access to the supply technology outside the clean zones. The advantage being: checks, maintenance work and repairs can be partly carried out without having to waive the clean room status.

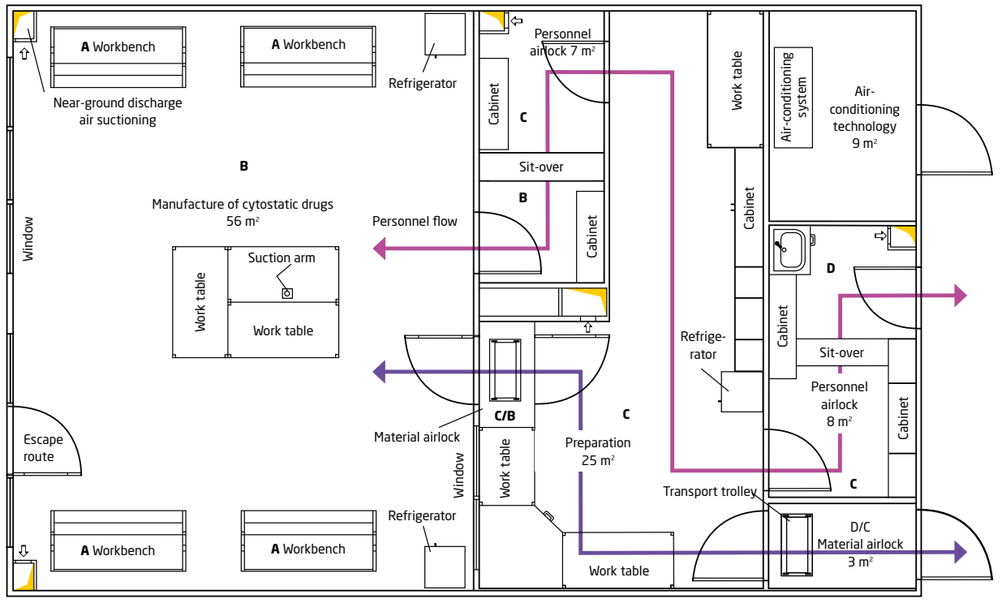
Intelligent ventilation technology.

Ventilation that is clean room compatible is a question of technology. Our air-conditioning systems and ventilation technology offer not only safe and effective operation but also a system that is optimally adapted to the overall concept of the units as far as energy is concerned. This saves both energy and costs.

Perfect room layout.

Personnel and material flow are given consideration from the very beginning. Optimum execution is complemented by the implementation of normative standards for the highest class of cleanliness and pressure stages. In this manner both personnel and product protection and a comfortable indoor climate at all times are given consideration from the start.

Planning example



Manufacture of cytostatic drugs A in B with four workbenches and identification of personnel and material routes

The compounding laboratory.

Ideal room climate.

As specialist for climate technology, we coordinate the heating, cooling and humidification to obtain the desired room climate. Normally the system is connected to the general power supply. In order to ensure a reliable shut-down in the event of an emergency, the unit together with its main systems can also be connected to an existing emergency power supply.

Everything under control.

The monitoring system is a significant element of quality assurance. It records, monitors and documents all operating parameters that are critical for clean room operation via measuring sensors. Deviations from the important physical parameters are signalised when alarm limits are exceeded.

Critical operating parameters:

- Particle concentration
- Room pressure
- Relative room air humidification
- Room air temperature
- Air velocity

Our clean room solutions comply with these standards and guidelines:

- EU GMP Guidelines
- DIN EN ISO 14644: clean rooms and associated clean room areas
- VDI 2083: clean room technology
- DIN 1946: room air technology
- DIN EN 13779: ventilation of non-residential buildings
- DIN 12980: safety cabinets for cytostatic drugs
- VDI 6022: room air quality

Individual clean room equipment with cytostatic safety cabinet, insulator technology and material 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	Not defined
	Type of air flow	TAV	TMS	TMS	TMS
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	Not defined
In operation	Max. number of colony-forming units in the air flow KBE/4h	< 1	10	100	200
In operation	Max. number of colony-forming units on sedimentation plates ø 90 mm KBE/4h	< 1	5	50	100
In operation	Max. number of colony-forming units on agar plates or contact plates ø 55 mm (in operation) KBE/plate	< 1	5	25	50

TAV = Low turbulence displacement flow TMS = Turbulent mixed airflow in operation = With product, machines in operation and personnel

The clean room blister packaging solution.

We regard ourselves as a partner for pharmacies and offer you the complete solution for blister packaging in the clean room: from the planning to realisation and qualification. We design the clean room according to the specific requirements, assist the pharmacies in acquiring the necessary certificates and coordinate matters with the relevant authorities.

A model for the future.

The mechanical, patient-specific blister packaging of medicines is gaining growing acceptance for good reasons: the automated processes save time and costs, prescriptions can be better controlled and the supply of medicines is safer.

After all the blister packaging service fosters the trust and confidence of the patients and nursing homes and in turn customer loyalty.

All requirements fulfilled.

The clean room guidelines for the blister packaging of medicines are identical for both manufacturing plants and patient-specific blister packaging in pharmacies. They correspond with the guidelines for the manufacture of solid dosage forms. We advise and support you throughout the entire project and offer you turn-key solutions that meet all requirements.

In addition to active ventilation with supply air and discharge air consideration must be given to the room temperature, relative humidity and room pressure. The ventilation of airlocks must also be considered.

With its overall room concept, we fulfil these requirements for our customers without exception in compliance with the valid regulations.

Conception of the installation rooms.

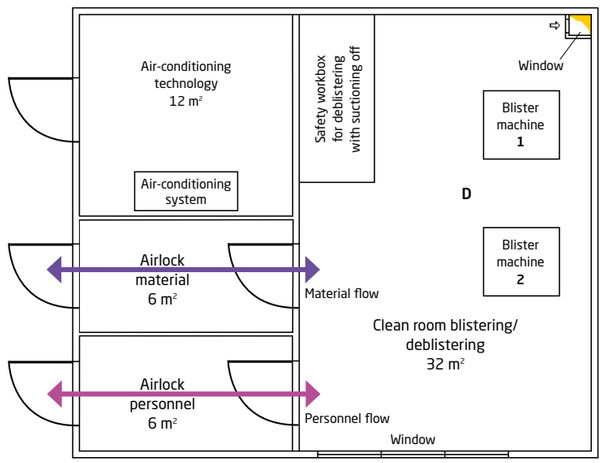
We not only give special attention to the areas for blistering and deblistering but also include the areas for quality control, storage of finished blistered packages and their dispatch in our planning and realisation. In order to comply with the clean room compatible handling of open products, the walls must be smooth and easy to clean and disinfect. A pressure stage concept and appropriate personnel and material airlocks are absolutely vital.

The clean room requirements:
- Active ventilation
- Filtered supply air
- Room temperature 20 °C / ±2 K
- Relative humidity 40-65 %
- Defined room pressure between blister packaging area and surrounding area
- Active or passive ventilation of the airlocks

GMP clean room with automatic blister packaging machine and deblister workplace

Planning example

The installation rooms and operating areas should be arranged to correspond with the logical sequence of operations:
- Room/area for the storage of the finished medicinal products that require blistering and packing material
- Deblistering
- Intermediate storage of finished blistered products
- Blistering
- Controlled area
- Storage of finished blistered products
- Dispatch



Our services: We're there when you need us.

As a group of companies operating worldwide, we support our customers with a global service network. Above and beyond the planning and technical realisation, we offer extensive after-sales services and customer-specific qualifications and training courses. Our customers thus receive all services in the customary high Weiss Technik quality from one source to ensure the optimum performance of your units.

We support you closely in the planning phase when cooperating with the relevant regional councils and authorities and assist you during the approval process. Our know-how and skills with regard to qualification ensure that the overall solution can be quickly realised and accepted. We offer commissioning by qualified personnel and instruct the operator in the use of the unit.

First-class service and extensive support.

After planning and realisation our extensive services are at your disposal throughout day-to-day operation of the clean rooms and clean room components.

The after-sales service carries out the necessary measurements, maintenance and possible repairs. Based on differentiated measurements, Weiss also issues the regular verifications of correct operation.

- Clean room and laboratory specialist planning
- Support of the approval process
- Assembly and commissioning
- Clean room acceptance test as per DIN EN ISO 14644, VDI 2083 and EU GMP
- Extensive after-sales service
- Monitoring
- Maintenance and repair
- Weak point analysis of existing units
- Inspections, measurements and calibrations

Qualified work.

As part of our clean room solutions we offer numerous qualification and training courses which simplify daily work and assist in fulfilling the legal requirements. They have been designed to improve above all the quality for the benefit of our customers and their patients.

We begin by familiarising your personnel with the clean room solution and offer special GMP personnel training.

Furthermore, we implement all the legally required qualification and re-qualification measures for clean room and air-conditioning technology.

Our comprehensive performance spectrum:

- GMP personnel training
- Risk analysis, validation master plan
- Functional Design Specification (FDS)
- Design Qualification (DS)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Re-qualification services

Commissioning, maintenance and qualification measurements: core competences 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
Test it. Heat it. Cool it.

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.

Climate Technology, Air Dehumidification, Clean Rooms

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.

Clean Air and Containment Systems

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 and airlocks.

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