WEISS TECHNIK

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Reliable Solutions for the Pharmaceutical Industry

The following companies already benefit from the solutions offered by Weiss Technik subsidiaries worldwide:

- Abbott Laboratories
- Actelion
- AKZO Diosynth
- Allergan
- Aspen Pharmacare
- Astellas
- AstraZeneca
- BASF
- Baxter International
- Bayer
- Beiersdorf
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Celanese Chemicals
- Clariant
- Covidien
- CSL Behring
- Daiichi Sankyo
- Dong-A
- Dr. Reddy's
- Eli Lilly
- Ferring Arzneimittel
- Gedeon Richter
- GlaxoSmithKline
- Hanmi Pharmaceuticals
- Ipsen
- Janssen-Cilag
- Johnson & Johnson
- Krka
- Lupin
- Meda Pharma
- MedImmune
- Merck & Co (MSD)
- Merck KGaA Darmstadt
- Merck Millipore
- Merz
- Novartis
- Novo Nordisk
- Pfizer
- Procter & Gamble
- Qilu Pharmaceutical
- Roche
- Sandoz
- Sanofi
- Santen
- Solvay
- Stada
- Takeda
- Torrent Pharmaceuticals
- UCB
- Vetter Pharma
- Wockhardt

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Reliable Solutions for the Pharmaceutical Industry

Weiss Technik is a fully competent provider of reliable solutions for the pharmaceutical industry in the field of environmental simulation as well as in heat, air conditioning and clean room technology. Wherever optimum climatic framework conditions are required for production processes and procedures for man and machine or for products: Devices and systems by Weiss Technik with its operating companies continue to prove their reliability.
The companies of Weiss Technik constitute an international corporation with 22 subsidiaries and a total of approx. 2005 employees and are part of Schunk Group, which operates worldwide.

Reliable solutions for the pharmaceutical industry encompass the following fields:

- **Stability Testing**
- **GMP Clean Rooms**
- **Barrier Systems**
- **Sterilization and Drying**

Products and production

We develop and manufacture devices and systems, components, special constructions, special systems and systems solutions, monitoring systems as well as all necessary software solutions in our production facilities worldwide.

Assembly and commissioning

A worldwide commissioning network is available for assembly and commissioning. We support our partners in all acceptance and clean room measurements and calibrations, with documentation as well as with qualification.

System consultancy services and development

At Weiss Technik, we provide comprehensive system consultancy services for you:

- Feasibility studies
- Concept planning
- Efficiency analyses
- Detailed design and participation in approval procedures

Training

In the field of training, all companies of Weiss Technik offer competent training courses regarding clean room technology, air conditioning technology, stability testing as per FDA 21 CFR Part 11 and regarding clean room behaviour.

Qualification and re-qualification

We advice you on all relevant questions of qualification – whether according to GAMP 4, GAMP 5 or other specifications - and co-ordinate the contents for the specific projects. Moreover, we can also carry out this qualification on site together with the customer.

Full after-sales service

Our after-sales service comprises spare parts management, a consignment warehouse as well as maintenance and service contracts – also including a specific response time, worldwide service as well as qualification and requalification.

Reliable Solutions for the Pharmaceutical Industry

Stability Testing

- Stability test cabinets
- Stability test chambers
- Photo-stability test systems
- Temperature change and climate cabinets
- DKD calibration laboratory as per ISO 17025 for in-house and on-site calibrations regarding the measurement parameters of temperature and humidity

Barrier Systems

- Open Containment Systems – Closed Containment Systems as tables or free worktables for
  - Weighing
  - Refilling
  - Sampling
  - Laboratory work with high potent API
- House-in-house systems
- Active personnel and material air locks
- Laminar flow units
- Isolators/ vario-isolators
- Lifting columns

GMP Clean Rooms

ULTRACLEAN® Clean Room Solutions

- Complete clean room systems
- Air conditioning systems
- Special systems/ process climate
- Clean room walls, ceilings, floors and lighting systems
- Mobile clean room containers/ tents
- Barrier systems/ high containment
- Cytostatics workbenches
- Clean workbenches and micro-biological safety workbenches
- Filter fan modules
- Mini-environments
- Air showers
- Monitoring
- Personnel and material air locks
- Planning
- Qualification services
- Training

Sterilization and Drying

- Hot air sterilization for continuous dry heat sterilization
- Heat and drying ovens
- Vacuum drying ovens
- Explosion protected heat and drying ovens
- Continuous oven in clean room design

Stability test chamber

Photo-stability test cabinet

Stability tests in line with GMP/ FDA requirements

In the field of stability testing Weiss Technik offers the full range of sophisticated environmental simulation for the pharmaceutical industry. Our products include:

- Stability testing
- Storage of pharmaceutical preparations under constant conditions
- Packaging tests
- Simulation of transport routes

according to the ICH guidelines Q1A and Q1B, as well as national and international specifications, e.g. WHO, GMP, cGMP and others.
The exact simulation of the specified climate values accelerates the exploration of new active pharmaceutical ingredients and enhances the quality and stability of your preparations, testing and storage. A comprehensive standard range of climate cabinets sizes from 34 l to 2160 l (1.2 cu ft to 76.2 cu ft) for a wide variety of stability tests and walk-in stability test chambers are offered. We also offer custom sizes that are an ideal solution regarding volume and construction for every application. Depending on your test requirement, numerous documentation possibilities each with control loop sensors or with independent sensors (upon request) are available to document the measured values of temperature, humidity and light. Whether it is analog or digital, with integrated recorders, data loggers or online via software, we provide the appropriate solution for every individual customer requirement. Our Simpati-Pharma software, which is in line with FDA 21 CFR Part 11, has an individually adjustable user administration capability. Other features include an on-line alarm system, the Simpati e-sign module (electronic signature with biometric data) and a bar-code scanner for batch administration. Comprehensive qualification documentation according to GAMP is also available.

GMP/ FDA compliant workstations

Weiss Technik develops and produces containment systems for the highest protection of humans, products and environment. Based on our leading position in the market, our long-standing experience and a dependable customer-supplier relationship we partner and advise our customers worldwide in the planning of their projects.
Our comprehensive range of products and services comprises design, production and assembly, commissioning, qualification and after sales service for devices and systems designed specifically for our customers, such as:

- Laminar flow clean air workbenches with horizontal or vertical air displacement flow,
- Laminar flow vertical flow modules for product protection, e.g. in filling lines and sampling,
- Class 2 and 3 microbiological safety workbenches according to DIN EN 12469 for the protection of products and humans.

WIBObarrier® OCS Open Containment or WIBObarrier® CCS Closed Containment/ RABS Systems

Multifunctional, ergonomic workstations for refilling, weighing and other handling of API, with protection of personnel having the highest priority. The special WIBObarrier® air guidance system ensures a robust retention capacity even with its very smooth air flow so that a product exposure of < 1µg/m³ can be complied with, even with an open front panel. Product protection of up to ISO class 5 according to DIN EN ISO 14644-1 can be implemented. A horizontal sliding front panel with glove ports ensures splash and contamination protection. The BDK isolators, which are also available for operation from both sides, in their customer-specific applications are designed for over- and under-pressure operation and with various RTP docking double cover locks, inertisation or CIP facilities for personnel and/or product protection. Active personnel or material locks, house-in-house systems and lifting/lifting-tilting columns complete the product range.

Laminar flow clean air system for product protection in filling of pharmaceutical products

Absolute personnel protection provided by the isolator when handling high potent materials

Clean room for cytostatics processing

Supply and exhaust air system for an aseptic filling machine

GMP clean rooms and climate technology

The clean room technology division of Weiss Technik covers the entire range of products and services in the field of clean room technology.
We implement clean room projects – ranging from planning to turnkey systems – for our customers.
Weiss Technik customer focused approach that includes; preparation and implementation of concepts in line with clean room requirements, high collaboration in the execution of the projects and a close cooperation in assembling and commissioning the systems constitute our strengths. Weiss Technik also offers factory trained qualification services, a comprehensive after sales service and customer-specific GMP training.

In industries in which particularly high requirements are placed on product quality and reliability according to the international standards, rules and regulations of DIN-ISO 9001, GMP/ FDA, ISO 14644, VDI 2083, etc., clean room technology constitutes a key element in state of the art and safe production processes. The protection of both products and processes as well as the protection of the humans involved against harmful effects and a contamination is critical.
Weiss Technik offers individual and innovative solutions according to the latest state of the art in which all relevant standards and specifications are taken into account – from clean workbenches to turnkey clean room systems.

Dry heat sterilizers – also under clean room conditions

Our Vötsch brand of products offers a comprehensive range of heat technology devices and systems for the pharmaceutical industry including dry heat sterilizers for clean room classes ISO 5 and 7 according to DIN EN IS 14644-1. All Vötsch series can be produced as free-standing systems or for installation into a wall as a hatch implementation with doors on the front and rear to separate the sterile and non-sterile work areas.

The nominal temperatures amount to max. 350 °C. Sterilization is effected under clean room conditions.
The dry heat sterilization procedure forms an interesting alternative to other sterilization procedures. The fact that air only is used in this procedure constitutes a major advantage. As a result, sterilization is possible at higher temperatures. Depending on the level of the temperature, the sterilization process proceeds much faster and chemicals are not required for sterilization.

Vacuum drying in the production of pharmaceuticals

The use of vacuum drying cabinets has become indispensable in the pharmaceutical, bio-technology and cosmetics industries. Intermediate and final products, such as granulate materials, powders and pastes can be dried gently at low temperatures under vacuum conditions by means of this drying procedure.
Pharmaceutical products which are sensitive to heat can be dried quickly and economically in this way. Moreover, Vötsch also offers innovative solutions for conventional drying procedures.

All systems are designed as GMP/ FDA compliant executions.

VHSF 100/ 150 GMP dry heat sterilizer

Continuous Oven for installation in the Clean Room DIN ISP 7