Together always one step ahead

To manage engineering, design, fabrication and validation of your pharmaceutical isolator process solution is the core competence of our Industrial Division.

Lab Equipment

The safety of the user, the product and the surrounding environment in your laboratory and cleanroom is the central focus of our Lab Division.

Changes may be made as a result of technical progress or improvements in services offered.

PSI-M Brochure EN
Material-Nr. 1211667
Version 199625_A / 20130719
SKAN

SKAN, founded in 1968, is one of the pioneer companies in the field of cleanroom equipment and construction of isolators for the pharmaceutical industry.

Innovative products, client-specific solutions as well as an efficient service organization have made SKAN a market leader and important partner of industry and research laboratories worldwide.

Demands

- Aseptic environment for production process
- Safety for product, operator and environment
- Aseptic or aseptic/toxic operation
- Effective, quick material transfer
- Flexible system for different requirements

Solution: PSI-M

The Pharmaceutical Safety Isolator - Modular, PSI-M, based on a high-quality, state-of-the-art system was developed especially for aseptic and aseptic-toxic applications. Preferred areas are sterility testing, pharmacies, quality testing laboratories and industrial preparations, which deal with active substances daily.

Features

- Short transfer times
- Easy to operate
- High-grade construction of stainless steel and glass
- Integrated H₂O₂ (hydrogen peroxide) decontamination
- GMP clean room class A, ISO 5, developed and documented according GAMP
- Automatic leak test

Options

- Integrated sterility test pump
- RTP and liquid waste ports
- Positive or negative pressure operation
- Particle counter
- Viable Air sampler

Technical Highlights

Safe and rapid transfer air lock SARA-M

- Fast cycle < 20 min. to < 1PPM H₂O₂
- 6 log reduction
- Independent from isolator
- Sliding door to the isolator, working area fully accessible

Integrated decontamination system with H₂O₂

- Fully integrated and automated
- Supported by a validation team up to the authority inspection
- H₂O₂ and material studies fully available with isolator

Air flow and filter technology

The air entering the isolator and air lock is protected by HEPA filters. A stable and rapid pressure control system enables operation with positive or negative pressure, according to the process. Inside the isolator the vertical air flow is unidirectional and is re-circulated either through return air filters or ducts.

FIBO: The innovative “safe-change” filter box

- The FIBO is designed for the segregation of airborne particulates of highly active substances like cytotoxics for live vaccines, viruses and bacteria
- The filters can quickly and easily be changed by a single individual without special safety gowning
- The isolator and the filter boxes remain safely sealed throughout the filter changing process
- Fully incineratable filters for easy disposal

Service package included

All isolators provided by SKAN come with a comprehensive documentation package to fulfill the requirements of authorities. After shipment, SKAN will support the customer up to the final approval by the authorities which includes installation, commissioning, IQ/OQ, cycle development and microbiological qualification (PQ). The highly specialized SKAN laboratory with H₂O₂ scientists offers support for all on-site validation activities and questions on processes.