Excellent Aseptic Conditions

Isolators for filling lines – state of the art technology for aseptic filling.

skan

SKAN AG,

the developer of the integrated hydrogen peroxide (H_2O_2) decontamination system, is the world's leading provider of pharmaceutical isolators for product and personnel protection.

In order to meet the demanding requirements of our clients in the pharmaceutical industry, our products are fully cGMP-compliant.

Our renowned isolators are in use in many FDA-approved facilities worldwide.

The advantages of isolator technology for the filling process

- Reproducibility and stability of the process
- The highest product quality with maximum efficiency
- Product and operator protection of the highest level
- The controlled production area is held to a minimum
- Excellent financial efficiency compared to traditional clean room technology

Isolator features

SKAN attaches considerable importance to the 'hygienic design' of the cGMP-compliant construction of its equipment.

- Our chambers are constructed free of crevices and with rounded corners
- Good reach and simple cleaning of all surfaces
- Construction with high quality stainless steel and FDA-approved gasketing material
- The material choice is a result of our technical research for optimal H_2O_2 decontamination and durability
- Low maintenance and minimal spare parts required result in high utilization of the equipment
- Large door openings for good accessibility to the equipment

Isolator for aseptic filling or for aseptic-toxic filling

Aseptic filling

In the technical floor

- HEPA filtered inlet air from the room
- Air treatment (temperature, relative humidity, nitrogen atmosphere)
- Pressure zone regulation
- HEPA filtered exhaust system

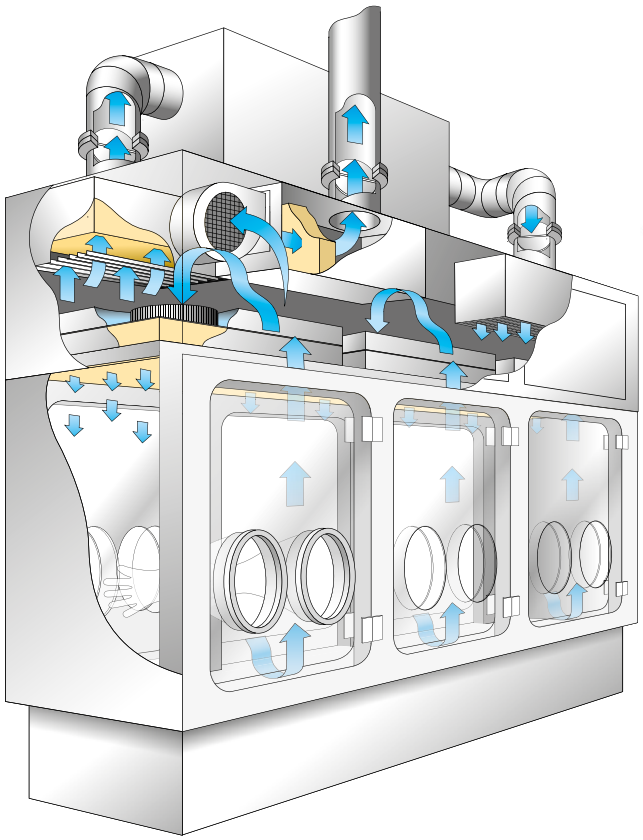
In the isolator chamber

- Dynamic sealed HEPA filters
- Monitoring of the filter pressure drop
- Vertical, unidirectional controlled air flow
- Recirculation air flow with double window design
- Monitoring: air velocity, differential pressure, temperature, relative humidity, particle counting, microbiological monitoring

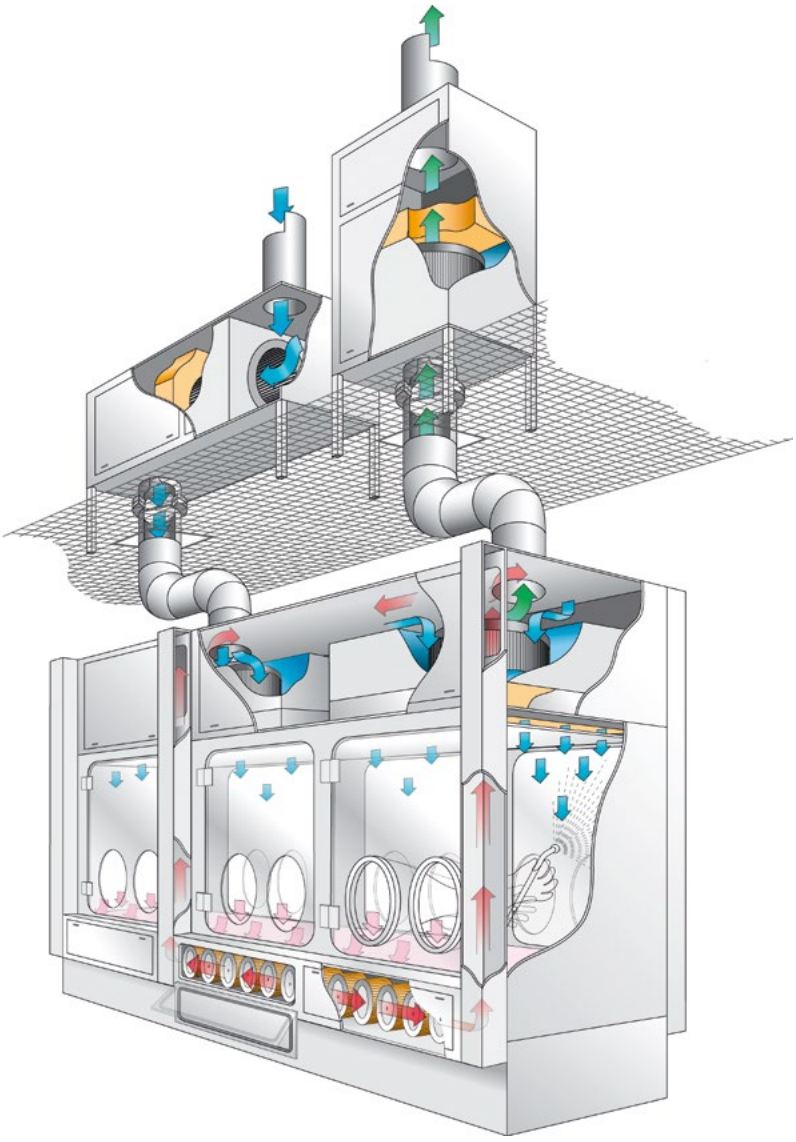
Aseptic toxic filling

In addition to the aseptic filling features, the following is required:

- Isolator chamber washable with spray balls and spray wands
- Quick drying capability
- Simple and safe filter change system for personnel protection



Isolator for aseptic filling



Isolator for aseptic filling of toxic products

SKAN integrated H_2O_2 decontamination system

SKAN's Core competence

The key feature of our isolators is the integrated H_2O_2 decontamination system.

In addition to the decontamination system SIS 700, SKAN has also developed detailed process know-how from a scientific perspective. Today, hundreds of these systems are being used with great success, providing users with the benefits of highly reproducible and reliable processes.

The decontamination system ensures the **rapid and fully automated H_2O_2 decontamination** of the equipment.

The stable and reproducible performance of the decontamination system guarantees quantifiable spore reduction on all exposed surfaces within the isolator.

In order to qualify the units quickly and successfully, SKAN has developed specific SOPs over the years. These methodologies are now referenced in the 2004 FDA guideline 'Sterile Drug Products Produced by Aseptic Processing'.

Skan has performed a wide range of experiments in connection with H_2O_2 for clients in its own microbiology laboratory. These experiments include: material compatibility, diffusion characteristics, spore reduction ability on various materials, D-value determination and H_2O_2 low residual studies.

SKAN scientific lab

Qualification

At SKAN, cGMP-compliant qualification accompanies the entire project, from the start of the planning phase up to the customers media fill. This guarantees our clients a targeted and effective qualification process within the project schedule.

SKAN's quality management system has been successfully audited many times by our clients in the pharmaceutical/ biotech industry as well as various regulatory authorities.

Process automation

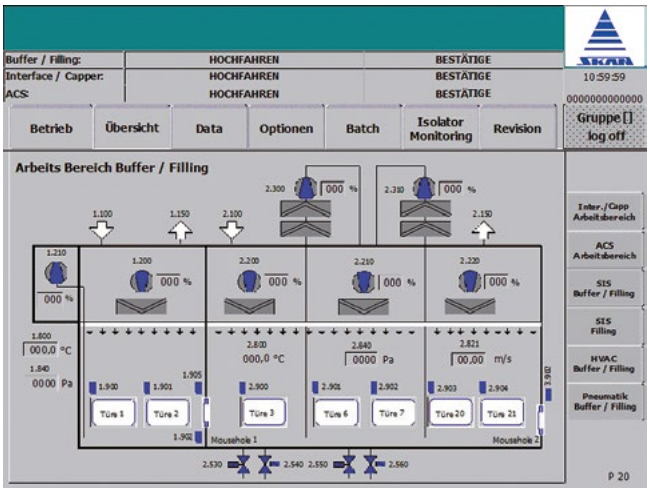
Overlaying the process technology is a modular automation process that offers a high level of process safety and optimal reliability. This can be combined with the SKAN Monitoring System and offers optimal process transparency with convenient evaluation tools.

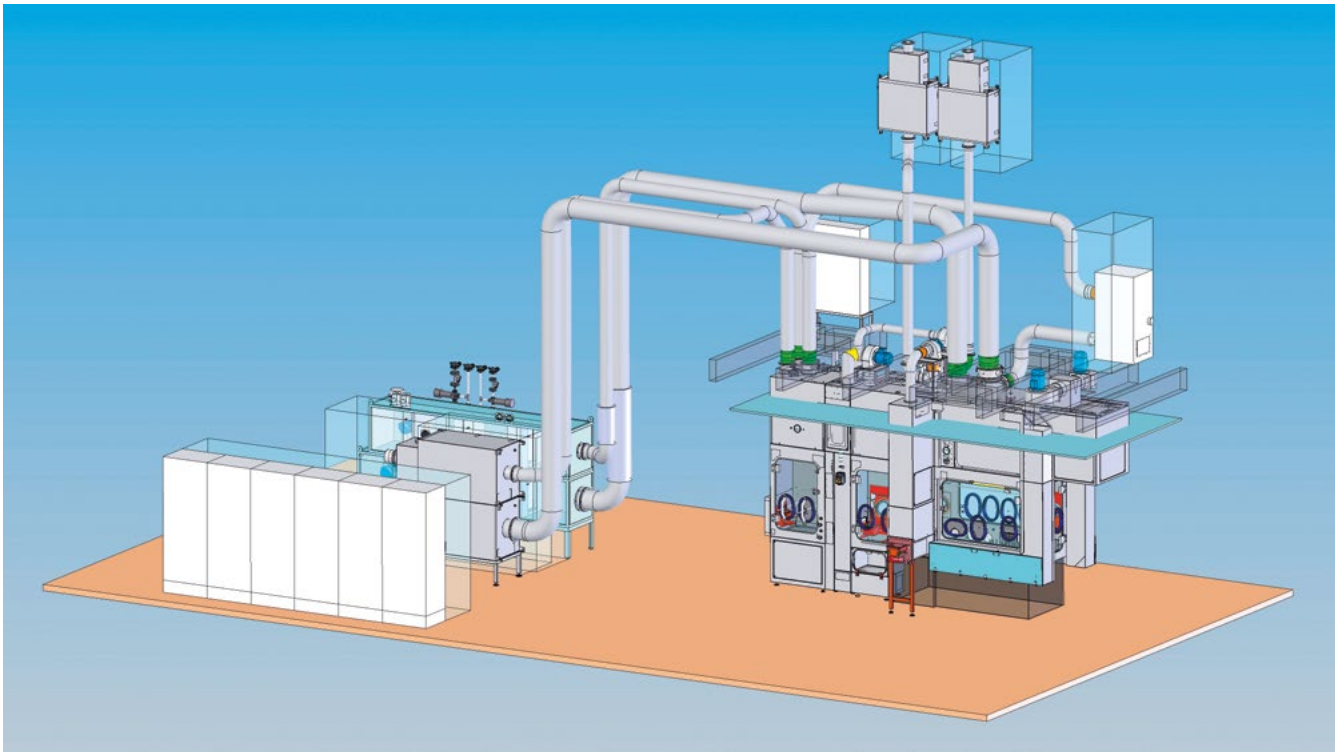
Controls

- The software complies with GAMP guidelines with regard to programming and documentation
- Electronic records are created in accordance with 21 CFR Part 11
- PLC's from Siemens, Allen Bradley or Mitsubishi are used
- All process data can be transmitted to customer SCADA systems

Visualization

- Clearly structured user interfaces with touch panels give the user the necessary process overview.





Design and equipment support

The thorough documentation of the equipment complies fully with GAMP requirements for pharmaceutical machines. The document package supplied is enhanced by operator and maintenance staff training.

Ancillary offerings

- Pre-engineering
- Mock up study
- Retrofits
- Qualification of existing or third party isolator equipment

Accessories

A wide range of accessories and services are an integral part of SKAN's isolators on filling lines. In accordance with customer requirements, SKAN uses the products developed both internally and by third parties.

SKAN Glove leak tester

In close collaboration with our customers, the SKAN glove leak tester has been enhanced on an ongoing basis by means of a series of documented experiments in the field. The tester can determine the process-critical integrity of up to twelve gloves with sleeves simultaneously.

SKAN E-beam system

The E-beam system allows a fast surface decontamination of tubs to a full kill of a 6 log population.

SKAN transfer airlock SARA-M

The SARA-M can decontaminate equipment and tools to a full kill of a 6 log population in less than 20 minutes with H_2O_2.

Isolator Technology

The engineering, design and validation of your pharmaceutical isolator process solutions 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.

Together always one step ahead

Together with our customers, our partners, suppliers and fellow employees and together with you.

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