Reliable Protection with RABS

Restricted Access Barrier System – Reliable Protection of Product and Process

Together always one step ahead
Reliable Protection of Product and Process with RABS

SKAN

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

Your needs

- Reliable safety for process and operator
- Aseptic working conditions: free of particles and microbiological contaminations
- Physical barrier between operators and the product
- GMP cleanroom class A (ISO 5)
- Upgrade of existing aseptic filling equipment

Our solution

The RABS system serves to physically separate the product and process from the production environment and operators. Designed according to GMP guidelines, RABS from SKAN are Swiss made products and feature premium quality.

Features

The RABS from SKAN are designed to ensure aseptic filling in a clean and safe environment.

- Providing cleanroom class A (ISO 5) laminar flow within a class B (ISO 7) area ensures process protection
- Flow optimized barrier design
- Integrated glove system for process interventions
- High-quality design
- Negative pressure filter plenum for additional product safety
- Door access audit trail
- GMP compliant documentation

Design

SKAN places great importance on the GMP design of process equipment, particularly in terms of hygienic design.

- GMP-compliant processing of high quality stainless steel profiles, exceptional finish and FDA-approved materials
- Easy cleaning of all surfaces / all cables within the frame
- Uncompromised access with angle/folding doors
- Process illumination free of glare and shadows
- No dead airflow corners by flush design
- Low maintenance and few wear parts for high system availability
Types of RABS

**Passive Open RABS**
- Passive airflow: Ceiling with HEPA filter-fan-unit
- Air overspill into the room
- Physical barrier, no differential pressure (Δp)
- Outside grade B (ISO 7) / inside grade A (ISO 5)
- 10⁻³ manual decontamination usual
- 10⁻⁶ decontamination with SKANFOG®
- Door opening possible during production
- Not suitable for toxic products

**Active Open RABS**
- Active airflow: Integrated HEPA filter-fan-unit
- Air overspill into the room
- Physical barrier, no differential pressure (Δp)
- Outside grade B (ISO 7) / inside grade A (ISO 5)
- 10⁻³ manual decontamination usual
- 10⁻⁶ decontamination with SKANFOG®
- Door opening possible during production
- Not suitable for toxic products

**Active Closed RABS**
- Active airflow: Guided air return through air ducts
- No air overspill into the room
- Physical barrier, positive or negative differential pressure (Δp) possible with intake and exhaust air systems
- Outside grade B (ISO 7), inside grade A (ISO 5)
- 10⁻⁶ decontamination with SKANFOG®, independent of the room
- Door opening possible during production (depending on customer’s definition)
- Also suitable for toxic products
Controlling the microbial load within RABS is a daily challenge. Surface decontamination of the equipment is a time-consuming procedure and validation is often complex.

SKANFOG® is decontamination technology based on the micro-nebulization of hydrogen peroxide (H₂O₂). Compared with conventional wiping, it simplifies and enhances both procedure and validation. Moreover, nebulized H₂O₂ in moderate concentrations can be used without concern regarding toxicity, corrosion and persistence. Scientific studies have shown that a total kill of a 10⁶ population of the test organism Geobacillus stearothermophilus can be achieved reproducibly. As an optional feature, the SKANFOG® decontamination technology can seamlessly be integrated into RABS, for easy, effective and reproducible decontamination.

### Comparison

<table>
<thead>
<tr>
<th>Item</th>
<th>Passive Open RABS</th>
<th>Active Open RABS</th>
<th>Active Closed RABS</th>
<th>Isolator</th>
</tr>
</thead>
<tbody>
<tr>
<td>production area class</td>
<td>grade A / ISO 5</td>
<td>grade A / ISO 5</td>
<td>grade A / ISO 5</td>
<td>grade A / ISO 5</td>
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<tr>
<td>surrounding room class</td>
<td>grade B</td>
<td>grade B</td>
<td>grade B</td>
<td>grade C / D</td>
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<td>active airflow system</td>
<td>no, HEPA ceiling</td>
<td>yes, overspill in room</td>
<td>yes, circulated</td>
<td>yes, circulated</td>
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<td>differential pressure</td>
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<td>no</td>
<td>possible</td>
<td>commonly used</td>
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<tr>
<td>H₂O₂ decontamination</td>
<td>possible, combined with cleanroom</td>
<td>possible, combined with cleanroom</td>
<td>possible, independent of cleanroom</td>
<td>necessary, independent from room</td>
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<tr>
<td>door opening for intervention</td>
<td>possible</td>
<td>possible</td>
<td>possible</td>
<td>not possible</td>
</tr>
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<td>products</td>
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<tr>
<td></td>
<td>non-toxic</td>
<td>non-toxic</td>
<td>optionally toxic</td>
<td>optionally toxic</td>
</tr>
</tbody>
</table>

### Material transfer

Working material can be inserted into the RABS in different ways:
- Chute for stopper bags: Ergonomical and low cost
- RTP interface with beta flange: High level of sterility and simplified validation efforts with existing bags
- Material airlock: Possible with SKANFOG® H₂O₂ decontamination

### Qualification

Qualification can be performed by SKAN at the customer’s site. SKAN’s qualification department has the expertise necessary for successful qualification. Every step of the qualification is performed according to industry standards including GMP and EN/ISO 14644-1 and 14644-3.

All protocols are handed over to the customer after completion of the qualification.
- Installation qualification (IQ)
  - Including delivery control, installation tests, line testing and more
- Operational qualification (OQ)
  - Including calibration of instruments, filter integrity tests, air flow pattern studies, functional tests and more

### Service

SKAN’s service commitment does not end at delivery. SKAN is dedicated to keeping your equipment reliable and available:
- Scheduled preventative maintenance
- Central contact for spare parts
- Technical services, using a variety of support tools
- Life cycle partnership
- Training of operators and service personnel by SKAN Academy
Isolator Technology
The experts in our Industrial Division manage the engineering, design, fabrication and validation of your pharmaceutical isolator process solution.

Lab Equipment
Our Lab Division is specialised in ensuring the safety of the user, the product and the surrounding environment in your laboratory and cleanroom.

Together always one step ahead
Together with our team of employees, our partners, our suppliers, and together with you.

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

RABS Brochure EN
Material-Nr. 1211703
Version 199691_B / 20131121