



SKAN

API - Isolators



**Isolator Systems for your Safety, Working
with Active Pharmaceutical Ingredients**



Welcome to the world of active pharmaceutical ingredients

You are processing highly active, powders with critical OEL (operator exposure level), which are subject to different process steps. Once released, the powder could be distributed everywhere.

How do you avoid:

- personal contact
- cross contamination with other substances
- escape of the product to the environment
- loss of product



The solution:

Barrier - Isolator Technology

- Clearly separates the operator from the process
- Ergonomically designed with the assistance of operators
- State of the art design sets standards in API isolator systems
- Negative pressure in isolator
- Rigid wall stainless steel housing with coved corners
- Doors and windows made from safety glass
- Small footprint
- Reduced infrastructure
- Sophisticated control systems



Benefits

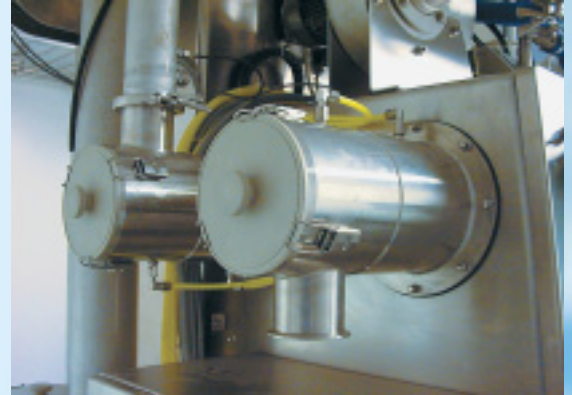
- Improves operators and process safety
- Avoids operator protection suits
- Improves personnel availability
- Improves operator comfort
- Diminishes the risk of cross contamination
- Reduces cost of production
- High safety level against operator errors
- Excellent containment against product loss
- The contaminated area is reduced to a minimum
- Filter change made easy and safe





Air flow and filter technology

- Turbulent or unidirectional air flow in the isolator
- Negative pressure versus the environment
- Intake- and exhaust air are protected by HEPA filters
- Safe filter change by push-through or bag-in-bag-out technology
- The filter cartridge can easily be safely discharged through a transfer system (RTP)
- The filter load is monitored by a pressure gauge
- The filter can be DOP (DEHS) tested in place
- The isolator can be operated with environmental air, nitrogen or any other required gas
- Any useful level of humidity can be established and controlled



Automatic and manual cleaning



- Connections for a vacuum cleaner wand allow the installation of a permanent or temporary, local vacuum cleaner
- The cleaning agent can be evenly distributed by rotating spray balls to all surfaces in the isolator
- The cleaning result is excellent due to the spray pressure and the surface quality
- A spray gun supports the CIP system on tenacious contamination
- The isolator floor is sloped to the drain

For easy and validatable cleaning



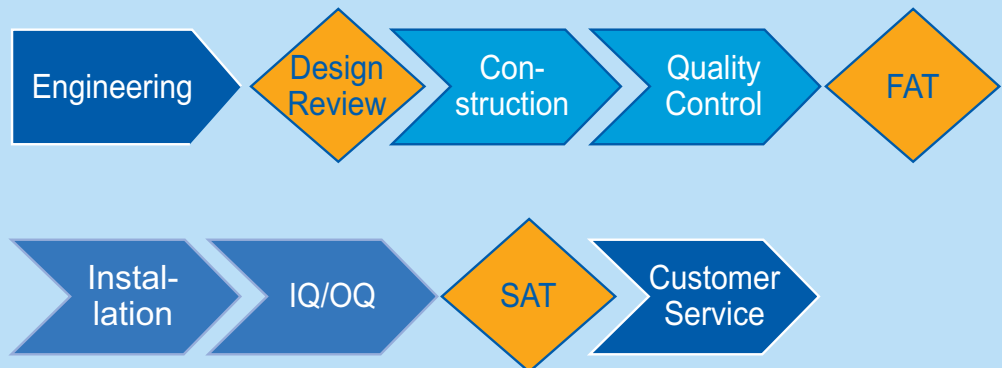
Applications

- Weighing and dispensing of actives and excipients
- Tank- and reactor charging
- Loading and unloading of mixers and granulators
- Process Isolators (milling, delumping, sieving, micronizing, roller compacting)
- Loading and unloading of tray- and filter dryers
- Filtration
- Sampling
- Product transfer
- Product packaging
- Powder filling
- Tablet and capsule filling (deduster and metal detection)
- Blister packaging
- Bottle counting, filling and cottoning
- Tablet inspection machines
- R&D laboratory isolators



Your containment solution:

Skan AG supports you from Project Evaluation to PQ



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We understand your process