Modernizations

SYNTEGON
PROCESSING & PACKAGING

RABS retrofit.

Revision of Annex 1 guidelines.

Annex 1 for the manufacture of sterile medicinal products in the EU GMP Guide was fundamentally revised. The new version was published in August 2022 and will come into force in August 2023. It explicitly recommends pharmaceutical manufacturers to apply barrier systems as part of their contamination control strategy.

Meet the requirements of this guideline by retrofitting your existing equipment with our Restricted Access Barrier Systems (RABS). This will sustainably improve your production quality.

RABS VERSIONS

Depending on your requirements, you can choose between an open or closed system in passive or active design with associated air handling unit.

The design of the RABS components such as the glove ports, material locks or transfer ports will be based on your individual specifications.

MOCK-UP

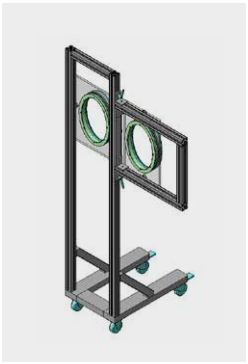
Prior to the actual retrofit, we recommend a mock-up to determine the glove ports and additional components to ensure operator-friendly and ergonomic machine handling.

The following options are available:

- Wooden mock-up at Syntegon site
- Graphic illustration of mock-up
- Mobile mock-up frame for on site usage

Active open RABS with corresponding air handling technology

Wooden mock-up, true to original



Mobile mock-up frame

YOUR BENEFITS

- Compliance with Annex 1 requirements
- Increased protection for operating personnel
- Improved product quality and safety through physical separation
- Customized and flexible retrofit of the system
- Consulting and implementation by experts

© Syntegon Group | PA/MBC3 | 05.2023 | Subject to change without notice

AVAILABLE VERSIONS AND AIR HANDLING

Based on the products processed and your safety requirements, you can choose between the following upgrade versions:

- Open RABS
- Closed RABS (e.g. for highly potent products)

Depending on the air handling type, the systems are differentiated as follows:

- Active RABS with LF unit from Syntegon or the customer
- Passive RABS with machine covering up to the ceiling provided by Syntegon or the customer

PANE MATERIAL

The following pane materials are available:

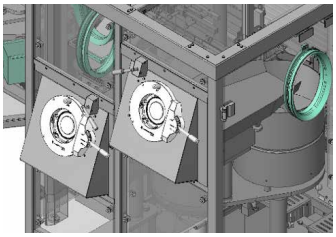
- Toughened safety glass (“ESG”)
- Polycarbonate (PC)

The machine can be equipped with glove ports either entirely or only partially, for instance in the filling area.

The machine frame is always made of stainless steel.

Passive RABS

RABS with airlock system



RABS with Rapid Transfer Ports (RTP)

DOORS

The feeding of packaging materials such as stoppers or caps can be done through:

- Airlock system for opening the sterile packaging materials under LF. The different working steps are separated from each other by separating panes.
- Sliding doors for direct refilling
- Rapid Transfer Ports (RTP) for sterile handling

Optional accessories:

- Rapid Transfer Ports (RTP) in automated version or manual version operated from outside in combination with packaging material feeding systems in order to reduce operator intervention into the process room to a minimum according to Annex 1
- Stopper supply chute for handling the stopper bags
- Bunker chutes at the sorting bowl

PARTICLE AND GERM COUNTS

On request, we can provide the following options:

- Installation of particle or germ count ports by Syntegon. Measurement and evaluation by the customer
- Installation of particle or germ count ports and measurement by Syntegon.

Together with the RABS retrofit and depending on your requirements, you can aseptically upgrade specific size parts, such as filling size parts, through the installation of glove ports. In addition, you can adjust existing components such as the filling path and stopper/capper feeder.

Furthermore, you have the possibility to implement software upgrades, for example with regard to batch logging, in order to comply with the FDA 21 CFR Part 11 guidelines. You can also replace obsolete parts or refurbish your line in combination with the RABS upgrade.

Please contact us. We will be pleased to advise you on the Annex 1 regulations. Together we will find the perfect upgrade solution for your machines.

Got a question for our experts?

Click here to find your local contact

Already registered for our E-Portal?

Get the latest information on our parts and services

What’s the level of service you need?

Click here to get your Service Agreement now

© Syntegon Group | PA/MBC3 | 05.2023 | Subject to change without notice