One Isolator for different filling machines and all packaging Formats

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Modular standard Isolator and features

Transfer options

Ready to use packaging material

Sample applications

Fast track project compared to conventional Isolator technology

Summary
Applications:
• Small scale production, startup batch sizes, clinical trial, stability batch, formulation, compounding, stopper refilling, aseptic toxic handling, ...

Environment:
• aseptic conditions
• high potent pharmaceutical ingredients

Packaging formats:
• glass bottle / vial, syringe, medical device, bag, ampoule, other...
The solution:
the adaptable, multifunctional Isolator platform
Isolator technology
A large choice of possibilities
Isolator technology
Scale up and production flexibility

Simple to scale up the filling capacity
or
parallel filling of different substances in one cleanroom
Decontamination with integrated H₂O₂ system

- Easy to use
- 100% automatic
- Decontamination SAL $10^{-6}$
- Working chamber < 210 min
Optional safe change filter system for handling of high active ingredients

Safe Change Filter System 1 - 4
Isolator technology
Material transfer with H2O2 decontamination

- Rapid transfer
- Integrated $\text{H}_2\text{O}_2$ decontamination system
- Grade A, ISO 5 with unidirectional air flow
- Automatic leak test
- Independent control system, air handling and deco-system
- Transfer time $\geq 15$ minutes
First setup and material:
• front-door / main chamber

Continuous transfer:
• RTP ports
• SART system (liquid)
• Rapid H₂O₂ airlock(s)
• Sterile endless tubing systems
• mousehole(s)
Isolator technology
Standard options

- Non-viable Monitoring stand alone unit
- Integrated particulate counter with isokinetic probe
- Air velocity sensor
- H$_2$O$_2$ sensors
- TLV sensor
- Glove stretcher
- Optional Safe-Change filter system
Isolator technology
Backside with interchangeable L-Flange
Isolator technology
L-Flange with inflatable sealing (red)
Ready to use (RTU) packaging material

- Ready to use means: washed, sterilized and packed under aseptic conditions
- Stoppers, caps in bags
- Washed, depyrogenated glass bottles in foil
- Sterile syringes in TUBs
- All packaging material needs to be $\text{H}_2\text{O}_2$ resistant
Small Scale GMP Production
Compounding process

- Connection of bulk vessel with L-flange
- Transfer of needed raw materials with RTP, SARA, etc.
- Weighing
- Blending
- Disconnection of bulk vessel
Small Scale GMP Production
Manual transfer, process automated
Small Scale GMP Production
Manual transfer, process automated

Foto: Bausch + Ströbel

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Small Scale GMP Production
Manual transfer, process automated

Foto: Aseptic Technologies

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Small Scale GMP Production
Bag filling (aseptic) max. 600 bags/h (500ml)

Foto: Bausch + Ströbel
Foto: Harro Hoefliger
Small Scale GMP Production
Vial filling, stoppering, lyophilisation, capping
Small Scale Filling
Detail vial filling, stoppering, capping machine

Foto: Bausch + Ströbel
Small Scale Process
3000 bulk vials/hour with lyophilisation, capping

2x standard lyo size of 4.5m², optional automatic loading system
Small Scale GMP Production
3000 bulk vials / hour process
Medium Scale
3000 bulk vials / hour

Foto: Bausch + Ströbel
Foto: SKAN AG
Medium Scale
3000 bulk vials / hour

Foto: Bausch + Ströbel
Stopper processor system

- Stopper/cap, siliconising, sterilisation, drying
- Sterile transfer of stoppers and caps into endless bags
- Second bag to exit the isolator
- Third bag outside isolator for transport

➡ Ready to use for several filling lines in other rooms / buildings
One single robotic machine to fill several ready-to-use containers:
- Closed Vials (filling, laser re-sealing, snap-fit capping)
- RTF glass vials (filling, stoppering, alu capping)
- RTF syringes (filling, plungering)

All containers are supplied and processed in nests

Easy change of the robot heads
Small Scale – Closed Vial Filling, Laser Re-Sealing, Capping

Foto: Aseptic Technologies
Small to Medium Scale
Up to 4000 nested syringes / hour
Medium Scale
Nested Syringe filling (4000 / h)

Foto: Bausch + Ströbel
Small Scale GMP Production
Nested Syringe Filling (front side)

Foto: Bausch + Ströbel

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Small Scale GMP Production
Plasma TUB decontamination

Foto: Groninger
Manual TUB de-nesting, automatic filling, stoppering

Foto: Groninger
Fast Track Projects

Conventional Line  <>  Small Scale Line

- air handling units
- switchboards
- pneumatics
- \( \text{H}_2\text{O}_2 \) system
- building structure
- piping, cableway
- 3m cleanroom ceiling
- Isolator
- filling machine
Conventional Line

- large technical area and cleanroom needed
- many interfaces to building structure, HVAC, media,
- more equipment's like WFI, steam
- long project time line
  - FAT after 14-20 months
  - Ready for media fill 23-33 months
- extensive custom made design and qualification
- high investment cost

Fast Track Project

Small Scale Line

- everything inside the smaller cleanroom
- only power and compressed air needed
- air from the room, back to the room with catalytic converter
- short delivery time, quick setup
  - FAT after 9 months
  - Ready for media fill 12 months
- design docs and qualification follows standards
- low investment cost
Cost comparison
(3000 2R vial per hour, 1.5m² lyo, isolator)

Conventional line
- glass vial 0.06 €
- WFI up to 0.32 € / vial
- tunnel el. power 0.01 € / vial
- cleanroom, building
- technical area needed
- > 6,0 Mio € equipment's
- engineering company's
- Requalification of add. equipment

Small Scale Line
- RTU vial ~0.35 – 1.50 €
- H₂O₂ <0.001 € / vial
- cleanroom, building -30% m²
- NO technical area
- 2,5 Mio € equipment's
- low engineering effort

All data from customers, SCHOTT, Bausch+Ströbel, Stevanato group
With the modular isolator and the described filling equipment, a flexible solution for small scale filling under aseptic, toxic conditions can be realized.

The isolator also protects the operator and the environment from hazardous material, which is processed inside. The filling equipment allows with adequate handling by the operator an automated output of 300 up to 70’000 objects per day/batch, depending on the automation grade of the system.

For small batches and clinical trials, modular filling isolators are the best alternative to a traditional clean room concept.
Thank you very much for your attention

SKAN AG
We are happy to support you

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