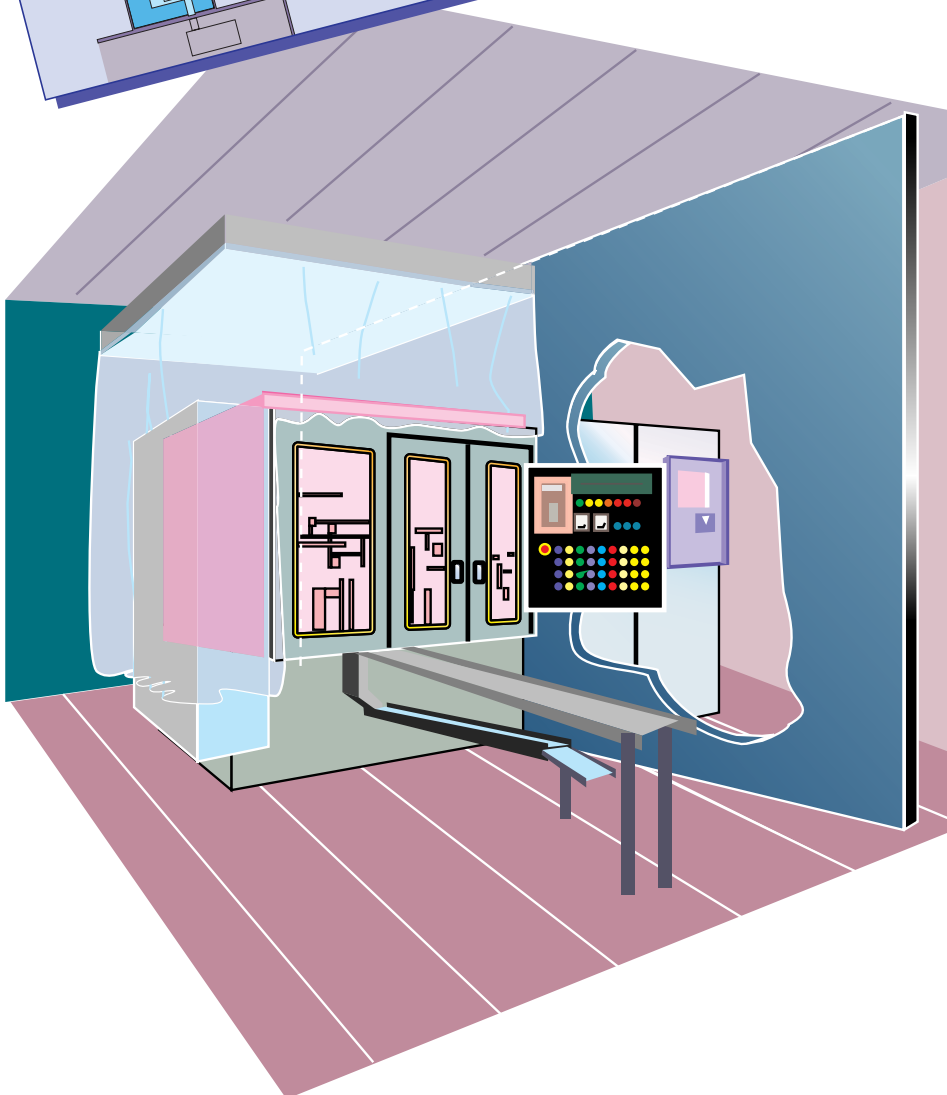
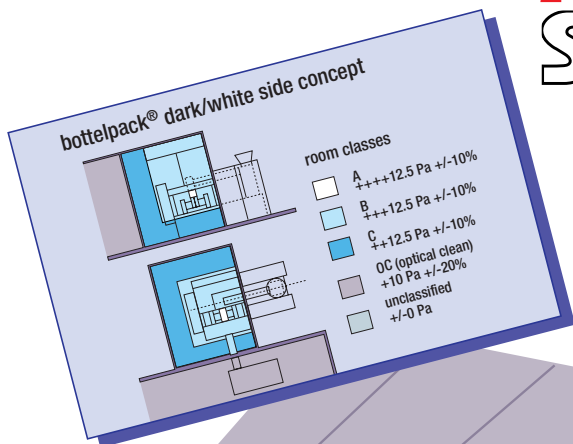


bottel

bottelpack® ASEPTIC SYSTEM

»bottelpack«®
*blow-fill
seal-technique*



The blow-fill-seal technology is today a widely accepted process in the pharmaceutical industry.

The high assurance level in the aseptic fill and the important cost savings are the main reasons for the increasing success.

Generally, it is expected that the technology will become more important in the future, as many of the expected new regulations, such as preservative-free products, tend to favour it.

Plastics in general offer a number of advantages. They can be used to produce medical packages that are patient friendly and comfortable to handle. They have reduced the risk of cross infections, they are tough, resistant to temperature shocks and are in many cases environmental friendly. They make a great contribution to health care and patient comfort.

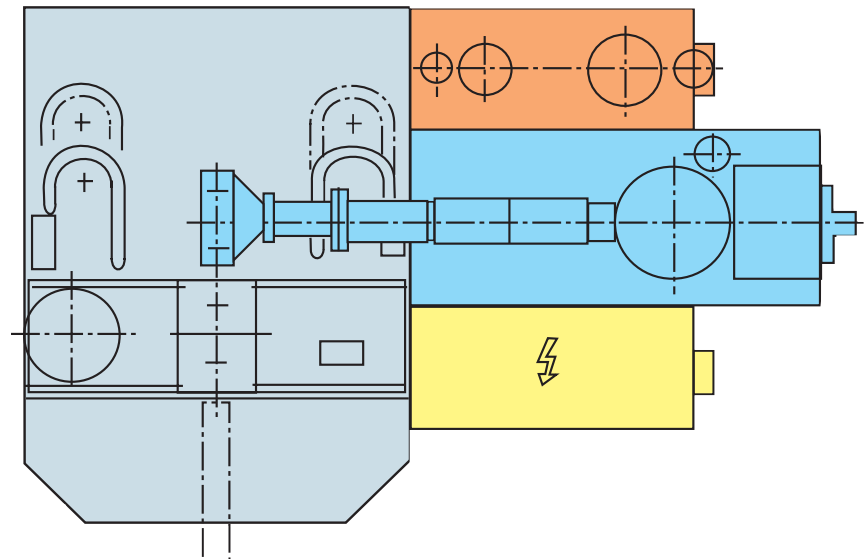
The Health Authorities worldwide are however having increasing demands and the pharmaceutical industry can expect stricter controls on aseptic processes.

Automation of the infrastructure and installations are becoming of increasing interest for the pharmaceutical industry.

The new machine generation of rommelag® is taking these requirements into account and therefore the machines are built in a way to comply with Health Authorities regulations. They are consequently constructed in order to minimise the particle generating, being potential vehicles for viable organisms.

The machine is constructed in a modular way. It consists basically of 4 individual modules:

- main frame
- extruder frame
- electronic cupboard
- service utilities



The reason for this way of construction is the achievement of

- high flexibility
- low particulate matter rate when running

The machine is in constant under-pressure towards the ambient room atmosphere.

All the service utilities are in a separate sealed cabinet, thus not generating any particles into the filling room.

In «Pharmaceutical Technology International» edition March 91, M. Rech, A. Panaggio and J. Bontempo state in their article «Current Trends in Facilities and Equipment for Aseptic Processing»: «Because personnel are a potentially significant source of contamination within the aseptic area, the more automated a filling or monitoring operation is, the less chance there is that product contamination will occur.» This statement coincides to rommelag®'s latest state-of-the-art concept.

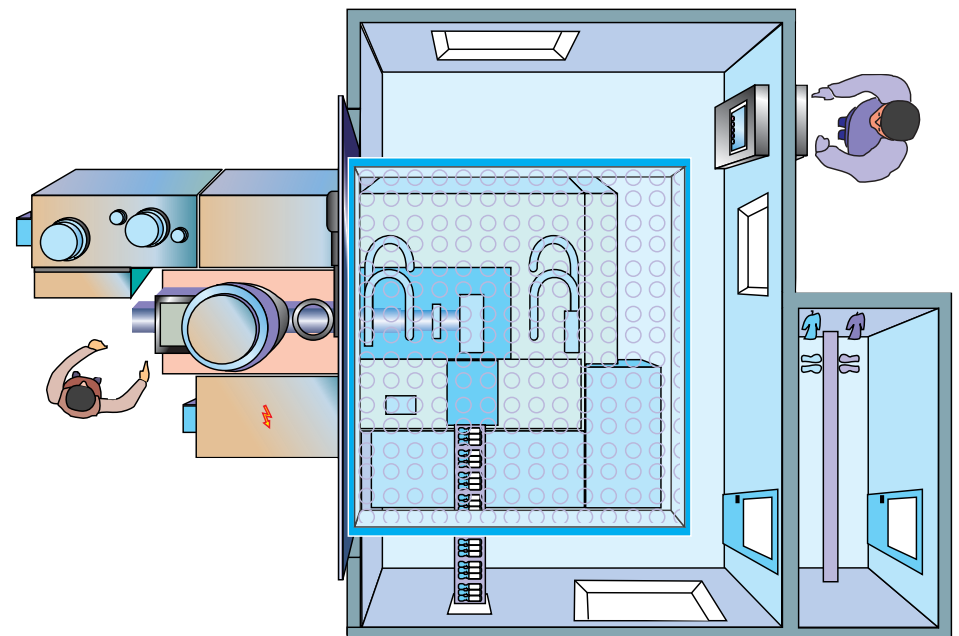
The «bottelpack»® is divided completely into two rooms

- the white side - the filling room
- the dark side - the service room

Human intervention is indeed reduced to an absolute minimum. The operator enters the filling room only for the start-up procedures. During the production no intervention in the aseptic area is required. Whatever adjustments may be

necessary, it will be done in the service room - the dark side - or with the remote control system in the packaging area. Additionally, the white side is equipped with a Laminar-Flow-Unit over the machine and the US Class 100 sterile air room around the point of fill.

Whilst it is true to say that an absolute guarantee may never exist, the latest development rommelag® offers to the industry may be considered as the most advanced technology in blow-fill-seal machinery aseptic processes.



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