

PennTech Newsletter

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Quote of the Week:

“You may have a fresh start any moment you choose, for this thing that we call ‘failure’ is not the falling down, but the staying down”
....Mary Pickford

Next Week's Topic:

- PennTech Complete Aseptic Production Lines -

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Introduction (per ISPE definition)

Human operators pose the greatest risk to product contamination during “conventional cleanroom” aseptic processing. Many different barriers of varying capabilities have been used to separate operators from critical sites during aseptic processing with the objective of reducing the probability of a contaminate unit. These range from simple flexible curtains used on many traditional aseptic processing lines to *advanced* aseptic processing in isolators. A Restricted Access Barrier System (RABS) is an advanced aseptic processing system that can be utilized in many applications in a fill-finish area. RABS provides an enclosed environment to reduce the risk of contamination to product, containers, closures, operator and product contact surfaces compared to the risks associated with conventional cleanroom operations. RABS can operate as “doors closed” for processing with very low risk of contamination similar to isolators, or permit rare “open door interventions” provided appropriate measures are taken.



Design

A RABS provides a level of separation between operator and product that affords product protection superior to traditional systems. There is no single design model for a RABS; however these systems share the following common “quality by design” characteristics:

- Rigid wall enclosure that provides full physical separation of the aseptic processing operations from operators.
- Unidirectional airflow systems providing an ISO 5 environment to the critical area.
- Sterilization-in-place (SIP) is preferred for contact parts such as fluid pathways. Where this cannot be achieved, such parts should be sterilized in an autoclave, transferred to the RABS via a suitable procedure and aseptically assembled before processing.
- Product contact parts such as stopper feed and placement systems should be sterilized in an autoclave and aseptically assembled before processing.
- Entry of material such as environmental monitoring materials, consumables, containers and closures shall be via a suitable transfer system that prevents exposure of sterile surfaces to less clean classification environments.
- Use of glove part(s), half suit(s) and/or automation to access all areas of the enclosure which need to be reached by an operator during filling operations.
- Gloves and gauntlets attached to glove ports are required to be sterile when installed; thereafter, gloves should be sanitized or changed as appropriate to minimize the risk of contamination.
- “High-level disinfection” of all non product contact surfaces within the RABS with an appropriate sporicidal agent before batch manufacture.
- Surrounding room classification should be ISO 7 minimum in operation.
- Product contact parts need to be sterilized and their sterility must be maintained. When appropriate, fitting of oversize equipment (such as stopper feeder parts) during filling setup should be followed by appropriate and thorough disinfection (product contact parts need to be sterilized).

PennTech has implemented RABS (manufactured by a third party) within its (semi and fully automatic) lyo loading and unloading systems, at both the infeed/outfeed station as well as the portable cart and AGV. The upcoming filling/stoppering/capping machine is designed to be fully RABS compatible.