

# ISPE Definition: Restricted Access Barrier Systems (RABS) for Aseptic Processing

by Jack Lysfjord

## Introduction

**A**septic processing evolved in the 1980s and 1990s with the use of isolators to separate the operator from the "critical zone" and thus reduce product risk. Restricted Access Barrier Systems (RABS) are another way to reduce the interventions that can occur in cleanroom processing through the use of a barrier and dynamic air flow and can be a viable alternative to isolators.

Because people are the "dirtiest" part of aseptic processing, reducing interventions into the "critical zone" can impact very favorably the cleanliness in the finished product. RABS incorporates a "barrier" with HEPA filtered airflow to significantly reduce the "Probability of a Non Sterile Unit" (PNSU). Stewart Davenport of Uppjohn (now Pfizer) in Kalamazoo, Michigan coined the RABS acronym in the early 1990s and presented data at the June 2001 ISPE Barrier Isolator Conference that showed media fill data from nine years of operation (almost a million cumulative media fills) from three filling lines with RABS yielded PNSU data similar to the use of isolators. Compared to isolators, RABS can allow for faster start-up time (agency approvals), ease of changeover, and reduced capital costs, particularly with retrofits and renovations.

RABS has an "S" that stands for system. Simply buying restricted access barrier hardware does not create a RABS. Many elements need to be in place to really have a RABS:

- properly designed equipment
- management oversight
- a quality system in place
- proper surrounding room design to maintain ISO 5 in critical zone
- proper gowning practice
- proper training

- initial high-level disinfection with sporicidal agent
- proper SOPs for rare interventions
  - disinfection
  - appropriate line clearance
  - documentation of event

The ISPE Barrier Isolator Technology Forums created the atmosphere for discussing the RABS definition issue. Discussions with user companies varied as to what constitutes a RABS. In discussions with Rick Friedman, FDA, many companies had been calling any enclosure a RABS whether or not it included the above-listed elements. Everyone was confused as to what is a RABS. He felt ISPE could help create a definition for RABS to help industry, the Agency and overall healthcare. We formed a committee comprised of RABS users, Agency representatives, and equipment manufacturers:

- Jack Lysfjord, *Valicore Division, Bosch Packaging Technology, USA*, Vice President, Consulting and Chairman of the RABS Definition Committee
- Michael Porter, *Merck and Company, USA*, Principal Engineer, Sterile Process Technology and Engineering
- John Shabushnig, PhD, *Pfizer Inc., USA*, Senior Manager, Global Quality Technical Services
- Joerg Zimmermann, *Vetter Pharma Fertigung GmbH & Co. KG, Germany*, Head of Aseptic Production
- Ian Symonds, *GlaxoSmithKline, UK*, Director Process Validation Global Quality
- Rick Friedman, *US Food and Drug Administration*, Team Leader for Guidance and Policy, Division of Manufacturing

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