

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

by Jack Lysfjord

Introduction

Aseptic 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 Upjohn (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

Ispe Definition Restricted Access Barrier Systems Rabs

**James Agalloco, Phil DeSantis, Anthony
Grilli, Anthony Pavell**



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Advanced Aseptic Processing Technology James Agalloco, James Akers, 2016-04-19 The preparation of sterile products using aseptic processing is considered perhaps the most critical process in the pharmaceutical industry and has witnessed continual improvement over the last half century New approaches that have transformed classical aseptic production methods are appearing almost daily This book reviews emerging technologies for aseptic processing that will markedly reduce the level of contamination risk for sterile products and includes coverage on The use of isolator and barrier concepts for aseptic processing and assembly The application of robotics as an alternative to gowned personnel The increasing reliance on automation to minimize or eliminate operator intervention The design operational monitoring and compliance changes necessary for success with advanced aseptic processing *Advanced Aseptic Processing Technology* is an essential reference for anyone working with sterile products and is recommended for individuals in manufacturing compliance regulatory affairs microbiology environmental monitoring sterility testing sterilization validation engineering development facility and equipment design component and equipment suppliers automation and robotics *Handbook of Validation in Pharmaceutical Processes, Fourth Edition* James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell, 2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations *Handbook of Validation in Pharmaceutical Processes Fourth Edition* examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry s leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes *Handbook of Validation in Pharmaceutical Processes Fourth Edition* is essential for all global health care manufacturers and pharmaceutical industry professionals **Key Features** Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture *CleanRooms*, 2008-08 A central resource of technology and methods for environments where the control of contamination is critical **ISPE Good Practice Guide** Ispe, 2011-10-18

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