

Restricted Access Barrier System (RABS)

- ISPE Definition
 - “... is an advanced aseptic processing system...”
 - “...can operate as “doors closed” for processing with very low risk of contamination similar to isolators...”



Courtesy of Telstar North America

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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

Process Intensification in the Manufacturing of Biotherapeutics, 2022-07-05 Process Intensification in the Manufacturing of Biotherapeutics Volume 59 in the Advances in Chemical Engineering series highlights new advances in the field with this new volume presenting interesting chapters on topics such as Evolution and design of continuous bioreactors for the production of biologics Continuous countercurrent chromatography for the downstream processing of bioproducts A focus on flow through technologies Application of multicolumn countercurrent

solvent gradient purification to the polishing of therapeutic proteins Continuous precipitation technologies for the recovery of bioproducts Continuous Recovery and Purification of Bioproducts on the Basis of Adsorption Technology General Platform for Development of Integrated Continuous Downstream Processes and more Provides the authority and expertise of leading contributors from an international board of authors Presents the latest release in the Advances in Chemical Engineering serials Updated release includes the latest information on Process Intensification in the Manufacturing of Biotherapeutics

ISPE Good Practice Guide Ispe,2011-10-18

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