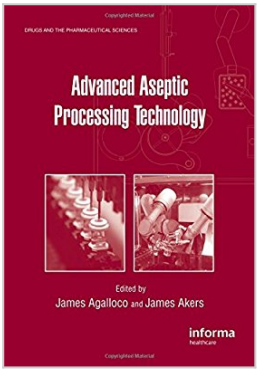

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- The use of isolator and barrier concepts for aseptic processing and assembly.
- The application of robotics as an alternative to gowned personnel.
- The increasing reliance on automation to minimize or eliminate operator intervention.
- The design, 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.

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Editorial Review

About the Author

James Agalloco is President of Agalloco & Associates. Since the formation of Agalloco & Associates in 1991, Jim has assisted more than 100 firms in the areas of validation, sterilization, aseptic processing and compliance. . He is a past President of the Parenteral Drug Association and a member of United States Pharmacopeia's Microbiology and Sterility Assurance Expert Committee since 2005. He has authored or co-authored 43 book chapters and over 100 papers, and has lectured extensively on process validation, aseptic processing, sterilization and isolation technology at various industry meetings, domestically as well as internationally. He also co-edited the book Validation of Pharmaceutical Processes, 3rd edition, Informa Healthcare, 2007.

James E. Akers Ph.D. is President and Co-Owner of Akers Kennedy & Associates and a Technical Consultant to Shibuya Kogyo, Co. LTD. Dr Akers received his BA in Biology from the University of Kansas in 1971 and his Ph.D. in Medical Microbiology from the University of Kansas, School of Medicine in 1976. He is past president of the Parenteral Drug Association (PDA) and has participated on many PDA Task Forces. He has written over 100 articles and 28 book chapters on subjects including aseptic processing, validation, biologics manufacturing, isolation technology, and environmental monitoring. Dr Akers is a Chairman of the Microbiology and Sterility Assurance Committee of Experts for the United States Pharmacopeia and has 35 years of experience working in, evaluating and providing design input for clean environments used in research and manufacturing applications.

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