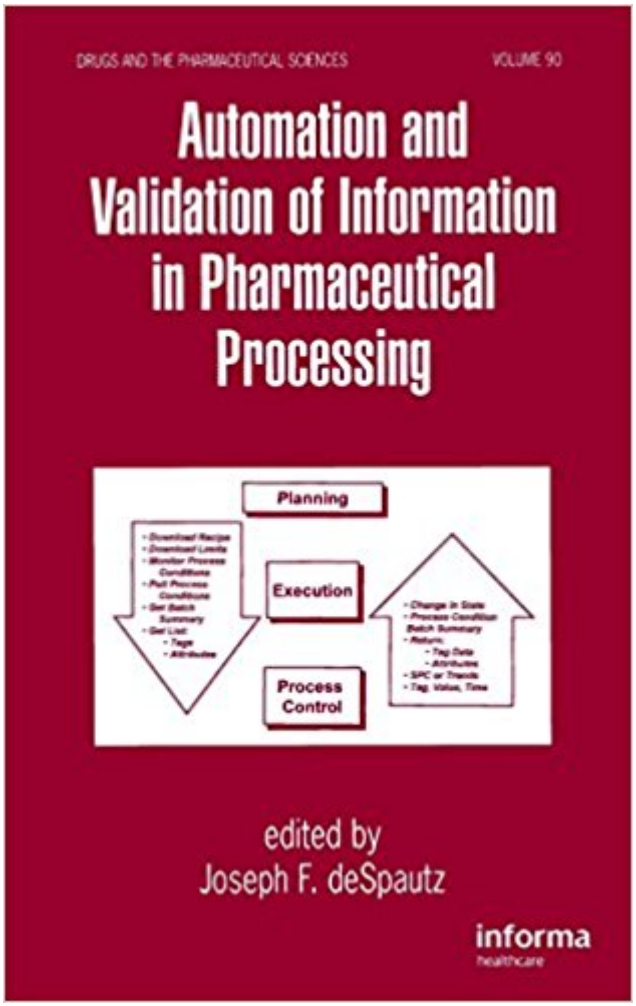
Automation And Validation Of Information In Pharmaceutical Processing (Drugs And The Pharmaceutical Sciences)



Synopsis

This thoroughly authoritative work furnishes organizational, technological, validation, project management, and business perspectives on pharmaceutical information automation from industry and system automation professionals-demonstrating how to fulfill computer system validation requirements for hardware, applications, networks, data center operations, and complex software management practices in pharmaceutical manufacturing. Explains how the Food and Drug Administration's latest Good Manufacturing Process guidelines supporting electronic identification and electronic signatures for batch record registration together with computer system technologies will influence pharmaceutical production automation! Designed to provide quick and easy access to a whole range of system development topics, Automation and Validation of Information in Pharmaceutical Processingdefines a complete life-cycle methodology that integrates equipment, people, and information presents concepts, guidelines, test plans, example forms, and application details for previously unavailable computer system validation of complex automated information systems introduces, for the first time in depth, PQ testing of integrated manufacturing execution (MES) and manufacturing resource planning (MRP) applications describes how human resource programs maximize productivity gains for automation initiatives discusses approaches to automating batch operations with process control systems using industry examples and applicable computer technology concepts provides an outline for IQ, OQ, and PQ test plans for process control systems, including forms for use in testing instrumentation and distributed control system installation and operations employs a business analysis standpoint on life-cycle planning to justify new automation projects, including multiyear drug manufacturing plans documents the successful application of life-cycle methodologies to supply chain functions and much more! Together with references, tables, and drawings, Automation and Validation of Information in Pharmaceutical Processing is an essential, hands-on resource for pharmaceutical scientists, manufacturers, and engineers; drug quality assurance and regulatory personnel; project and program manufacturers; information system professionals and software developers and analysts; information technology practitioners; and graduate-level and continuing-education students in these disciplines.

Book Information

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Customer Reviews

"For many workers in the pharmaceutical industry, the present volume will give them more information on the validation aspects of process automation than they ever dreamed possible. However, for those whose lives center around such work, the editor has developed a very comprehensive handbook. There is little about the planning, execution, and validation of automated processes that is lacking from this book, and I would think that it would become the little red book carried by every worker seeking entry into this area. "-Pharmaceutical Development and Technology "gives a splendid overview on information technology in the pharmaceutical industry.It is worth reading, or rather working with, the book. "- International Journal of Production Research

Automation of Pharmaceutical Operations Validation of Aseptic Pharmaceutical Processes Clinical Drug Trials and Tribulations, Revised and Expanded, Second Edition (Drugs and the Pharmaceutical Sciences) Transdermal Drug Delivery Systems: Revised and Expanded (Drugs and the Pharmaceutical Sciences) Controlled Drug Delivery: Fundamentals and Applications, Second Edition (Drugs and the Pharmaceutical Sciences) Drug Permeation Enhancement: Theory and Applications (Drugs and the Pharmaceutical Sciences) Microencapsulation: Methods and Industrial Applications (Drugs and the Pharmaceutical Sciences) Protein Formulation and Delivery (Drugs and the Pharmaceutical Sciences) Microparticulate Systems for the Delivery of Proteins and Vaccines (Drugs and the Pharmaceutical Sciences) Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and Development (Drugs and the Pharmaceutical Sciences)