



Validation of Pharmaceutical Processes: Sterile Products, Second Edition

F. J. Carleton, J. P. Agalloco, Carleton

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Featuring contributions from 25 specialists, this book provides a single-source reference on the design of systems, qualification of equipment, calibration and certification. It covers explicit procedures for the validation of systems required in the preparation of aseptic and nonaseptic pharmaceutical products. Topics include installation qualification, operational qualification, and change control, F, D, and Z values, steam sterilization-in-place technology and validation, sterilization methods, protocols that allow procedures to be applied directly, obstacles that may be encountered at any stage of the validation program, and suggested solutions.

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