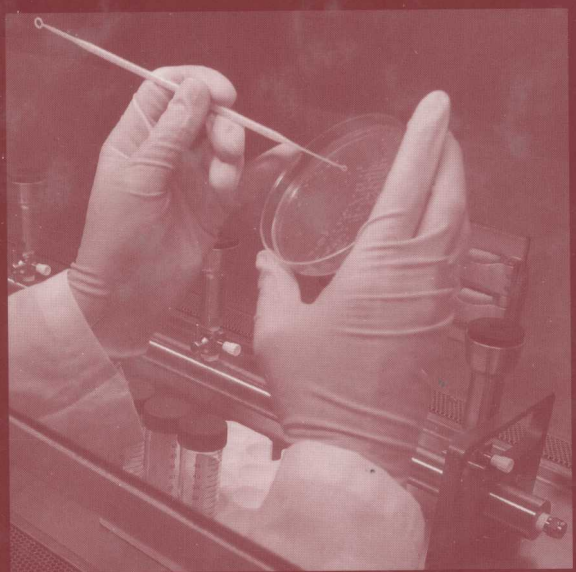
DRUGS AND THE PHARMACEUTICAL SCIENCES VOLUME 142

Microbial Contamination Control in the Pharmaceutical Industry



edited by
Luis Jimenez

Microbial Contamination Control in the Pharmaceutical Industry

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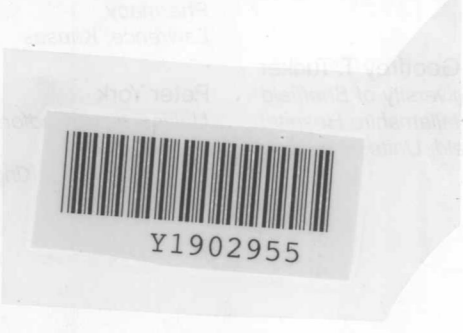

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Preface

Since the implementation of good manufacturing practices (GMPs) in the early 1970s, major improvements have been achieved in the control of microbial contamination in pharmaceutical environments. However, microbial contamination of pharmaceutical products is one of the major reasons for product recall and manufacturing problems. Knowledge of the distribution and survival of microorganisms in pharmaceutical environments is critical in the process control of nonsterile and sterile pharmaceutical products. This knowledge is somewhat limited by the ubiquitous distribution of microorganisms in manufacturing facilities, the diversity of microorganisms in environmental samples, and the flexibility of microorganisms in surviving under different environmental fluctuations. Optimization of pharmaceutical manufacturing has led to more efficient testing systems to monitor the analysts, environment, water, raw materials, and finished products that are the major sources of introduction of microorganisms into the processes. However, to avoid microbial contamination, adherence to GMP is the foundation for manufacturing safe and efficacious pharmaceutical products.

With the latest developments in computer science, automation, genomics, combinatorial chemistry, and process control, the manufacture and quality control analysis of pharmaceuticals will be changed significantly. Therefore, optimization of quality control analysis in pharmaceutical oper-

ations has become an interdisciplinary endeavor that requires communication and cooperation between microbiologists and other scientists. This book discusses major issues regarding testing and quality control in pharmaceutical manufacturing, which will ensure product and process integrity. Why is it important to control the presence of microorganisms in a manufacturing facility? What systems do we need to prevent this contamination? What tests do we perform to guarantee the safety and efficacy of the products manufactured under those conditions? What new technologies are available to optimize sample analysis and manufacturing? What regulations must be followed to provide quality products? We hope to provide answers to all these questions. This book is aimed at pharmacy students, chemists, engineers, pharmaceutical scientists, and microbiologists working in or associated with the pharmaceutical industry, with the intention of being a first step toward the understanding of microbial control in pharmaceutical environments.

Luis Jimenez

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