DRUGS AND THE PHARMACEUTICAL SCIENCES VOLUME 64

Achieving Sterility in Medical and Pharmaceutical Products

Nigel A. Halls

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Preface

The purpose of this book is to help practitioners in the field who manufacture sterile products, pharmaceutical products, and medical devices to understand what needs to be done to achieve sterility. It is not intended for experts in specific sterilization technologies; indeed, that would necessitate a multivolume, multiauthor work.

Achieving sterility is an important aspect of quality assurance. In the pharmaceutical industry, quality assurance is most often dominated by personnel in analytical chemistry. In the medical device manufacturing industries, engineers tend to be most strongly represented. Real expertise in sterilization, particularly in sterilization science, is often concentrated among a limited number of microbiologically qualified staff who have gained their knowledge through hands-on experience of specific technologies. This book attempts to cover a wider spectrum of sterilization technologies than most practitioners might ever encounter in a working lifetime with one company or organization. It is intended to increase the breadth of knowledge of the sterilization specialist beyond the boundaries of his or her hands-on experience and to assist in communicating the fundamentals of the main sterilization technologies to interested personnel who work in this area but do not have a strong microbiological background.

A further purpose of this book is to bridge the knowledge gap for students and recently qualified graduates who may be moving or wishing to move into the sterile products manufacturing industries. There are few sources of information

on achieving sterility lying between the general academic texts on microbiology and the level of detail and minutiae contained in advanced research papers, reviews, and guidelines on specific technologies.

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