# MICROBIAL IDENTIFICATION: THE KEYS TO A SUCCESSFUL PROGRAM



# Mary Griffin and Dona Reber Editors

# Microbial Identification: The Keys to a Successful Program

Mary Griffin and Dona Reber Editors

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### FOREWORD

My excitement about the publication of *Microbial Identifications: The Keys to a Successful Program* resonates with me on several levels. The first fulfills a need as an FDA regulatory microbiologist and the second as a university professor. Finally, the authors' contributions are vital because they are internationally recognized experts in their respective microbiological niches. Many of these individuals are personal friends of mine, and I have collaborated professionally with many of them for over 30 years. My respect for their credentials and communicative abilities is unqualified. For anyone who pursues a career in the pharmaceutical, medical device, cosmetic, biotechnology or related health care industries; and those who participate in the regulations of these industries this publication is a must-read.

Those of us who are career industry/government/academia microbiologists are well aware of numerous other publications that address the topic of Microbial Identification. Although one should not minimize their contribution to the fields of microbiology and healthcare, the difference between these preexisting references and the contents of *Microbial Identifications: The Keys to a Successful Program*, should be made clear. The defined chapters in this book

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present a well-balanced scientific rationale for the application of current technology together with personal experience/experiments in conjunction with data derived from these classic textbooks and peer review literature. The synergism of sound fundamental microbiology, emerging contemporary instrumentation and the application of today's risk-assessment priority will label this work as a new benchmark for literature excellence in pharmaceutical microbiology.

The ubiquitous presence of microorganisms, whether bacteria, fungi or viruses, have been the cause of contamination in people, processes and products throughout time. The need to identify and track the specific species when these outbreaks occur is critical for the epidemiology and trace-back activities associated with locating the microbial source in an effort to remediate the cause. The range of topics covered in the 16 chapters of this reference book will make the task unequivocally easier when investigating microbial problems and proposing pragmatic solutions or explanations. The authors are insightful, comprehensive and balanced in their prospective viewpoints and allow the reader the full availability of additional citations in support of their positions. This book is uniquely written in order to assist with the understanding and application of "The Keys" to address the microbial identification for the many industrial component and government responsibilities performed by pharmaceutical microbiologists. Individual scientific facts are always important, but detailed advice from experts, with decades of experience, is priceless.

The regulatory and industrial application of this book cannot be overemphasized. There has been a global realization regarding the importance of microbiological identification by governments and standard setting institutions. The risk assessment of microbial intrusion on a wide range of consumer products (or their manufacturing environments and components), both sterile and nonsterile, has become codified in regulatory requirements as well as compendial standards. *Microbial Identifications: The Keys to a Successful Program* clearly and effectively describes these changes so that the reader is not caught unprepared to meet the paradigm shift that has emerged from both domestic and international cGMP regulations. Foreword

Perhaps one may be confronted with the need to purchase a new rapid micro method (RMM) platform for microbial identification. The choices are numerous. Consequently, this makes selecting the best RMM for your purposes all the more challenging. The principles and benefits of most RMMs are clearly described in this book. The reader gets real solutions to the essential questions of "Why, When and How" when making these important decisions. I assure you that the reader will find an appropriate chapter to address their microbiological quandary.

I am grateful for the opportunity to write the foreword to this text book. Its contents will be beneficial to a multitude of readers: inclusive of industrial/government/academic microbiologists, quality assurance and control, risk management and decisionmaking personnel.

> Dennis E. Guilfoyle, Ph.D. Pharmaceutical Microbiologist Northeast Regional Laboratory US Food and Drug Administration

*Disclaimer: These comments are those of the author only and do not necessarily represent the positions of the FDA.*