# Microbial Control and Identification

## Strategies

## Methods

## Applications

Dona Reber and Mary Griffin
Editors

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We dedicate this book to Cynthia Sarnoski, Ph.D., our long-time mentor and advisor who offered invaluable encouragement and support throughout the writing and editing of this book.

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# FOREWORD

Many years have gone by since I first dabbled in microbiology, specifically as it relates to the manufacture of medical products and the impact microbiology has upon the pharmaceutical industry worldwide. I would have greatly appreciated being better versed back in those days with *Strategies, Methods, Applications*, all topics that remain to be within our focus and scientific realm of interest.

The book's stable of authors are subject matter experts, world renowned and highly respected microbiologists in their respective field of science. That said, you will appreciate reading their depth and breadth of experience regarding current microbiological challenges. For example, Cundell, Moldenhauer, Mateffy and Sandle provide their perspectives on strategies that you will find worthy of your consideration.

The microbiological control and identification as well as microbiological assessment are areas that we all, and quite rightly so, continue to focus our energies and resources. Part and parcel with microbial identification includes trending of the microbial data and corrective measures that may need to be implemented to preclude and/or reduce the presence of microbial and bacterial endotoxin contamination. We all appreciate an inability to escape

from having a scientific discussion without including some form of risk assessment and risk management, which is no less important with regards to viral inactivation. I dare say you will find the chapter worthy of your read.

The rapid microbiological methods (e.g., MicroSEQ®, MALDI-TOF) are more common place in todays' laboratories and a far cry from someone who used to prepare a sea of the biochemicals, micro-bial test reagents, poured a river of agar plates and yes, indeed I washed my share of test tubes. The chapter includes laboratory equipment qualification considerations that historically may have not been performed by the laboratory staff. The reader will find it rewarding as they come to better understand and better appreciate how the equipment qualification can impact the microbiological results.

There is a subject that has captured much of our time and to a notable extent has stretched precious resources. Jeanne Moldenhauer provides welcomed guidance and perspectives on this subject, Data Integrity, which you will find worthy of consideration to address and implement the necessary measures to preclude the accidental or unintentional deletion or omission of microbiological data.

I continue to assess how well a company understands the microbiological impacts upon the manufacturing processes. Irrespective of whether the commodity is sterile or non-sterile, a comprehensive microbiological assessment is value added to any manufacturing operation. Equally important, which all have heard me say throughout the years, did the comprehensive assessments include a Microbiologist at the discussion table during the evaluation and implementation process. The individual topics within the text are of welcomed value to any organization. That said, when considering the *Strategy, Methods and Applications*, *collectively*, I would point out that is not unlike how I might possibly assess a medical products manufacturer.

**Thomas J. Arista**
June 14, 2018

# PREFACE

It has been six years since we edited our initial volume on *Microbial Identifications: The Keys to a Successful Program* for the PDA and DHI Publishing, LLC. Microbial identification continues to evolve with new technologies and expectations, yet remains so fundamental to microbial control of quality biopharmaceutical products.

We decided it was the perfect time to once again bring together a group of expert microbiologists and biopharmaceutical industry leaders to discuss microbial identifications in a new light, that of how microbial identification knowledge is a cornerstone in the concept of microbial and contamination control programs. The chapters show how microbial control programs for our facilities, equipment and personnel result in a positive impact on our products and ultimately our patients.

Some of these authors were included in our initial volume and we welcome them back for their continued support and excellent and informative chapters: Drs. Anthony M. Cundell, Jeanne Moldenhauer, Martina Kopp and Houman Dehghani. The remaining authors are new for us, but not to our industry by any means – all are

well known for their expertise, and we are very pleased that they have joined us here. Please open the book and you will most likely recognize some of these authors, others are newcomers to writing chapters, and we are delighted they all rose to the challenge.

This book has three sections: Strategies, Methods and Applications. Strategies cover regulations and regulatory expectations as well as strategies for trending, risk assessments, and risk management. Methods include current best practice microorganism identification methods, both conventional and emerging rapid methods for bacteria, viruses, mycoplasma and fungi. Applications include microbiology laboratory training for identifications, use of environmental and control microorganisms, disinfectant effectiveness and best practices, and an up and coming chapter subject, biosafety for laboratories, manufacturing facilities and personnel.

It is recognized that each author has taken time from his or her very busy schedules and free time because of a passion for microbiology and microbial control, and with it the desire to share knowledge with others in our industry. This is very much appreciated by us. We also share this passion and dedication as evidenced by our many years of working and presenting on microbiological issues.

This text will provide valuable information for the new microbiologist as well as a reference for well-seasoned professionals. We sincerely hope you enjoy the book.

Dona Reber and Mary Griffin
June 2018

# ABOUT THE EDITORS

**Dona Reber** has more than 25 years of academic and industrial microbiology experience, including developing and implementing contamination control strategies for aseptic/non aseptic manufacturing, microbiology testing/development, and managing/networking microbiology laboratories. She is Senior Manager of Microbiology and Aseptic Support, Global Quality Operations for Pfizer, responsible for assessing aseptic processing facilities, investigations, troubleshooting, and developing policy documents for microbiology.

Dona holds B.S. and M.S. degrees in related sciences, is (SM) NCRM certified, has been a PDA member for 20+ years, and a longtime chair of the Pharmaceutical Micro Expert Discussion Group. She has numerous publications on microbial identifications systems, environmental monitoring and microbiology risk assessments. She has co-authored three PDA Technical Reports: TR#13, Fundamentals of an Environmental Monitoring Program; TR#67, Exclusion of Objectionable Microorganisms from Non Sterile Pharmaceutical, Medical Devices and Cosmetics; and TR#70,

Fundamentals of Cleaning and Disinfection. She is on a PDA Task Force for Low Bioburden Environmental Monitoring. She has participated in instructing new FDA inspectors, and is an instructor for the PDA on TR#13, Fundamentals of an EM Program. She presented at the most recent PDA Micro Conference on environmental monitoring for low bioburden processes.

**Mary Griffin**, Principal, MG Quality Microbiology Consulting, LLC, is a subject matter expert in microbiology with more than 35 years of academic (University of Michigan; University of Massachusetts) and global biopharmaceutical experience.

She initiated and directed the Quality Control Microbial Science and Technology department at Pfizer (previously Wyeth, Andover, MA) during a period of significant growth. She adapted her extensive knowledge of microorganisms and classical identification techniques to successfully implement both identification and rapid automated detection systems to keep the facility on the cutting edge of novel technologies.

She continues to support the industry as a consultant through the application of her microbiological identification and rapid technologies expertise for microbial control. She holds a M.S. degree in Microbiology and is certified as a Specialist Microbiologist SM (NRCM). She is an active member of the Parenteral Drug Association (New England Chapter) and is published in the pharmaceutical industry.