# ENVIRONMENTAL MONITORING



## COMPREHENSIVE HANDBOOK

VOLUME 8



### Jeanne Moldenhauer



### ENVIRONMENTAL MONITORING

A Comprehensive Handbook

JEANNE MOLDENHAUER Editor

Volume Eight

PDA Bethesda, MD, USA DHI Publishing, LLC River Grove, IL, USA

To order the book, please visit: go.pda.org/EM8

### 10 9 8 7 6 5 4 3 2 1

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### **PDA Global Headquarters**

Bethesda Towers, Suite 600 4350 East-West Highway Bethesda, MD 20814 United States www.pda.org/bookstore 001-301-986-0293

### Davis Healthcare International Publishing, LLC

2636 West Street River Grove IL 60171 United States www.DHIBooks.com

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### INTRODUCTION

This is volume 8 of the *Environmental Monitoring Handbook* series. Each volume of this series discusses different aspects of environmental monitoring. The Appendix describes the various topics and authors that can be found in volumes 1 through 7 of this series.

There are a variety of topics covered in this book. In some cases, it may be a topic introduced in other volumes, but this chapter is a new take on an old subject. Other topics are brand new to the series.

Dr. Tim Sandle discusses the changes in ISO 14644-1 and 2. Like all of Dr. Sandle's work, you won't want to miss this definitive piece! In other regulatory topics, Dr. Claudio Denoya and Dr. Gilberto Dalmasso provide a detailed discussion on the Suggested Use of Contamination Rates as shown in USP <1116> for Aseptic Processes. Both of these authors have a long history working in production facilities, so this is a really practical chapter. Fran McAteer wrote a great chapter on compounding pharmacies and implementation of USP <797>. This is a hot topic in the industry. Ending this section Jeanne Moldenhauer provides an update on changing regulatory requirements — presenting information presented by Dr. Lynne Ensor and Mr. Thomas Arista at recent PDA meetings.

Dr. Olivier Chancel has a great chapter on environmental monitoring excursions, with lots of interesting case studies. Dr. Randy Hutt and Dr. Robert Westney also provide their perspective on environmental excursions. Jeanne Moldenhauer and Brian Hubka have a chapter on changing the paradigm for disinfectants and cleaning. Another great chapter is by Michael Hodgkinson, which deals with handling aging facilities.

Elvira Engelmann and Frank Kugler work in a company that is a major source of microbial identifications in Europe. They have extensively evaluated the Maldi-TOF for organism identification. Their chapter describes the pros and cons of using this instrumentation. Claire Briglia, Anne Connors, and Tim Cser describe environmental monitoring methods to utilize for production isolators. Parsa Famili and Susan Cleary describe a new automated tool used in the cleaning validation program to determine when validation is due, and whether new product formulations fit into your validation matrix.

There is a wealth of useful information that you can use in establishing, maintaining and updating your environmental monitoring program!