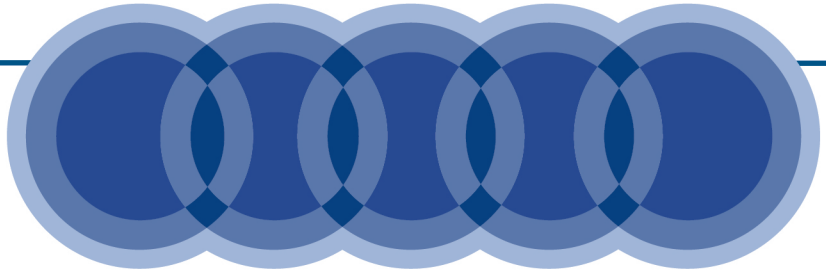
Environmental Monitoring

A Comprehensive Handbook

Volume 7



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ENVIRONMENTAL MONITORING

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

10 9 8 7 6 5 4 3 2 1

ISBN: 1-933722-85-1

Connecting People, Science and Regulation®

This book is printed on sustainable resource paper approved by the Forest Stewardship Council. The printer, Gasch Printing, LLC, is a member of the Green Press Initiative and all paper used is from SFI (Sustainable Forest Initiative) certified mills.

PDA
4350 East West Highway
Suite 200
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 7 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 6 of this series.

One of the first topics discussed in this volume is the topic of cleanrooms and ways to prevent contamination. This is important — as an industry and we are changing the paradigm from reacting to contamination to a mode of preventing contamination. Dr. Tim Sandle provides a great guide to cleanrooms. This is followed by a discussion of methods to protect cleanrooms from contamination. Jan Eudy describes the methods to be used for gowning and gowning qualification to protect from contamination. Jim Polarine and his group have written a discussion on the cleaning and disinfection of cleanrooms. As we are always looking for new and/or better ways to do things, John Lindsay has a chapter on the qualification of a new disinfectant. This disinfectant is effective with approximately one minute of contact time! Two new methods of contamination control: Brian Hubka discuss the use of gaseous/vaporized ozone and David Opie discusses the use of nitrous oxide.

The second section of the book describes various environmental monitoring techniques and methods. As you have seen in various earlier volumes, Burke has a chapter on how to set up an environmental monitoring program. It is useful to look at the various different methods individuals have used to customize the program that will work best for your site. Another hot topic in today's compliance arena is sampling plans. Marinelli discusses the methods to use in setting up a sampling plan for your site. Klees and Hedderich provide useful information on the

efficiency of microbiological methods that are used for environmental monitoring. Many times wrong assumptions are made about the environmental data, because we don't understand the efficiency of these methods. When using growth-based methods, a common complaint is the long time it takes to get results. Dr. Sage has identified how to optimize the time you need to get results using these types of methods. In recent years several companies have evaluated and/or implemented newer environmental monitoring methods that are based upon the use of viability methods. One on-going concern with these types of methods is how you could do an investigation should you have a contamination event. Sean Toler describes a program implemented that conducts real time risk assessment along with a viability-based methodology. Tim Cser explains the conduct of environmental monitoring for compressed gases and Claire Fritz-Briglia provides information on the conduct of environmental monitoring to support sterility testing in an isolator environment.

The third section of the book deals with changes to standards. Memarzadeh and DiBerardinis explain the changes that occurred for ANSI Standard 29.14 and how this is applicable in pharmaceutical environments.

The last section of this volume talks about new technologies and aids that can be used in evaluating these methods. Dr. Sage provides a defined program for creating and using stressed organisms in the validation of alternative microbiological methods. Dr. J.P. Jiang explains how the IbioScan works. This technology detects the presence of viable biological particles in water monitoring in real time.

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