

PMF Book Review October 2025

Environmental Monitoring – A Comprehensive Handbook Volume 9 Jeanne Moldenhauer (Editor) Euromed Communications/PDA 381pp Member Price \$269

Jeanne Moldenhauer must be congratulated for editing the 9th edition of the series of books entitled *Environmental Monitoring* which begun as a two-volume set in 2005. A 20-year commitment is remarkable. Her selection of 17 book chapter authors certainly justifies the subtitle of *A Comprehensive Handbook*. Very welcomed are the chapters on material transfer in controlled areas and airflow visualization, which are emphasized in regulatory inspections (Tim Sandle) and mold remediation (Crystal Booth). Mold contamination has been an under appreciated risk in sterile product manufacturing facilities, so it was apt that 4 chapters address this topic. However, not mentioned in the book was the PDA Technical Report No. 55 *Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries*. 2012, which indicated that the taints to tablets were derived from fungal growth on chemical-treated wood pallets stored outdoors. In this case, a comprehensive understanding of the mechanism of taint generation has eliminated the problem.

This reviewer does not share the view that an increased level of environmental monitoring is necessary to compensate for the well-known lack of efficacy of the sterility test. I believe that better risk assessment driven by the 2003 EU Good Manufacturing Practices Annex 1, the implementation barrier systems (restrictive access barrier systems and isolator systems) that exclude people from aseptic processing areas, vapor or gaseous decontamination of critical areas, and advances in in-process control using the biofluorescent particle counting technology will diminish the levels of traditional environmental monitoring, reversing the 20-year trend.

The book certainly will help microbiologists, quality professionals, manufacturing personnel, and process engineers better understand environmental monitoring and control. Those newly implementing an environmental control program will find the chapters on pharmaceutical (Marsha Steed) and 503A sterile compounding programs (Susannah Davis) very useful. The chapter on facility decontamination (David Shields et al) and biofluorescent particle counting (Christine Troutman), clinical mycology (Maria Lampou and Michael Mansour) and risk assessment (Vanessa Figueroa) are all timely.

From a book production point of view, the generous use of tables, figures, photographs to illustrate concepts and provide images of fungi enhance the usefulness of the book.

I recommend that pharmaceutical microbiologists arrange to purchase this book either as a hardcopy or eBook as reference material.

Tony Cundell, Ph. D.
Microbiological Consulting, LLC
Rye, New York, USA