

# WORKSHOP ENVIRONMENTAL MONITORING

**São Paulo, September 11 - 13, 2019**

## **September 11 - Jeanne Moldenhauer**

- 08:00 • Introduction to Environmental Monitoring Programs
- Regulatory Requirements
- Definitions

---

- 10:00 • Elements of an Environmental Monitoring Program
- Master Plan Requirements
- Environmental Monitoring Action Committee
- Selection of Sampling Locations

---

- 13:00 • Types of Monitoring, Methods and Equipment

---

- 14:30 • Completion of Monitoring Types
- Sampling Frequency
- Temperature, Relative Humidity, and Differential Pressures
- Use of Anaerobic and Selective Media
- Incubation Conditions
- Identification of Isolates

---

- 16:00 • Risk Management for EM Programs

---

- 17:00 • Questions/Comments

## **September 12 - Jeanne Moldenhauer**

- 08:00 • Qualification of the Environmental Monitoring Program

---

- 09:00 • Alert and Action Levels
- Trending
- Investigating Non-Conformances

---

- 11:00 • Product Impact Assessment
- Objectionable Organisms / Organisms of Concern
- Burkholderia Cepacia Complex
- Corrective Actions

---

- 13:30 • Evaluating the Effectiveness of Corrective Actions
- Changing from Remediation to Prevention
- Adverse Findings

---

- 15:30 • Questions/Comments from Day 2
- Wrap Up for Two Day Course

## **September 13**

- 08:00 EM Sampling - Rodrigo Oliveira
  - Nonviable Particles
  - Viable Air and Surfaces
  - Personnel Monitoring
  - Equipment examples

---

- 09:00 Establishing Cleaning and Sanitization Program - Jose McCall - Steris  
Selection of cleaning and disinfectant agents
  - Mopping
  - Rotation
  - Disinfection efficacy studies
  - Spore and mold problems How to clean/sanitize clean areas

---

- 13:00 EM Personnel Certification for Sampling and Reading - Rodrigo Oliveira
- 14:00 Data Integrity for EM - Tereza Amaral
- 15:00 Environmental Monitoring Plan pos-shutdown/ "at rest" and "under operation" scheme - Vitorio Santos
- 16:15 Contaminated Media Fill Investigation - practical training  
Vitorio Santos e Rodrigo Oliveira



## **BRAZIL CHAPTER**

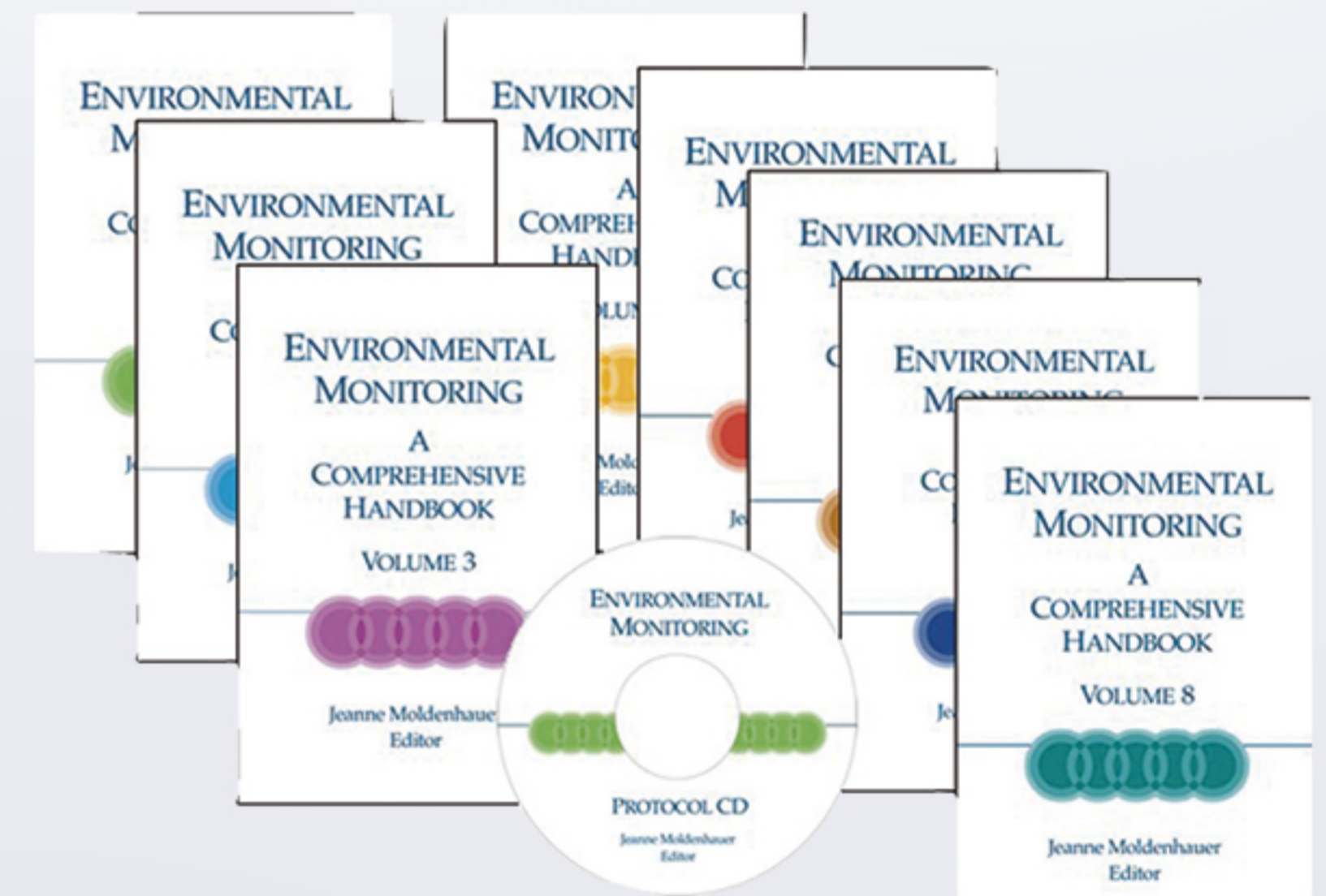
### **SPEAKER - SEPTEMBER 11 - 12**

## **Jeanne Moldenhauer**

Consultant in the Pharmaceutical, Biotech, and Device Industry. Experienced in environmental monitoring, remediation of regulatory inspection issues, compliance assessments, microbiology, quality assurance, quality control, validation, risk management, software validation, Sterility Assurance, Sterilization, Aseptic Processing, Process Analytical Technology-PAT, and Contamination Control.

### **ENVIRONMENTAL MONITORING BOOKS**

You can buy by [www.pda.org](http://www.pda.org)  
and Jeanne will sign it



### **SPONSOR**



**CONTACT:** [ma@pdabrazil.org](mailto:ma@pdabrazil.org)  
(11) 2894 - 9730/31

**Price:** PDA member : R\$ 1.700,00  
Non member : R\$ 2.000,00