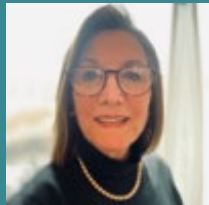




Knowledge is Power

New England Chapter of the PDA is excited to offer the next webinar in our series.

Environmental Monitoring (EM) Trending Concepts



WEBINAR

Presenter: Dona Reber

Director, Microbiology and
Aseptic Control (Retired)
Pfizer

When.....: May 18, 2022 2:00pm - 3:30pm EDT

Fee.....: PDA Members \$25 / Non-Members \$65



Presenter: Peter McGarrigle

Director, Environmental Monitoring
Business Lead, Global Supply
Pfizer

Current Environmental Monitoring (EM) trends and industry expectations:

Are you trending in the right direction?

Don't miss this opportunity to work with EM experts, share their experiences
and analyze group exercises to assess control.

Discussion points will be:

- Introduction to EM Trending
- EM Trending and the recently revised PDA TR#13, Fundamentals of an Environmental Monitoring Program
- EM Trending and the latest draft of EU GMP Annex 1: Manufacture of Sterile Medicinal Products
- Examples of Visual EM Trending Data
- EM Group Exercises, "Is the Area in control?"
- Summary, comments and questions

Who will benefit:

- QA / QC
- Operations / Manufacturing
- Regulatory
- Contamination Control Programs

Dona Reber has more than 35 years of academic and industrial microbiology experience, most recently as Director of Microbiology and Aseptic Support for Pfizer, where she and her team globally transformed the EM trending program during 2020-2021. She has developed and implemented contamination control strategies and performed troubleshooting for aseptic manufacturing and led the networking of aseptic and non-aseptic microbiology laboratories for Pfizer and Wyeth.

She participated in authoring the most recent revision of *PDA's Technical Report (TR) #13, Fundamentals of an Environmental Monitoring Program*, and is an author of the new draft TR on Contamination Control Strategy. She has been a co-instructor of the PDA's course on EM for the past 8 years and has participated in the instruction of new FDA inspectors. She is the co-editor of the following textbooks: *Microbial Identification: The Keys to a Successful Program* (2012) and *Microbial Control, and Identification, Strategies, Methods, Applications* (2018) for which she received the PDA's Distinguished Editor/Author Award. In 2020 she received a Global R&D and Medical Quality Team Award at Pfizer for her support in development of the Covid-19 vaccine. She strives to make microbiology-related issues understandable for non-microbiologists, including EM trending.

Peter McGarrigle has more than 25 years of pharmaceutical production and quality experience, currently as Director, Environmental Monitoring Business Lead for Pfizer, where he works closely with digital and manufacturing site teams to modernize Environmental Monitoring programs. For more than ten years he has supported aseptic and biotech manufacturing sites in roles focused on aseptic training, contamination control, and investigations. Since 2019 he has worked with global teams to accelerate EM business processes at critical aseptic and biotech production sites including those manufacturing the COVID-19 vaccine. Peter is focused on ensuring life-saving medicines reach patients globally.

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