

# RAPID MICROBIOLOGICAL METHODS (RMM)

September, 04 - 06, São Paulo - 2019

## TRAINING COURSE AGENDA

- Introduction to RMMs and the Need for Change
- Overview of Implementation Strategies and Applications
- Regulatory Policies and Validation Expectations (FDA, EMA, global compendia, rest of world)
- New Policies for Rapid Sterility Testing of ATMPs
- Technology Reviews
  - Growth-based methods
  - Cellular-component-based methods
  - Viability-based methods
  - Spectroscopic-based methods with a focus on real-time environmental monitoring
  - Gene amplification-based methods
  - Next gen methods (e.g., lab-on-a-chip, microarrays)
- Comprehensive Review of Validation Strategies
- Overview of statistical analyses when validating RMMs
- How to Calculate a Return on Investment for RMMs
- Course Summary
- Review of Online Resources

### **Speaker Dr. Michael Miller**

Dr. Michael J. Miller is an internationally recognized microbiologist and subject matter expert in pharmaceutical, biotech and medical device microbiology and the design, validation and implementation of rapid microbiological methods (RMM). Dr. Miller holds a Ph.D. in Microbiology and Biochemistry from Georgia State University and a B.A. in Anthropology and Sociology from Hobart College.

For almost 30 years, he has held numerous R&D, manufacturing, quality, business development and executive leadership roles at multinational firms such as Johnson & Johnson, Eli Lilly and Company and Bausch & Lomb. In his current role, Dr. Miller consults with multinational companies in providing technical, quality, regulatory and training solutions in support of RMMs, sterile and non-sterile pharmaceutical manufacturing, contamination control, isolator technology, environmental monitoring, sterilization, antimicrobial effectiveness and pharmacy compounding. He has also served as a pivotal microbiology expert witness on numerous patent infringement and product liability cases.

Dr. Miller has authored more than 100 technical publications and presentations. He currently serves on the editorial and scientific review boards for the PDA Journal of Science and Technology. He is currently the President of Microbiology Consultants, LLC

