Rapid Microbiological Methods

Overview

This comprehensive course is designed to provide an intensive review of currently available rapid microbiological method (RMM) technologies, validation strategies, applications, regulatory expectations, financial justification models and implementation plans. The use of rapid methods for conventional pharmaceuticals, biotech and short shelf life products, including advanced therapeutic medicinal products (ATMP; gene and cell therapy) will be specifically integrated into the discussions. Taught by one of the industry's global leaders in rapid methods, the attendee will be immersed in discussions that will provide a meaningful and understandable roadmap for how to evaluate RMMs and employ them in their own laboratory and manufacturing areas.

Who Should Attend:

- Departments: Microbiology, Compliance, Engineering, Manufacturing, QA/QC, CMC Documentation, Regulatory Affairs, Research and Development, Validation, QP
- Level of Expertise: Senior Management, Scientists/Technicians
- Job Function: Supervisor, Researcher, Analyst, Operative Personnel

Learning Objectives:

- Discuss the benefits of alternative and RMM technologies as compared with classical microbiological methods
- Describe the scientific basis for a variety of technologies that may be qualified as alternative methods to classical microbiology procedures; explore case studies and actual workflows for dozens of commercially-available technologies
- Explain the regulatory environment, guidance, policies and expectations for validation, submissions and implementation from FDA, EMA, TGA, PMDA, ISO and WHO; understand when and how to change acceptance levels
- Develop business plans and return on investment justifications, follow an actual case study in significant cost savings and cost avoidances by implementing a RMM for environmental monitoring
- Apply industry best practices for validating these new technologies in order to demonstrate that the methods are acceptable for their intended use via IQ, OQ and PQ qualification strategies; understand the differences between PDA TR 33, USP <1223> chapter and Ph. Eur. Chapter 5.1.6
- Appreciate new guidance for rapid sterility testing of advanced therapeutic medicinal products (ATMP; gene and cell therapy) including compendial expectations and regulatory acceptance; justification for sample size allowances and the latest validation strategies

Michael J. Miller, *PhD, President, Microbiology Consultants, President*

Michael J. Miller is an internationally recognized microbiologist and subject matter expert in pharmaceutical microbiology, contamination control, aseptic processing, sterilization, laboratory design and the validation and implementation of rapid microbiological methods (RMM). He is currently the President of Microbiology Consultants, LLC. For 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, Michael 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 and antimicrobial effectiveness. Michael Miller has authored more than 100 technical publications and presentations and is the editor of PDA's Encyclopedia of Rapid Microbiological Methods and was also the chairperson during the revision of PDA Technical Report #33: Evaluation, Validation and Implementation of New Microbiological Testing Methods. He currently serves as an advisor to the USP Microbiology Expert Committee in the area of rapid sterility testing. Michael Miller holds a Ph.D. in Microbiology and Biochemistry from Georgia State University (GSU), a B.A. in Anthropology and Sociology from Hobart College.

25 Jun 2018

Wednesday, 17 October 2018	9:00 – 18:00
9:00	Welcome
9:15	Introduction to RMMs, Applications, Implementation Strategies, Opportunities
	Growth-based RMMs; Scientific Principles, Applications and Case Studies
10:30	Coffee Break
11:00	Regulatory Policies and Expectations: FDA, EMA, TGA, PMDA, ISO and WHO
12:30	Lunch Break
13:30	Cellular-component Based RMMs; Scientific Principles, Applications and Case Studies
	Viability-based RMMs; Scientific Principles, Applications and Case Studies
15:30	Coffee Break
16:00	Spectroscopic-based RMMs; Scientific Principles, Applications and Case Studies
	Genetic and Gene Amplification-based RMMs Part 1; Scientific Principles, Applications and Case Studies
18:00	End of Day 1

Thursday, 18 October 2018	9:00 – 16:30
9:00	Genetic and Gene Amplification-based RMMs Part 2; Scientific Principles, Applications and Case Studies
10:30	Coffee Break
11:00	MEM-based RMMs; The Future of Alternative Technologies
	Validation of RMMs Part 1; Due Diligence Activities, Vendor Expectations, IQ, OQ and PQ Strategies, Validation Acceptance Criteria, Use of Statistics
12:30	Lunch Break
13:30	Validation of RMMs Part 2; Equivalence, Method Suitability, Comparison of PDA TR33, USP <1223> and Ph. Eur. 5.1.6
	Review of ATMP (gene and cell therapy) expectations for rapid sterility testing according to the revised Ph. Eur. Chapter 2.6.27
	A Case Study on Conducting Economic Assessments and Return-on-Investment (ROI) Calculations
15:00	Coffee Break
15:30	References, On-line Resources and Final Remarks
16:30	End of Course