

# Classical or Rapid Microbiological Methods?

The best approach for the modern pharmaceutical lab

## Overview

The monitoring of microbial contamination is one of the critical procedures in the control of the manufacturing process and quality of the finish products in pharmaceutical industry. Many compendial methods used today offer low probability of detection except for gross contaminations. Rapid microbiological methods start to gain track in the industry, due to their increased adoption and validation, but also because of the clarification from the regulators. There are several well-developed rapid microbiological methods now becoming available that may have useful applications in pharmaceutical and medical devices.

The advent of the new therapies like the Advanced Therapy Medicinal Products, Cell and Gene Therapy that makes products with a short shelf life or products prepared for immediate use sorts the needs for rapid microbiological methods that allowed the minimization and mitigation of the risk of contamination.

The pharmacopeias have evolved as well to provide guidance on the selection, evaluation, validation and proper implementation of rapid microbiological methods as alternatives to compendial methods.

This training will be focused on the understanding of the classical methods described in the pharmacopeia and the currently available rapid microbiological method technologies, the regulatory requirements, the validation strategies and implementation plans.

## Who Should Attend

### DEPARTMENTS:

- Microbiology Compliance
- Engineering
- Manufacturing,
- QA/QC
- CMC documentation

- Regulatory affairs
- Research and development
- Validation QP

### LEVEL OF EXPERTISE: MICROBIOLOGY

- Senior Management
- Scientists/technicians

### JOB FUNCTIONS:

- Supervisors
- Researchers
- Analysts
- Operative Personnel
- Manufacturing

## Learning Objectives

Upon completion of the course participants

- Know the benefits of alternative and rapid microbiological methods in regards of the compendial methods
- Know the pros and cons of classical vs. alternative/rapid methods
- Can describe the scientific science behind the different technologies: classical, alternative and rapid methods.
- Apply the regulatory frame governing the rapid methods. USP 1223, Ph Eur Chapter 5.1.6, PDA TR33
- Explain the implementation and validation of rapid methods
- Develop a return on investment scenario
- Rise the new USP 1071 Rapid Sterility Testing of Short-Life Products: A Risk-Based Approach



**Félix Alejandro Montero Julian, PhD, Scientific Director, BioMérieux**

Félix is a Scientific Director of the Healthcare Business of BioMérieux. Félix has over 25 years of experience in industrial and clinical diagnostics and previously served as the Chemunex R&D Director in BioMérieux. Félix graduated from the Autonomous Metropolitan University in Mexico as Industrial Biochemistry Engineer and obtained a PhD in Immunology from the Aix Marseille II University in France. Félix is a member of different scientific organizations (PDA, ISAC) and served as an expert in a panel for the Development of Compendial Rapid Sterility Tests for the USP. Félix has been and continues to be extensively involved in the implementation and acceptance of rapid and alternative microbiological methods.

**Thursday, 5 September 2019** **9:00 – 16:45**

9:00	Welcome and Introduction
9:10	Why Be Interested in Alternative and Rapid Methods? Rapid Versus Classical Methods?
10:30	Coffee Break
10:45	What is the Pharmacopeias Request? • Regulatory policies and their expectations
11:40	Lunch Break
12:40	What Are the Main Rapid Micro Methods?
13:40	Automatization of Traditional Techniques
14:30	Coffee Break
15:00	Direct Measurement and Technologies
15:50	Based-growth Technologies
16:45	End of Day 1

**Friday, 6 September 2019** **9:00 – 16:45**

9:00	Technologies Based on the Detection of Cellular Components
9:50	Technologies for Real Time Measurement
10:40	Coffee Break
11:10	Validation Part 1
12:10	Lunch Break
13:10	Validation Part 2
14:10	Rapid Sterility Testing/ATMPS /Trends
15:00	Coffee Break
15:30	ROI of Rapid Methods
16:20	Recap, Q&A
16:45	End of Course