

Pharmaceutical Microbiology *for Non-Microbiologists*

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PHARMACEUTICAL MICROBIOLOGY FOR NON-MICROBIOLOGISTS

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Overview

Controlling microbiology throughout the manufacturing process is a key success factor for production. Microbiology is unseen and data is history, effective control requires all disciplines to be involved in the control measures and any out of specification investigations. Therefore, all key personnel should have a thorough understanding of microbiology.

This course is designed to give non-microbiologists a comprehensive introduction to microbiology so that they can engage in the required control measures, investigations and corrective actions.

Course Objectives & Learning Outcomes

- Understand the basic principles of pharmaceutical microbiology
- Be able to understand how microbiology is of a concern to your manufacturing processes
- Understand the main sources of microbiological contamination
- Be able to constructively participate in microbiological risk assessments
- Understand how to effectively reduce microbiological hazards and contamination within your facility
- Review microbiological data and understand the methods of analysis control within the cleanroom
- Appreciate the importance of microbiological data and control in pharmaceutical and medical device manufacture
- Micro requirements for sterile and non-sterile product manufacture
- Micro limit testing
- Monitoring methods: sampling methods, isolation and counting
- Interpretation of microbiological data
- Gram positive and gram negative bacteria, and gram staining
- Bacterial identification (bacteriology and mycology)
- Spores and spore forming microorganisms
- Reading micro-organisms on Agar plates
- Be able to participate in out-of-specification investigations and
- Implement control measures



Virtual Training

Who Should Attend?

Anyone who works in a sterile manufacturing operation who is not directly involved in microbiology or is new to this area.

This includes persons who review data but are not qualified



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Course Programme

Day One

- Micro Spectrum
- Microbial Nutrition and Media Selection
- Microbial Virulence
- Microbial ID
- Microbial Testing
- Microbiological Practical Sessions
- EM, Identification, Benchtop tests, Objectionable Organisms, Media

Day Two

- Sources of Contamination
- Bioburden Control
- Environmental Monitoring
- Objectionable Organisms
- Data Interpretation
- Trend Analysis
- OOS Investigation
- Plate Reading Practical Microbial Testing
- Objectionable Organisms Demonstration
- Learning Assessment
- End of Course Questions

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Portsmouth Hospitals
NHS Trust

Microbiology Manager,
Portsmouth Hospital



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[Microbiology for Non-Microbiologists](#)

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