

Pharmaceutical Microbiology



MODULE 1

Introduction to Pharmaceutical Microbiology and Technology

This introductory and compulsory module will provide an overview of the Pharmaceutical Industry and Regulatory Affairs covering all aspects of QA, QC, GMP, GLP and consider Documentation and Health & Safety issues. The design of Premises and Equipment for the Laboratory and Facility including Quality Audits will be covered. Commonly encountered micro-organisms and Basic Laboratory Techniques, including Rapid Methods will be discussed along with Validation of Processes & Methods.

MODULE 2

Water Aspects

This module will look at the Compendial Water Qualities used in the industry. The Design of Water Generation, Storage and Distribution Systems together with the options for Validation & Change Control, System Operation and Management and System Sanitisation will be reviewed. The Methods of Testing, including the Common Contaminants encountered as well as the Sampling Regimes & Techniques will be explained. Data Management, Trending and Interpretation will be covered.

MODULE 3

Microbiological Environmental Monitoring & Control (sterile & non-sterile manufacturing areas)

This module examines the requirements of a robust and flexible environmental monitoring programme, which can be applied to both sterile and non-sterile manufacturing units. It includes an examination of the current Regulatory Requirements; an exploration of Environmental Monitoring Methodologies, including aspects of their Validation, together with a look at the Commonly Isolated Micro-organisms. Data Management and Trending including Basic

Statistics will also be covered. A look at Risk Management of procedures, the role of Disinfectants and Rapid Methods will also be explored to enable the student to gain a balanced understanding of this key aspect of pharmaceutical microbiology.

MODULE 4

Microbiological Aspects of Sterile Pharmaceutical Manufacturing

This module will cover the concepts of Sterility and Sterility Assurance, Pyrogenicity and Endotoxins. A look at the Methods of Achieving Sterility such as Steam, Dry Heat, Radiation, Ethylene Oxide and New Technologies will also be covered. Aseptic Manufacturing Processes and Principles of Contamination Control will be explored. The Validation and Monitoring of Aseptic Manufacturing areas will include Media Fills, Environmental Monitoring and New Technologies. Disinfection & Sanitisation relating to sterile products will be explained. The Confirmation of Sterility will include the Test for Sterility and Parametric Release.

MODULE 5

Quality Assurance in Microbiology Laboratories

Principles, Concepts and References used in the QA, QC, GMP & GLP of the Microbiology Laboratory will be covered in more detail here. The Laboratory Facility, Equipment and Consumables used along with the Validation of Processes, Equipment and Methods will also be covered. A more detailed look at Quality Audits and Training issues together with the Documentation Control required will be detailed. The Management of Microbiology Laboratory Customers will be explained.

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The Pharmaceutical Microbiology Interest Group (Pharmig) was established in 1991 and is a non-profit making professional organisation based in the UK, that represents the interests of people who are working in, or having responsibility for (including the provision of commercial services), pharmaceutical microbiology.

MODULE 6

Engineering Principles for Pharmaceutical Microbiologists

A list of the Engineering Terminology and Engineering Regulations commonly encountered will be explained. The Project Design & Management of a Facility, Critical Services and Utilities will be covered. The concepts of Hygienic System Design and HVAC Systems and Environmental Control will be included and Sterilisation Issues and Validation will be covered in the module.

MODULE 7

Application of Microbiology in Biopharmaceuticals

A review of the current Legislation & Guidelines in Biopharmaceuticals will be conducted. The module will cover Hygienic Plant Design and Sanitisation CIP/SIP. A detailed look at Biopharmaceutical Technology (growth techniques, cell & tissue culture, fermentation, purification, harvesting, final drug products) will be conducted. The Viral Load Reduction/Detection Techniques together with those available for Mycoplasmas will be explained. Lyophilisation Techniques as well as Test Methods for Biotechnology Products will be included.

MODULE 8

Antimicrobials

Disinfectants

The current Regulatory Requirements for disinfectant use along with GMP Associated with Disinfectants will be covered in this module. The Types of Disinfectants and their Selection will be included covering aspects of Practical Usage. A detailed look at Test Methods and Validation will be described.

Preservatives

The Preservatives Available for Use in Mixtures, Suspensions & Syrups will be examined as well as the Preservation of Sterile Products. The test methods for evaluation of formulations such as Preservative Efficacy Testing and Stability of Drugs & Stability Testing will also be included. The Resistance towards Preservatives in Pharmaceutical Products will be mentioned.

MODULE 9

Antibiotics and Vitamins

Following an overview of Antibiotic Classes and Mode of Action, the current Regulatory Requirements and GMP Associated with their manufacture will be covered. Particularly, Test Methods, Assays and Validation of Antibiotics, as well as Growth Promotion by Vitamins will be included. Shelf-life and Stability Testing will be described.

MODULE 10

Key Management Tools*

This module provides students with a perceptive insight into their management and leadership styles and strengths. It builds the skills that will enable students to lead their teams effectively, manage change successfully and interact with and influence colleagues in other areas of the business. It has been designed and written by Leigh Casey on behalf of the Chartered Management Institute.

*Assessed by assignment only (no written examination).

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The Chartered Management Institute is the professional body for leadership and management' and is the only Chartered Body able to offer the prestige Award of Chartered Manager.

Three further modules are in preparation and due for completion in the autumn of 2008:

- Risk Management
- Computer Systems
- Microbiological Aspects of Packaging