

G(QC)LP

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Microbiology and QC

This module provides an introduction to the basic concepts and requirements of QC for microbiological testing laboratories under GMP requirements. The module discusses issues focused on by laboratory auditors and specific pharmaceutical regulatory requirements.

Objectives:

- Identify different classes of micro-organisms
- Describe and list typical objectionable organisms for different products
- Follow correct procedures for safe disposal of cultures
- List the key attributes of the flow of samples and materials through the laboratory

Course Outline

BASIC MICROBIOLOGY

- o Introduction
- o Defining micro-organisms
- o Eukaryotes/Prokaryotes
- o Classifying bacteria
- o Counting difficulties
- o Review

OBJECTIONABLE ORGANISMS

- o Introduction
- o Concerns
- o Sources and examples
- o Review

GLP REQUIREMENTS

- o Introduction
- o Role of the laboratory
- o Sampling requirements
- o Overcoming issues
- o Lab system elements
- o Key media requirements
- o Culture collections
- o Biological indicators
- o Reporting results
- o Positive/Negative controls
- o Issues affecting validity
- o Review

HOUSEKEEPING AND WASTE DISPOSAL

- o Introduction
- o Risks of contamination
- o Entering/exiting the lab
- o Contaminated samples
- o Review

MATERIALS FLOW

- o Introduction
- o Importance
- o Key attributes
- o Stages
- o Review

CONCLUSION

- o Summary