# **Environmental Monitoring Basics – Part II. Surveillance Support.**

What Everyone Working in Sterile Manufacturing Must Know Copyright © 2004

**Core Competency Training** 

Version: 1.0.1

Duration: 45 minutes Number of Chapters: 7

Number of Course Pages (including test pages & title pages): 66

Number of Test Questions: 34

# Course Description

Seven (7) chapters with qualifying tests after each chapter cover the course content. Chapter 1 introduces the trainee to the fundamentals of a comprehensive environmental monitoring program. Chapter 2 explains the importance of cleaning and sanitization/disinfection. Chapter 3 details the requirements for meaningful site selection. Chapter 4 provides guideline for the determination sampling frequency. Chapter 5 focuses on the need for proper data management. Chapter 6 teaches what is required for meaningful investigations/corrective actions. Chapter 7 concludes by detailing the documentation requirements for surveillance support.

## Learning objectives summary

- Understand the requirements for a comprehensive environmental monitoring program
- Understand the characteristics of cleaning & sanitization/disinfection
- Understand the objectives for site selection & monitoring frequencies
- Understand the requirement for meaningful data management
- Understand the critical issues to be considered for investigations/corrective actions
- Understand the documentation requirements for surveillance support

#### Intended Audience

The course is intended for every employee who works in sterile manufacturing.

#### Prerequisites

Trainees are recommended to possess basic competency in Good Manufacturing Practices and Environmental Monitoring Basics – Part I. Introduction to Environmental Classifications.

### Related courses

Environmental Monitoring Basics – Part I. Introduction to Environmental Classifications. This course provides sound foundation for understanding environmental classifications.

**Environmental Monitoring Basics** – **Part III. System Surveillance.** This course provides the trainee with the necessary background to understand the requirements for system surveillance.