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Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities

PDA Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities Technical Report Team

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1.0 Introduction

While sterile product manufacturing has the most stringent application, these concepts can also be used to design a program for the manufacture of nonsterile products. To ensure a consistently controlled production environment, a comprehensive cleaning and disinfection program together with a contamination control program should be supported by the following:

- Sound facility design and maintenance
- Established documentation systems
- Validated/qualified disinfection procedures
- Reliable process controls
- Good housekeeping practices
- Effective area traffic and access controls
- Effective training, certification/qualification, and evaluation programs
- Quality assurance of materials and equipment
- Risk management mitigation

The purpose of the cleaning and disinfection program is not only to control microbial contamination, but also to serve as a corrective action for the loss of control for viable excursions contamination. While the destruction of viable cells are an integral part of the cleaning and disinfection program, the use of disinfection as a singular focus without efforts to control contamination from entering the area is without technical merit. Environmental monitoring (EM) evaluates the efficacy of controls on the manufacturing environment. It is through control of bioburden levels entering the area, along with cleaning and disinfection, that acceptable viable control of the manufacturing or appropriate testing environment is achieved. This technical report provides comprehensive information and suggested best practices as well as appropriate references to support such guidance.

For individuals wanting a historical perspective of disinfection, a summary can be found in Appendix I (**Section 17.0**).

The technical report team consisted of members who are cleaning and disinfection experts from various global pharmaceutical and biopharmaceutical companies, academia, and companies that manufacture agents used in disinfection.

1.1 Purpose

The purpose of this document is to identify systematic elements that are essential to assuring an appropriate and compliant cleaning and disinfection program for aseptic and bioburden controlled manufacturing facilities and classified environments.

1.2 Scope

The document covers cleaning and disinfection within controlled and noncontrolled environments using chemical agents that reduce or destroy microorganisms. The document provides guidance for non-product-contact surface cleaning and disinfection. This document is not intended to fully address product-contact surface cleaning from a clean-in-place (CIP) or clean-out-of-place (COP) system which is specifically addressed in PDA's *Technical Report No. 29 (Revised 2012): Points to Consider for Cleaning Validation* and *Technical Report No. 49: Points to Consider for Biotechnology Cleaning Validation* ***(1,2)***.

This document should be considered as technical guidance; it is not intended to establish any mandatory or implied standard.