Technical Report No. 13 (Revised 2022)

Fundamentals of an Environmental Monitoring Program

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1.0 Introduction

The design and implementation of an environmental monitoring (EM) program allows the confirmation that controls to minimize the risk associated with processes, people, equipment, utilities, and facilities are designed correctly and continue to be effective in the manufacture of sterile pharmaceutical products. As such, it forms an important part of the contamination control strategy (CCS).

PDA first published *Technical Report No. 13* in 1990 and revised it two previous times, 2001 and 2014. This third revision intends to align the content of the document with current industry trends and regulatory expectations. Specifically, it will provide additional guidance and focus on the:

- Use of quality risk management (QRM) principles to establish a robust EM program by suggesting practical step-by-step approaches
- Increased expectations concerning data management and data integrity
- Prerequisites to an effective EM program
- Qualification of controlled environments and how to maintain them in a qualified state
- Rapid microbiological methods (RMM) or automated monitoring systems, since becoming more and more convenient, performant and accepted, or even recommended, by regulatory bodies.

Members of the task force who developed this technical report represent or provide expertise to global companies to ensure that the methods, terminology, and practices reflect not only U.S., but also international procedures. Technical peer reviews were completed by prominent EM scientists.

Although this TR has been updated to ensure its alignment with existing current regulations and guidelines, current and/or newly updated regulations or guidelines should be consulted when implementing or changing an environmental monitoring program. This TR should be viewed as technical guidance, it is not intended to replace existing or future regulations, nor should it be considered an all-inclusive document.

1.1 Purpose

This document was created to aid in the establishment of an environmental monitoring program that is robust, meaningful, and practical whilst embracing innovation and the principles of quality risk management. This revision updates microbiological and total airborne particulate control concepts and principles as they relate to facilities involved in the manufacture of sterile pharmaceutical products and other designated cleanroom environments.

1.2 Scope

TR-13 serves as a resource applicable for controlled environments in general however its primary focus is environmental monitoring for sterile product manufacturing.

This document discusses international standards and regulatory guidances, elements of an EM program, and EM application. Current (at the time of publication) guidelines for typical EM levels and frequencies are presented in **Section 3.0** and levels for pharmaceutical water are covered in **Section 6.8**.

A comprehensive environmental monitoring program should demonstrate the effectiveness of a solid CCS focusing on:

- Sound facility design, including barrier systems (e.g., isolators and RABS), operation and maintenance
- Established documentation systems
- Qualified sanitization, disinfection, and decontamination procedures
- Reliable process controls
- Good housekeeping practices
- Effective area access controls
- Consistent sample collection and analysis