

Technical Report No. 13 (Revised)

Fundamentals of an Environmental Monitoring Program

2014



PDA Fundamentals of an Environmental Monitoring Program Technical Report Team

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Disclaimer: The task force for this report consisted of members representing global companies to ensure that the methods, terminology, and practices reflect international and not just U.S., procedures. Technical peer reviews were completed by prominent environmental monitoring scientists.

The content and views expressed in this technical report are the result of a consensus achieved by the authoring task force and are not necessarily views of the organizations they represent.

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Table of Contents

1.0 INTRODUCTION	1	5.3 Isolation Technology	21
1.1 Purpose	1	5.4 Water	22
1.2 Scope	1	5.4.1 Sample Site Selection and Frequency of Monitoring	22
1.2.1 Exclusions	1	5.4.2 Sample Collection and Testing	22
1.2.1.1 Bioburden Monitoring	1	5.5 Air	23
1.2.1.2 Other Environmental Control Support Activities	1	5.5.1 Nonviable Monitoring	23
2.0 GLOSSARY OF TERMS	3	5.5.2 Viable Particulates	24
2.1 Acronyms	5	5.5.2.1 Sampling Sites	24
3.0 ENVIRONMENTAL CLASSIFICATIONS: REGULATORY EXPECTATIONS	6	5.5.2.2 Methods	24
4.0 ENVIRONMENTAL MONITORING	10	5.5.2.3 Equipment	24
4.1 Cleaning and Sanitization or Disinfection	10	5.6 Compressed Gas Monitoring	25
4.2 Sample Site Selection	12	5.7 Surface Monitoring	25
4.3 Sampling Frequency	13	5.7.1 Test Methods	25
4.4 Alert and Action Levels	14	5.7.1.1 Contact Plates	25
4.5 Data Management (Data Collection, Analysis, Approach, and Interpretation)	15	5.7.1.2 Flexible Films	26
4.5.1 Collection	15	5.7.1.3 Swabs	26
4.5.2 Analysis	16	5.7.1.4 Surface Rinse Method	26
4.5.3 Interpretation	16	5.8 Personnel	26
4.6 Characterization and Identification of Isolates ..	17	5.8.1 Introduction	26
4.7 Investigations and Corrective Actions	18	5.8.2 Training and Certification of Personnel for Aseptic Manufacturing Areas	27
4.8 Documentation	20	5.8.3 Causes for Requalification or Retraining ..	27
5.0 ENVIRONMENTAL MONITORING BY APPLICATION	21	5.9 Environmental Monitoring During Product Sterility Testing	27
5.1 Terminal Sterilization	21	6.0 REFERENCES	28
5.2 Aseptic Processing	21	7.0 BIBLIOGRAPHY	30
		8.0 APPENDIX A: CURRENT GUIDELINES FOR TYPICAL ENVIRONMENTAL MONITORING FREQUENCIES AND LEVELS—WATER	32

FIGURES AND TABLES INDEX

Table 3.0-1 Cleanroom Standards— Airborne Particulate Limits	8	Table 4.5.4-1 USP Chapter <1116> Suggested Contamination Recovery Rates	17
Table 3.0-2 Environmental Monitoring Requirements/Guidance	9	Table 4.6-2 Recommended Scheme for Microbial Identification	18
Table 4.2-1 Examples of Sampling Sites	13	Table 4.7-1 Examples of Investigation Elements for Different Systems	19

1.0 Introduction

Environmental monitoring is adjunct to a sterility assurance program and is used to evaluate the effectiveness of microbial controls used in the manufacture of sterile pharmaceutical products.

PDA first published guidance on environmental monitoring in the form of *Technical Report No. 13* in 1990, and revised the guidance in 2001. This is the second revision of that guidance.

The task force chose to reference the ISO cleanroom classifications as benchmark recommendations throughout the Technical Report. However, cleanroom classifications expectations are different per region. Regulatory and compendial classifications have been identified in **Tables 3.0-1** and **3.0-2** for the United States of America, the European Union, and Japan.

1.1 Purpose

This document was created to aid in the establishment of an environmental control and monitoring program that is meaningful, manageable, and defensible. This revision updates microbiological and particulate control concepts and principles as they relate to facilities involved in the manufacture of sterile pharmaceutical products and other designated controlled environments. It expands on PDA's 2001 revision of *Technical Report No. 13* to reflect substantial changes to regulatory guidelines, international standards, and scientific advances in environmental monitoring procedures and equipment.

This document should be viewed as technical guidance; it is not intended to establish any voluntary or mandatory standards.

1.2 Scope

This document serves as a resource on controlled environmental test methods, and although some nonviable particulate information is included, the report's primary focus is microbiological control for sterile product manufacturing.

This document addresses international standards and regulatory guidances, elements of an environmental monitoring program, and environmental monitoring by application. Current guidelines for typical environmental monitoring frequencies and levels for pharmaceutical water are covered in the appendix.

1.2.1 Exclusions

1.2.1.1 Bioburden Monitoring

Product or component bioburden monitoring is not considered part of all environmental monitoring programs and is therefore outside of the scope of this technical report. Incubation media, times, and conditions are also not addressed in this document, as individual monitoring circumstances and requirements will vary and most regulatory expectations are that the sampling conditions should be justified and validated.

1.2.1.2 Other Environmental Control Support Activities

In order to ensure a consistently acceptable controlled environment, a comprehensive environmental control program should be supported by:

- Sound facility design and maintenance
- Established documentation systems
- Validated/qualified sanitization/disinfection procedures
- Reliable process controls