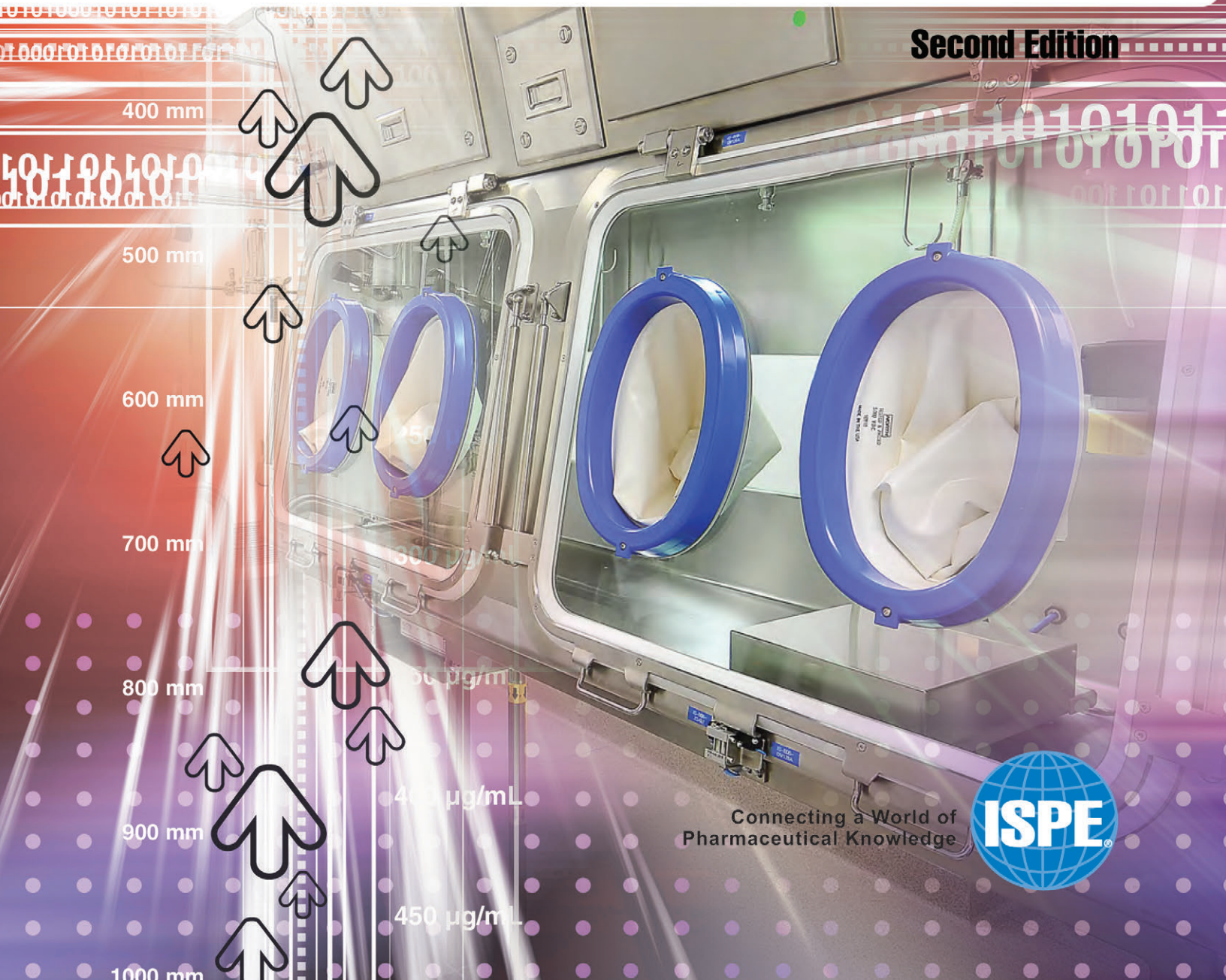
Good Practice Guide

Assessing the Particulate Containment Performance of Pharmaceutical Equipment

Second Edition



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Disclaimer:
This Guide describes methodologies for evaluating the containment capability of systems and equipment in the pharmaceutical and biotechnology industries under defined conditions. The ISPE cannot ensure and does not warrant that a containment system and equipment tested in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for involving professional industrial hygienists, engineers, or scientists.

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ISBN 978-1-936379-35-4

Preface

The purpose of the ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment is to provide technical guidance and consistent methodologies for evaluating the particulate containment performance (particulate emissions) of pharmaceutical equipment and systems.

This Guide aims to define current good practices in this area, providing information to allow organizations to benchmark their practices and improve on them. Specifically, the Guide provides a methodology to derive data associated with handling of pharmaceutical ingredients that can be useful in the assessment of potential risks such as:

1. the potential exposure of the operator

2. the potential for uncontrolled release of pharmaceutical ingredients within the facility

3. the potential exposure of the outdoor environment

The intended audience for this Guide is global, but is not intended to address any region-specific regulatory requirements. Users of this Guide should consult local authorities/experts to make sure that, in addition to addressing the above mentioned risks, worker safety, product quality, and environmental quality meet local regulations.

The information provided in this Guide reflects the cumulative knowledge and experiences of the authors, editors, and reviewers with input from members of the ISPE Containment Community of Practice (COP) and general membership.

Acknowledgements

The Good Practice Guide was produced by a Task Team led by George Petroka of IES Engineers and James P. Wood of Eli Lilly and Company.

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The Document Task Team would like to express their grateful thanks to the Extended Review Team for their contribution as reviewers of the Guide.

The Document Task Team also wish to thank the following individuals for their further contribution to the Guide in producing new materials, revising existing materials, and re-reviewing material.

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The Document Task Team also utilized ISPE's Containment Community of Practice (COP) membership as an extended team of subject matter experts for their review and comment during development of the Guide, with grateful acknowledgement.

Many other individuals reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

The Document Task Team also wishes to thank ISPE for technical writing and editing support by Gail Evans (ISPE Guidance Documents Writer/Editor).

Cover photo: courtesy of Eisai, Inc., www.eisai.com.

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1 Introduction

1.1 Background and Purpose

This Guide is a second edition of the ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment. The revision was undertaken to allow the Guide to address a broader selection of containment technologies and processing equipment than those covered in the first edition of the Guide.

The containment capability of equipment is an important factor in evaluating the risks associated with the handling of pharmaceutical ingredients; of specific interest are:

1. the potential exposure of the operator

2. the potential for uncontrolled release of pharmaceutical ingredients within the facility

3. the potential exposure of the outdoor environment

For the purpose of this Guide, the term “equipment” applies to containment systems and technologies, and processing equipment.

The Guide intends to provide a set of principles and standardized methodologies for evaluating the containment capability of pharmaceutical equipment. The methodologies involve the sampling and analysis for airborne emissions and surface contamination of a surrogate material manipulated within the equipment.

The principles and methodologies are intended to provide a standardized and repeatable process for determining the containment capabilities of equipment used in the pharmaceutical and biotechnology industries under specific, defined conditions.

This Guide can be used to evaluate *in situ* equipment both prior to use and over time. The Guide also may be used to evaluate and compare similar or different types of equipment from different suppliers.

Test data generated by following this Guide can be used to help to identify limitations of equipment being tested.

The materials and conditions specified in this Guide have been selected to reflect the “typical operation” of the equipment. This allows analysis of typical containment performance, while minimizing the risk of exposure to hazardous materials and background interference. Industry accepted test materials (surrogates) are recommended to best mimic the handling of actual pharmaceutical ingredients while allowing:

- safe handling

- ease of procurement

- sufficient limits of detection

The limits of detection should be sufficiently sensitive to evaluate the containment capability required for Active Pharmaceutical Ingredients (APIs), including potent or highly hazardous materials.

The methodologies recommended for sampling and analysis reflect pragmatic good industrial/occupational hygiene practice and should be followed to help to ensure reliable results.