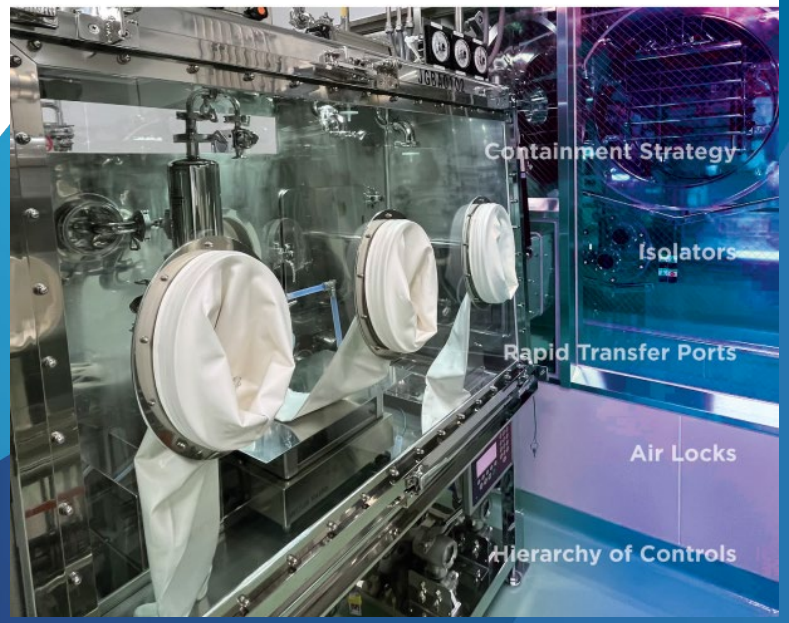
CONTAINMENT COP OVERVIEW

Peter Schofield

July 9th 2024



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- Product Owner Engineering Consulting
- Subject Matter Expert «Containment Technology»
- Engineering Background
- > 25 Years Experience in Contained Handling of Substances

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Peter Schofield

- The DEC Group (Extract Technology)
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- Engineering Background
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Why having an ISPE Good Practice Guide? History of the Guide

ISPE D/A/CH e.V. CoP Containment 1st Edition 2015 German

Germany/Austria/Switzerland Affiliate

Containment-Handbuch

1. Auflage 2015

ISPE D/A/CH e.V. CoP Containment 1st Edition 2017 English Translation

ISPE Germany | Austria | Switzerland Affiliate

ISPE D/A/CH Affiliate: Containment Manual

(English Translation)

ISPE D/A/CH e.V. CoP Containment 2nd Edition 2021 German

ISPE Germany | Austria | Switzerland Affiliate

Containment-Handbuch

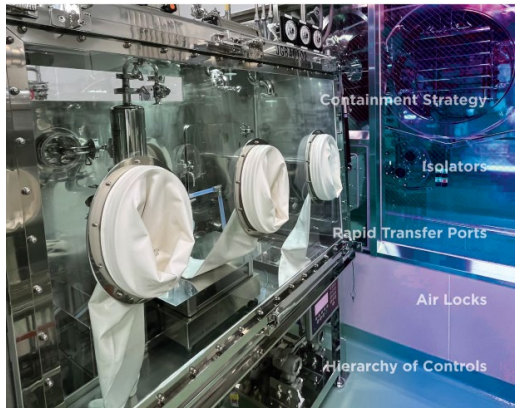
2. Auflage 2021

ISPE Org. CoP Containment 1st Edition 2022 English

ISPE

GOOD PRACTICE GUIDE:

Containment for Potent Compounds



CONTAINMENT FOR POTENT COMPOUNDS

WHY CONTAINMENT?

WHY AN ISPE GOOD PRACTICE GUIDE?

WHAT CAN YOU EXPECT FROM THE GUIDE?

Why containment?

A good reason for containment is the prevention of adverse effects of

- **Gases**
- **Liquids**
- **Solids**
- **Biological Agents**

on people and environment.

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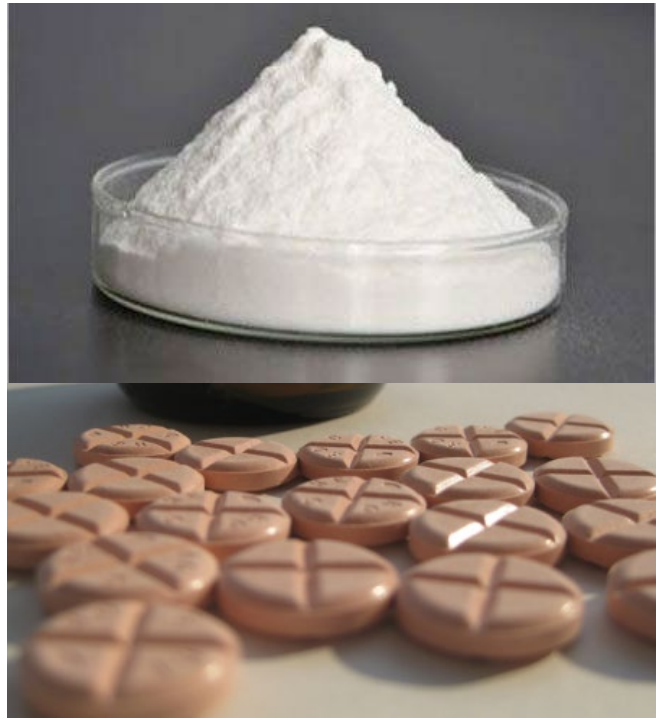
Focus of the ISPE Good Practice Guide «Containment for Potent Compounds»



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CONTAINMENT FOR POTENT COMPOUNDS

WHY CONTAINMENT?

WHY AN ISPE GOOD PRACTICE GUIDE?

WHAT CAN YOU EXPECT FROM THE GUIDE?

Why an ISPE Good Practice Guide?
Different Aspects on Guidance: GMP versus EHS

Common Ground for «Containment» from different perspectives:

GMP (Patient Safety)

- **Prevention of chemical and biological (Cross-)Contamination**

EHS (Operator and Environmental Safety)

- **Prevention of Overexposure of Operators and the Environment**

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Why an ISPE Good Practice Guide?
Different Aspects on Guidance: GMP versus EHS

GMP (Patient Safety)

- Regulated by national authorities, enforced by inspections conducted by these authorities. Highly respected references from the Pharmaceutical Inspection Co-operation Scheme (PIC/S) or the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- GMP guidelines are globally well-harmonised and in many cases, the inspection result of one authority is also accepted by others.

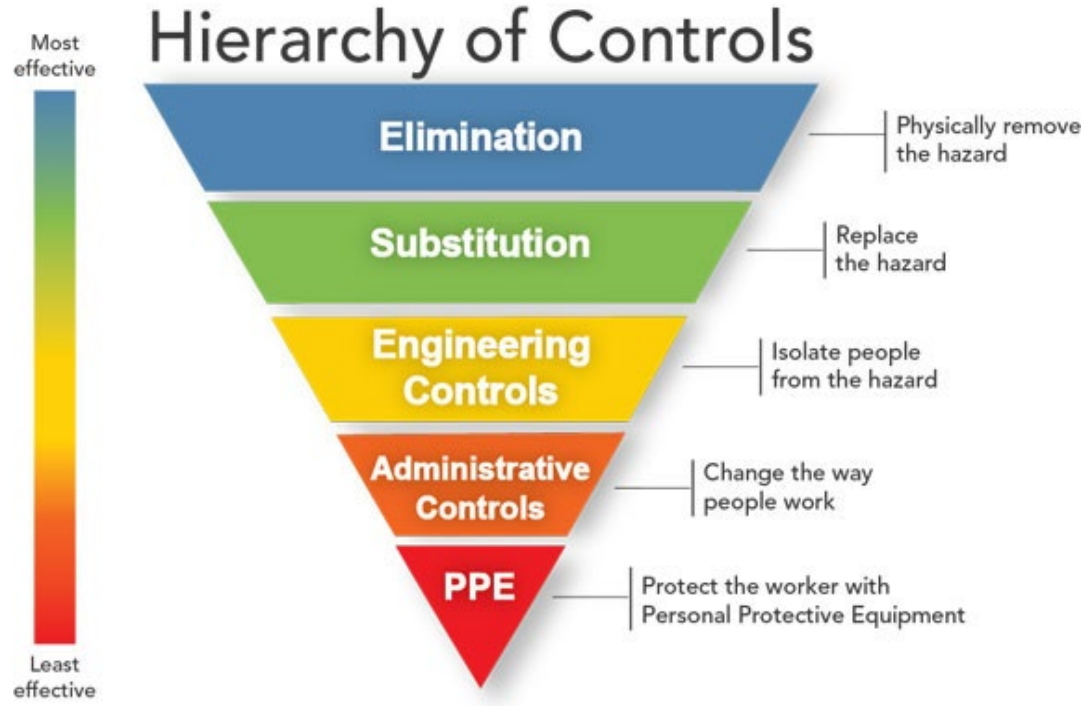
GUIDELINE ON SETTING HEALTH BASED EXPOSURE LIMITS FOR USE IN RISK IDENTIFICATION IN THE MANUFACTURE OF DIFFERENT MEDICINAL PRODUCTS IN SHARED FACILITIES

PIC/S Guideline

Why an ISPE Good Practice Guide?
Different Aspects on Guidance: GMP versus EHS

EHS (Operator and Environmental Safety)

- Regulated by national authorities.
- EHS aspects are less systematically enforced, but are getting more and more in the focus of inspections by authorities locally and by clients of CDMOs.
- EHS aspects are not globally harmonized



Centers for Disease Control and Prevention, "Hierarchy of controls", January 13, 2015.

Why an ISPE Good Practice Guide?
Purpose of the Guide

Common Ground for «Containment» from different perspectives:

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CONTAINMENT FOR POTENT COMPOUNDS

WHY CONTAINMENT?

WHY AN ISPE GOOD PRACTICE GUIDE?

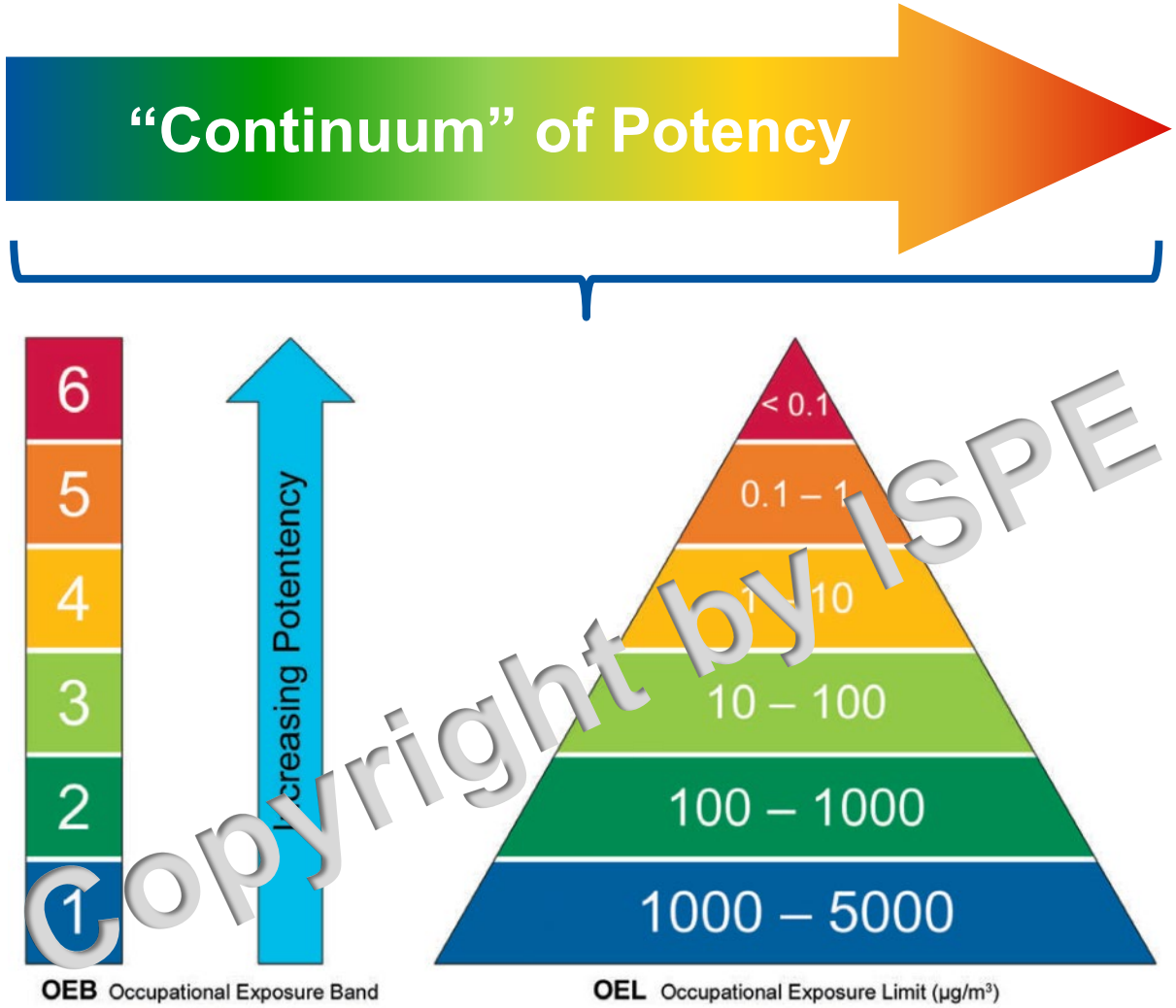
WHAT CAN YOU EXPECT FROM THE GUIDE?

What can you expect from the ISPE Good Practice Guide? Overview of Content

What can you expect from the ISPE Good Practice Guide? OEBs

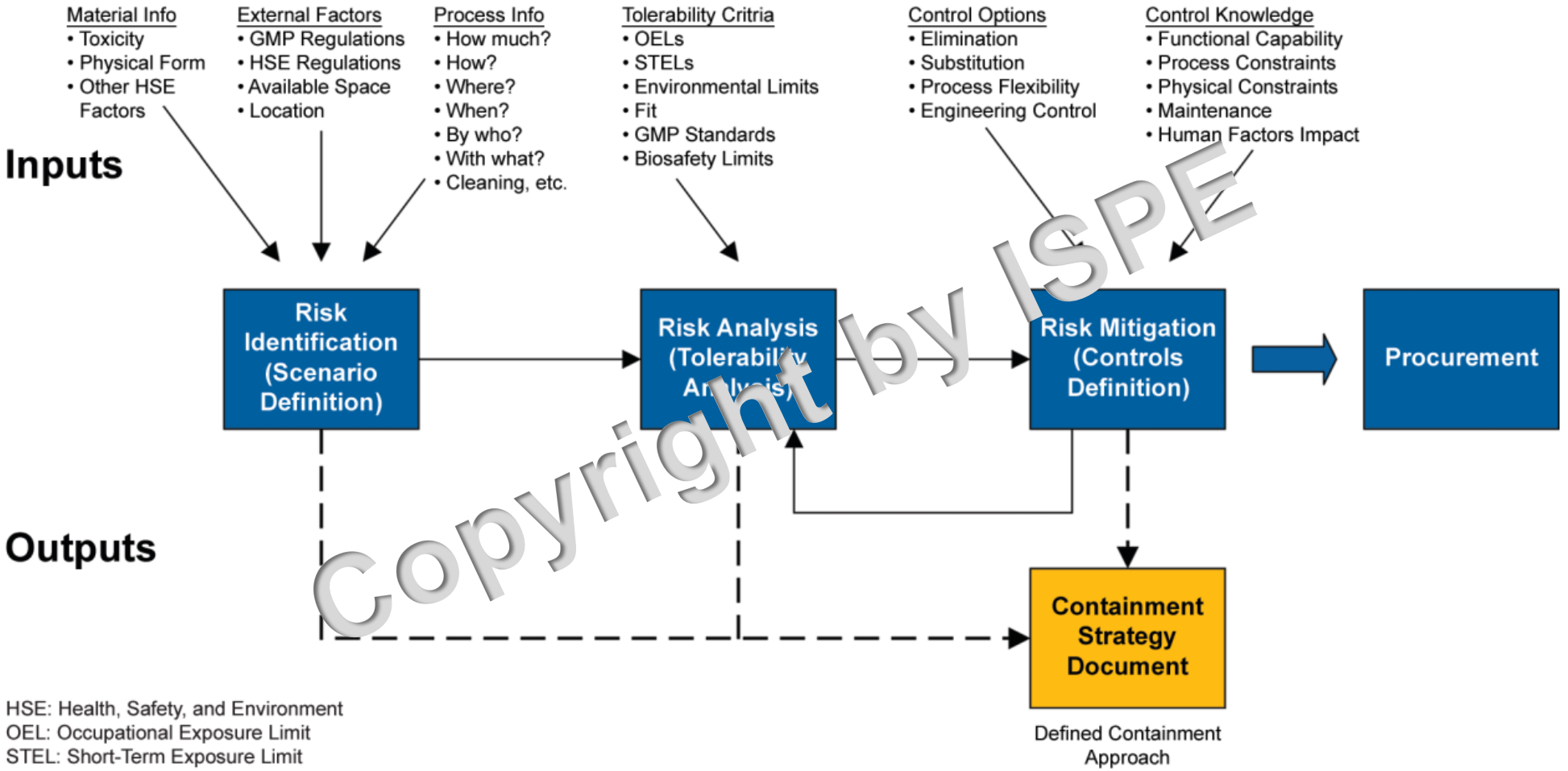
Classification of compounds into Occupational Exposure Bands (OEB):

- Easier to categorize substances than set a precise OEL
- Also applicable if only few toxicological data are available
- Easier to understand at the shop-floor level than OELs
- +/- translatable into process technologies: **Compounds that are in the same OEB must be handled by means of the same process technology**



Source: ISPE Good Practice Guide: Containment for Potent Compounds

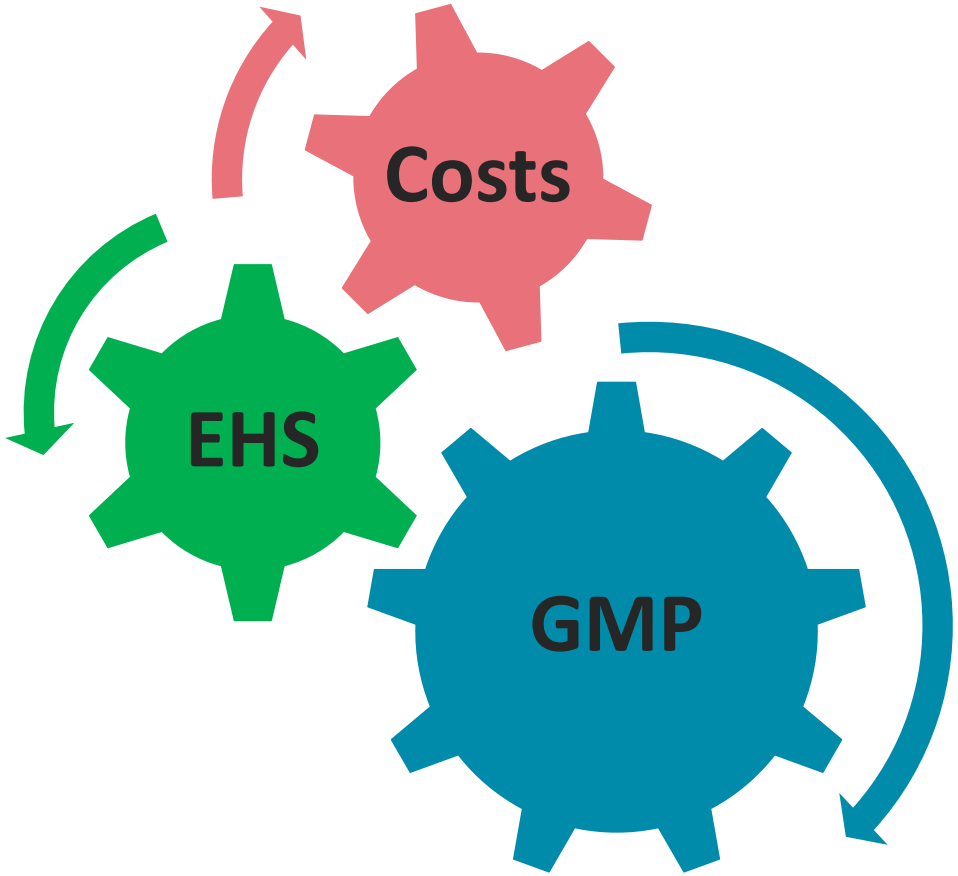
What can you expect from the ISPE Good Practice Guide? Defining Containment Requirements



Source: ISPE Good Practice Guide: Containment for Potent Compounds

What can you expect from the ISPE Good Practice Guide? Multivariable Optimization…

GMP, EHS and Costs are not completely independent!



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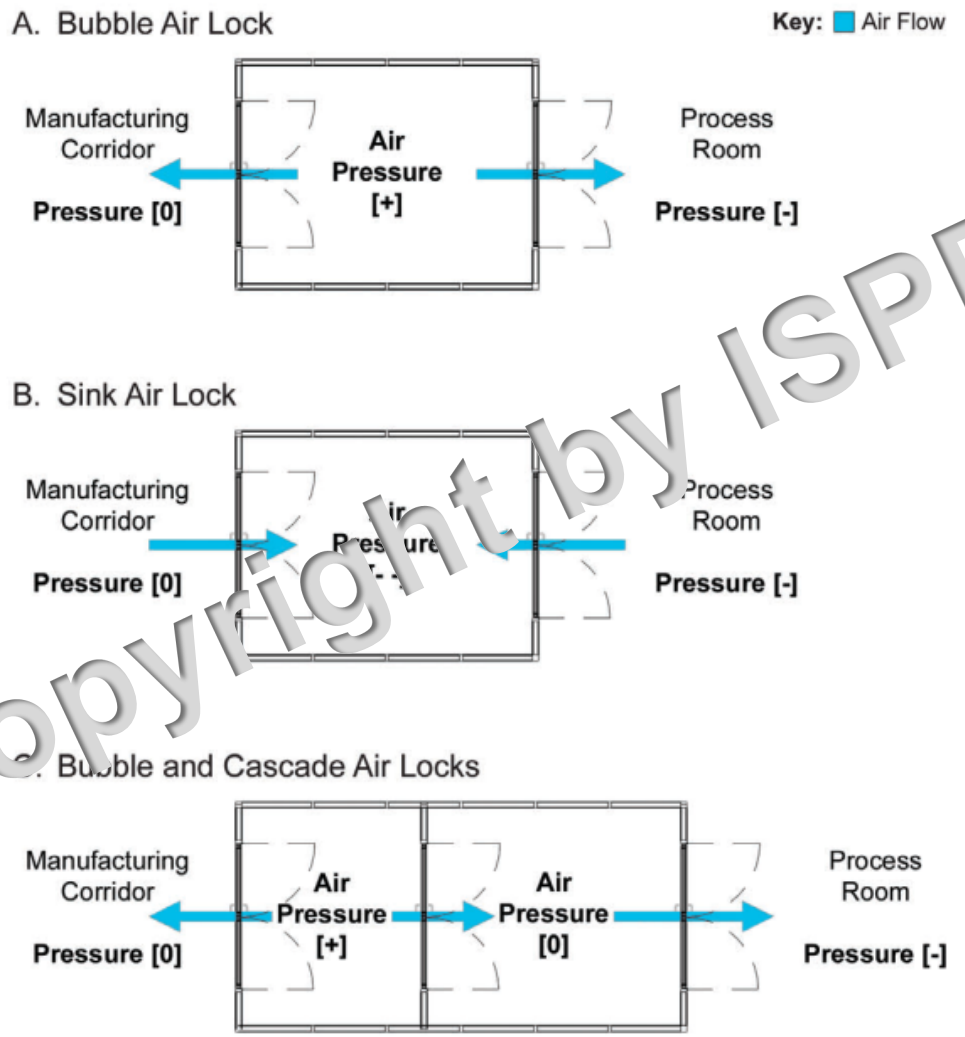
What can you expect from the ISPE Good Practice Guide? Multivariable Optimization…

Example: GMP versus EHS in an OSD facility

Airlocks may look different but serve the same purpose!

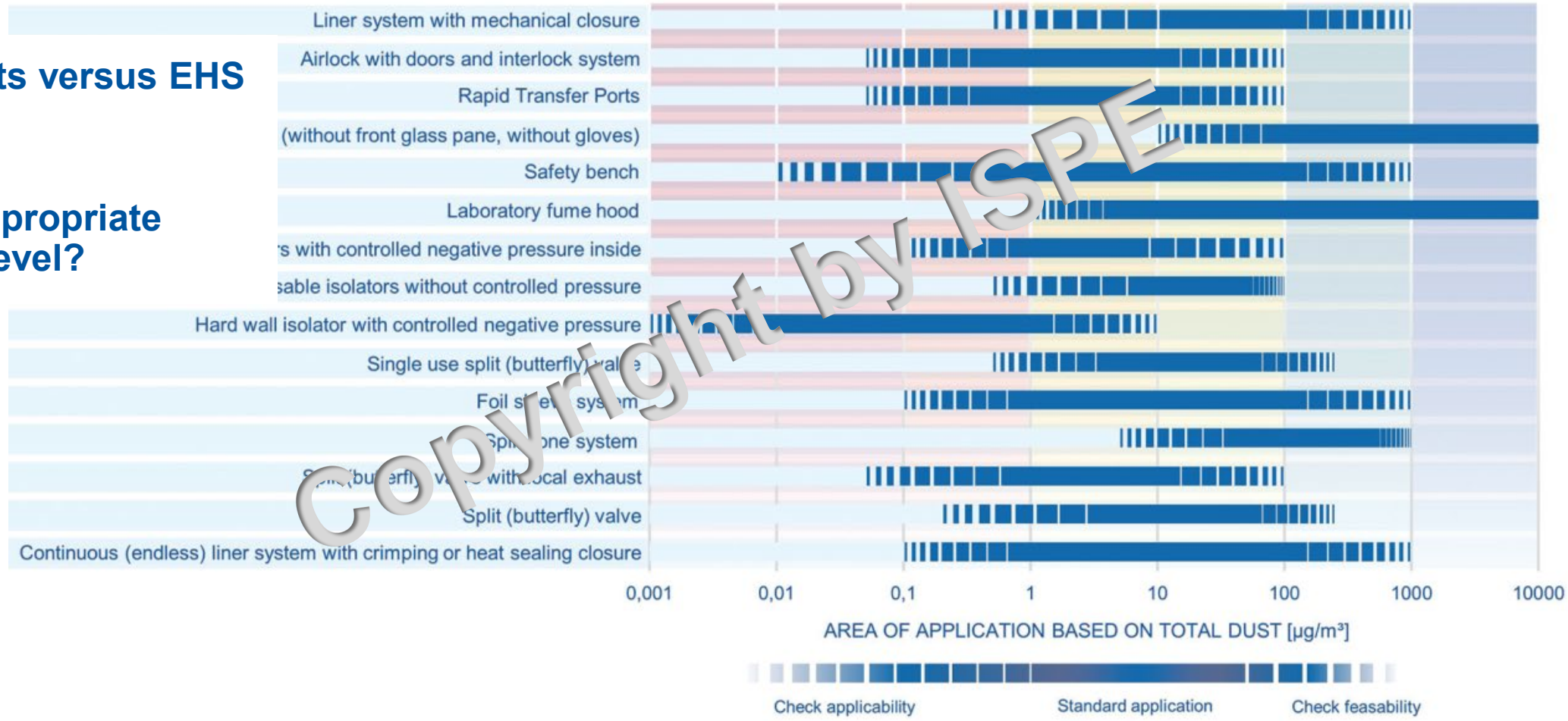


Source: ISPE Good Practice Guide: Containment for Potent Compounds

What can you expect from the ISPE Good Practice Guide? Multivariable Optimization…

Example: Costs versus EHS

What is the appropriate containment level?



Source: ISPE Good Practice Guide: Containment for Potent Compounds

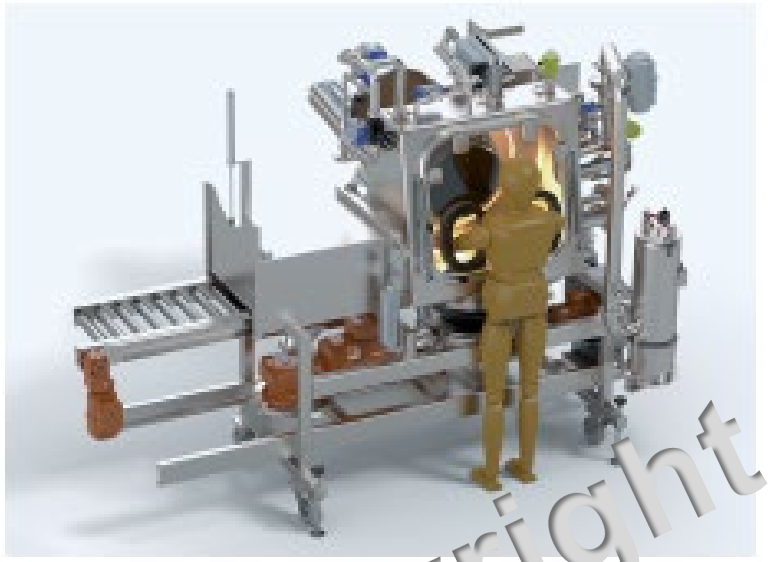
What can you expect from the ISPE Good Practice Guide? Primary Containment: Local Exhaust Ventilation LEV

Local Exhaust Ventilation LEV

Source: ISPE Good Practice Guide: Containment for Potent Compounds

What can you expect from the ISPE Good Practice Guide? Primary Containment: Downflow Booth/VBE's

What can you expect from the ISPE Good Practice Guide?
Primary Containment: Complex Isolators



Examples of Use:

- Closed discharge of drums/bags into a reactor via gravity
- Docking of the drum to allow introduction of the bag into the isolator connected to the reactor
- Reactor is located on floor below in this example

Source: ISPE Good Practice Guide: Containment for Potent Compounds

What can you expect from the ISPE Good Practice Guide? Primary Containment: From the Past to the Future

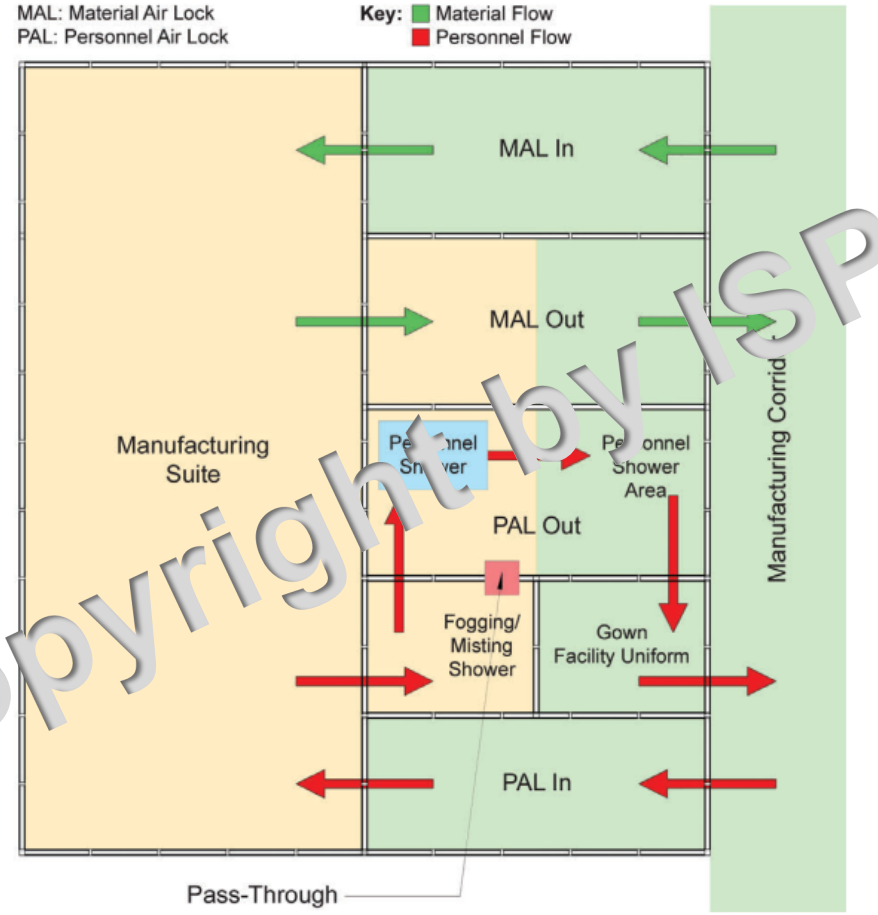
Rethinking Material Handling

Enhancing Primary Containment!

Source: ISPE Good Practice Guide: Containment for Potent Compounds

What can you expect from the ISPE Good Practice Guide? Secondary Containment: Examples

Examples for Secondary Containment



Source: ISPE Good Practice Guide: Containment for Potent Compounds

What can you expect from the ISPE Good Practice Guide? Key Facts

- Contribution of > 30 authors representing the industry related to manufacturing of medicines
- Covers all aspects of the E2E value chain: from regulatory basics to the end of lifecycle of manufacturing equipment
- Represents the current state of the art of the technology compiled on > 250 pages

Current Focus – Updating SMEPAC document

PURPOSE OF THE GUIDE

This ISPE SMEPAC Good Practice Guide is intended to be used by industry professionals for the planning, , containment verification, and operation of pharmaceutical equipment.

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 exposure of the operator
2. The potential for release of pharmaceutical ingredients within the facility
3. The potential exposure of the outdoor environment

The principles and methodologies described in this Guide are intended to provide a standarized methodology to provide reproduceable data for assessing the containment capabilities of equipment used in the pharmaceutical industries under specific, defined conditions.

Thank you for your attention!