

How to define an OSD Containment



HIGH POTENT PRODUCTS

HOW TO HANDLE IT?

What is the problem?

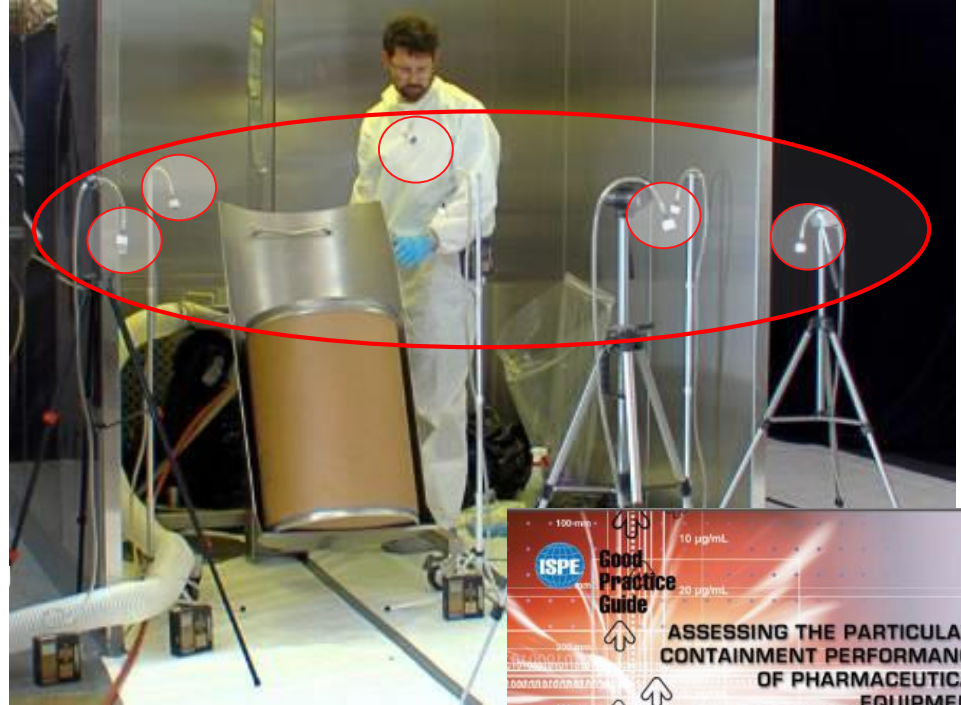


What is the problem? - Analyse the Risk

- Airborne product dust visible
- No mask protection
- Which quantity the operator is breathing?
- What is the risk for the operator?

Sampling and measurements acc. to **SMEPAC**
(Standardized Measurement of Equipment Particulate Airborne Concentration)

- Used substitute substance:
 - a) Lactose: 342.29 g/mol
 - b) Naproxen-Natrium: 230.26 g/mol



HOW TO USE THE

“CONTAINMENT TRIANGLE”

TOOL?

How to set pharmaceutical containments

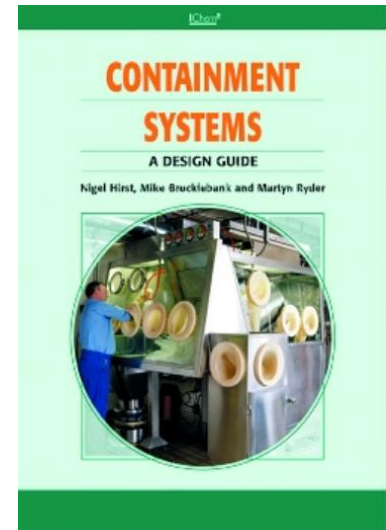
This procedure dates from 2002 and allowed a first approach of containment design

Written by:

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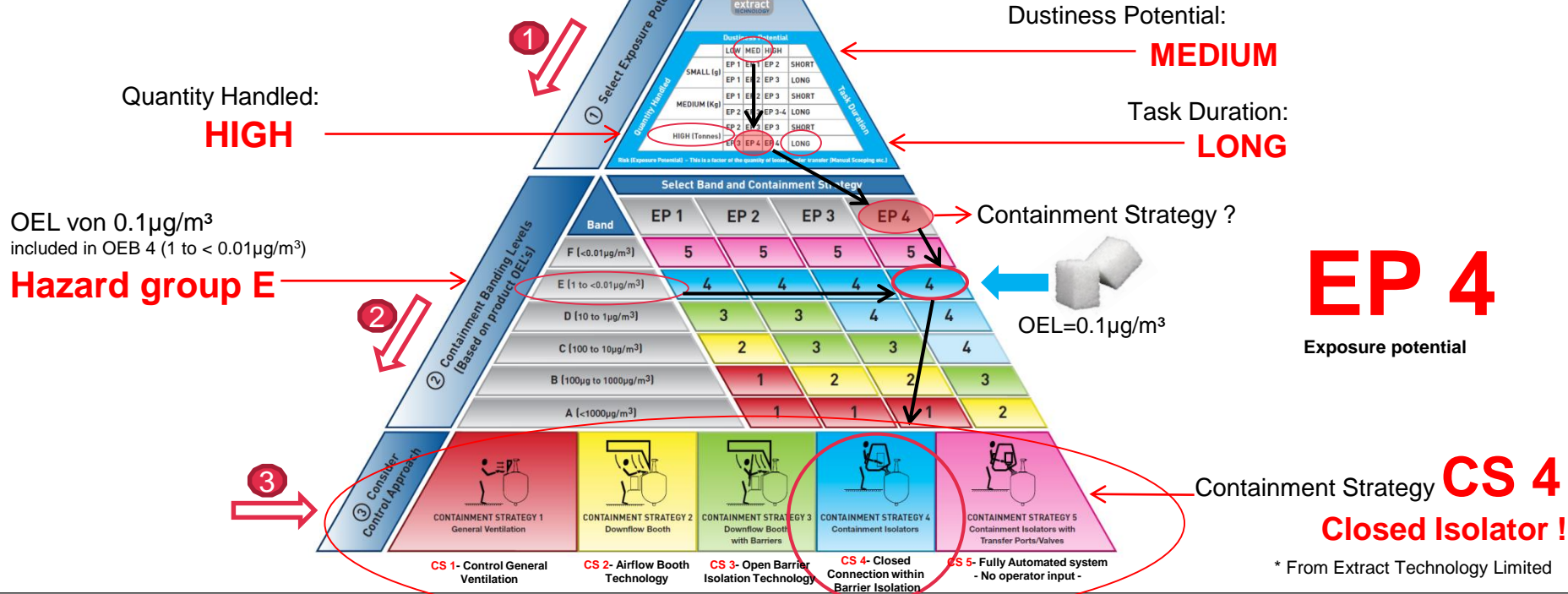
Mr. Martyn Ryder, Director for **Extract Technology Ltd.**



Containment

strategy selection chart

CASE 1 : OEL von $0.1\mu\text{g}/\text{m}^3$



- Take 2 sugar sticks of total **12 g**
- Dilute it in the Empire State Building **113Mio. m³**
- Correspond of **0.1 μg** Naproxen in a volume of **1 m³**



How to set pharmaceutical containments

Dustiness potential

+

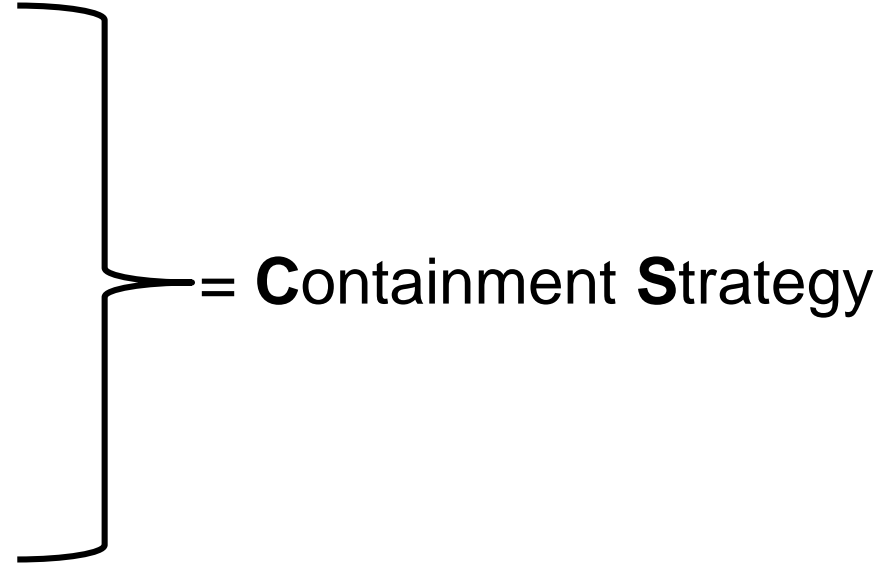
Quantity handled

+

Task duration ■

+

Occupational Exposure Limit



HOW TO USE THE NNE PHARMAPLAN

*“RISK ASSESSMENT
- REAL OPERATOR INTAKE - SIMULATION”*

TOOL?

The NP chemical risk assessment tool – ROI simulation

- Calculation of **ROI (Real Operator Intake)** at the various process steps

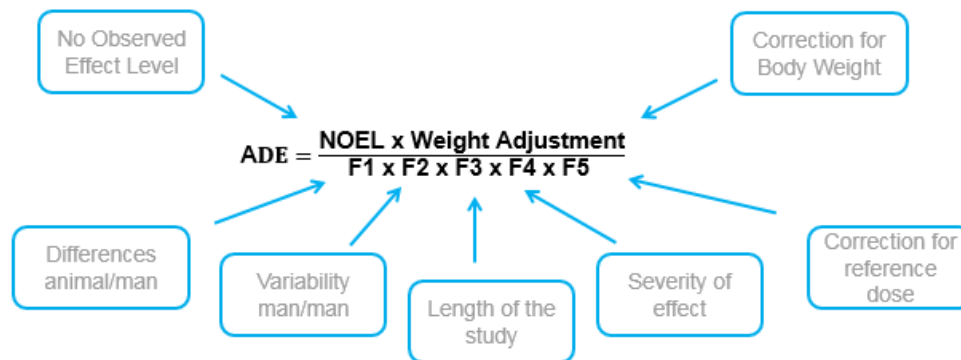
The **ROI** describes the amount of API which gets into the body of the operator, while being for a certain period of time in an area with a certain airborne drug concentration.

$$\begin{array}{c}
 \text{NNE} \quad \text{Breathing} \quad \text{API +} \quad \text{100\% powder,} \\
 \text{Data bank} \quad \text{volume} \quad \text{excipients} \quad \text{or granulates or tablets or capsules...} \\
 \\
 \text{ROI}_{15\text{min}} = \text{STTWA} \times V_{15\text{min}} \times \text{dilution factor} \times \text{volatility factor} \quad \left(V_{15\text{min}} = \frac{10\text{m}^3/\text{day}}{32 \text{ quarter hours/day}} \right) \\
 \\
 \text{ROI}_{15\text{min}} [\mu\text{g}] = \text{STTWA} [\text{mc}\mu\text{g}/\text{m}^3] \times 0,3125 \frac{\text{m}^3}{15\text{min}} \times \text{dilution factor} \times \text{volatility factor}
 \end{array}$$

ST TWA (Short Term Time Weighted Average) is the measured exposure of the equipment according to SMEPAC.

Acceptable Daily Exposure (ADE)

- “Acceptable Daily Exposure (µg)
The ADE represents a substance-specific dose (in µg/day) that is unlikely to cause an adverse effect if an individual is exposed, by any route, at or below this dose every day for a lifetime” (*).



➤ ADE (µg) ~ 10 x OEL µg/m³

ROI ≤ ADE

PERSPECTIVE AND POTENTIAL

Perspective and potential

Justification of the containment performance → justification for the right investment

Risk Assessment via - Real Operator Intake :

- customer specific risk analysis
- accurate results in a short time
- huge ST TWA NNE Pharmaplan data bank
- continuous growing platform for process support with solids

Remember, it is a simulation tool to evaluate the ROI > **IT IS NOT THE BIBLE !**

THANK YOU VERY MUCH FOR YOUR ATTENTION !

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