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## Trends in Containment I solation Technology

## Progression in containment equipment over the decades





Legislation led to a rapid increase in the use of dust collectors in the early 1970s and isolators emerged from nuclear applications into pharma applications in the mid 1990's.

#### Why do we need containment?

#### There is an increased need for CONTAINMENT due to:-

- Greater drug potency
- Reduction on reliance of operator PPE and RPE
- Prevention of workplace contamination & avoidance of quality issues
- Implementation of new legislation for operator safety (e.g. COSHH & OSHA)
- A greater awareness through industry bodies & baseline guides developed by industry societies e.g. ISPE, PDA, etc.
- Plant upgrades driven by introduction of new products
- Avoidance of cross-contamination



#### Isolators now the most common Containment choice in the Pharma Industry



#### What is 1µg/m<sup>3</sup>?

Imagine 1/3rd of a single grain of sugar

Now, cut 1/1000th of that & place it in a  $1m^3$  box  $\longrightarrow$ 





#### That's 1µg/m<sup>3</sup>

Isolators are now regularly required to achieve operator exposure levels of <5ng/m<sup>3</sup>

That's 200 times lower

Where next? Increasingly tighter operator protection levels are continually being demanded.



#### Observed containment levels for Isolators over the last 25 years.





Creating new bandings is the easy element...

#### Current accepted bands...

#### Logical extension...

OEB Band	OEL Range (µg/m³)
OEB 1	1000 – 5000
OEB 2	100 – 1000
OEB 3	10 – 100
OEB 4	1 – 10
OEB 5	<1

OEB Band	OEL Range (µg/m³)
OEB 5	1 - 0.1
OEB 6	0.1 – 0.01
OEB 7	0.01 – 0.001
OEB 8	<0.001

Therefore OEB 8 at <1ng/m<sup>3</sup> is effectively entering the picogram domain...

### Containment Isolators in the future?

Interfaces, transitions & cleaning are the weakest elements and these aspects need careful consideration







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Thank you for your attention