

# *Occupational Exposure Banding*

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# *IH Terminology Refresher*

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- **OEL – Occupational Exposure Limit**
  - *A Level of Exposure to an Airborne Contaminant the is Considered Safe to Nearly All Employees*
- **OEB – Occupational Exposure Banding**
  - *Aligns Chemicals in Groupings based on OEL if Known or Inherent Toxicity & Potency Characteristics if no Data Exists in Order to Establish Safe Handling Guidelines*
  - *Almost Every Company has Their Own Version*
- **TWA – Time Weighted Average**
  - *The Exposure Divided Over A Time (Typically 8 or 12 Hours)*
- **Task Based**
  - *The Exposure Over the Specific Task Time*
  - *Also termed “STEL – Short Term Exposure Level”*

# *Evidence Containment Needs Are Growing*

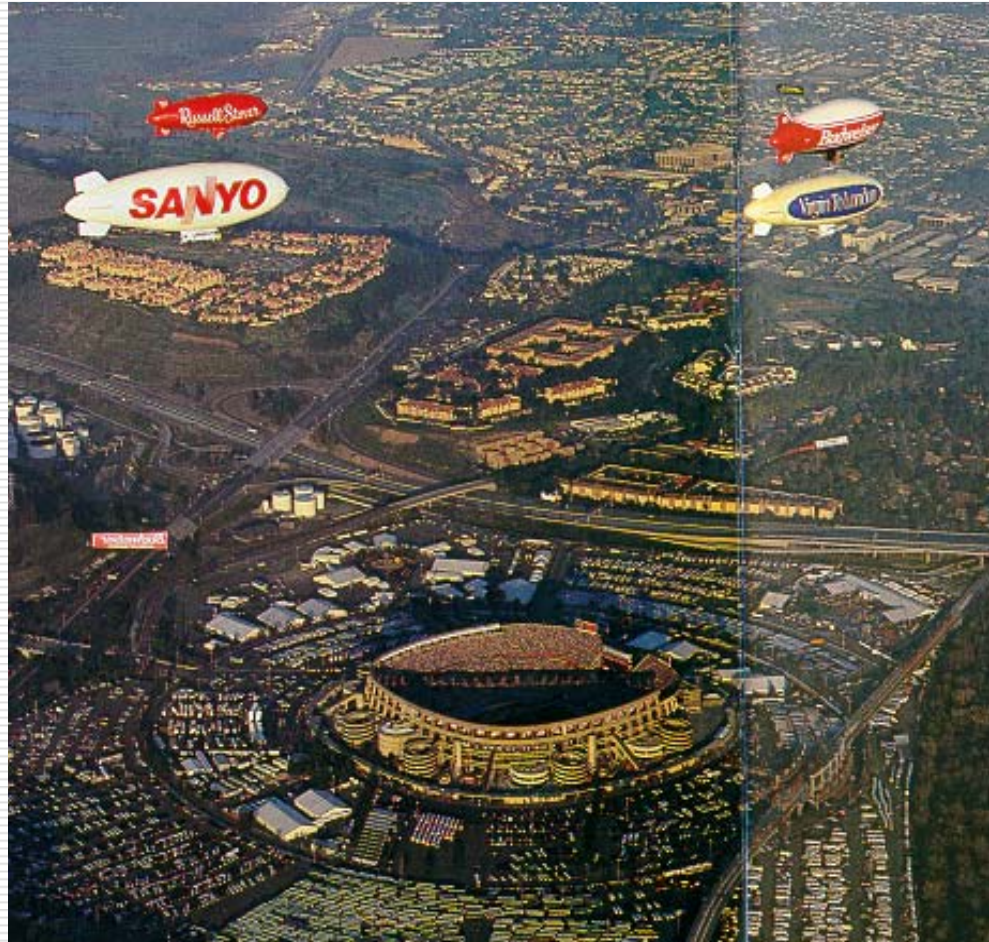
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- **Potent Drugs in The Pipeline**
  - *1980 – 5%*
  - *1990 – 20%*
  - *2000 – 50%*
  - *2010 – 90%*
  
- **At Least 3 Leading Pharma Manufacturers Are at 95% Now**

From ISPE Presentation

# What is $1 \mu\text{g}/\text{m}^3$ ?

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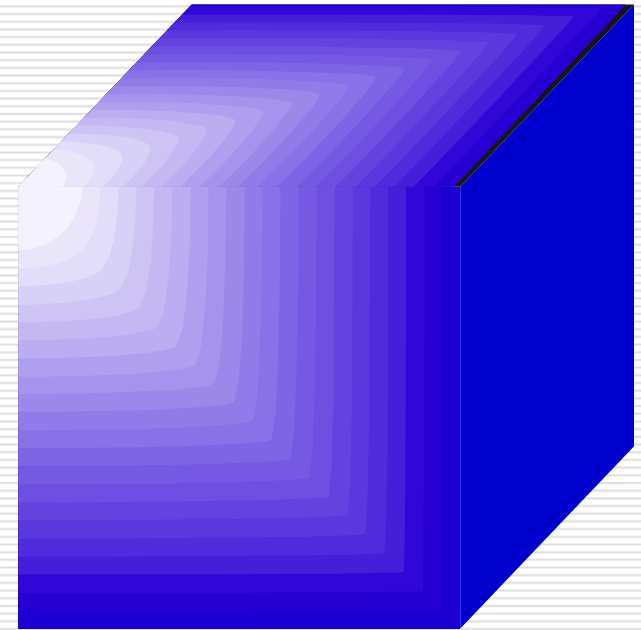
**Find the guy in Section 244, Row M, Seat 22.**

**Now grind up his hamburger and scatter it throughout the entire stadium.**

**That's  $1 \mu\text{g}/\text{m}^3$**

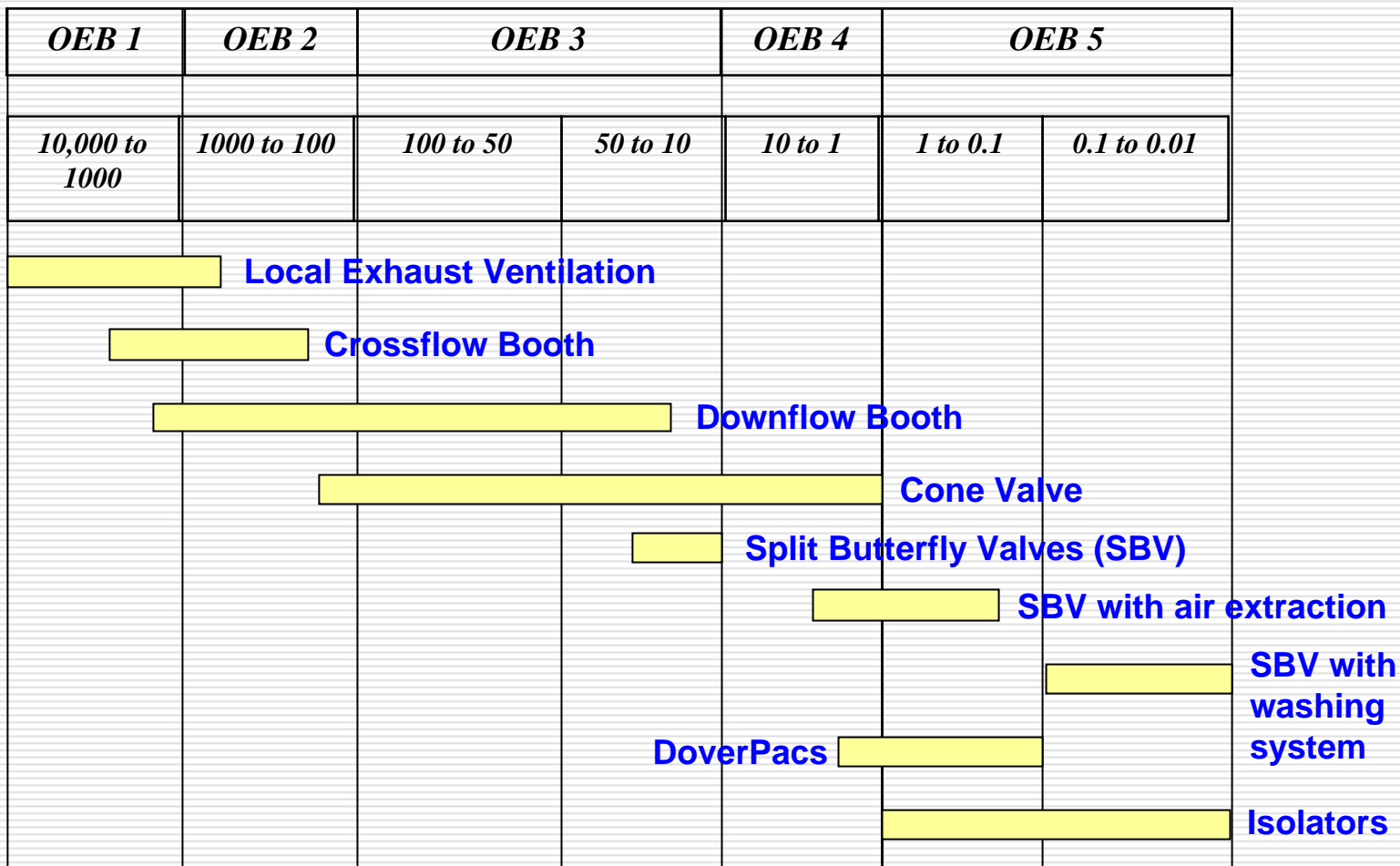
# *Another Way to Look at 1 $\mu\text{g}/\text{m}^3$*

- One Grain of Sugar is 3 mg
- Take 1/3rd of that Grain of Sugar
- Now, take 1/1000<sup>th</sup> of that
- Place it in the 1m x 1m x 1m box
- That's a 1  $\mu\text{g}/\text{m}^3$  Concentration



# Occupational Exposure Banding

## Comparing Current Industry Offerings



Information used is from ISPE and Other Presentations by Industry Experts and Supplier Web Searches  
 Bands vary by Pharmaceutical Manufacturer.  
 These are provided here as an overall guide and should be verified with each companies IH group.  
 All are TWA Ratings.

# Occupational Exposure Banding of Validated Flexible Containment Options

<i>OEB 1</i>	<i>OEB 2</i>	<i>OEB 3</i>		<i>OEB 4</i>	<i>OEB 5</i>	
<i>10,000 to 1000</i>	<i>1000 to 100</i>	<i>100 to 50</i>	<i>50 to 10</i>	<i>10 to 1</i>	<i>1 to 0.1</i>	<i>0.1 to 0.01</i>
	<b>G2Pac</b>					
	<b>Continuous Liners with Secondary Containment</b>			<b>23" Diameter Continuous Liner</b>		
				<b>14" Continuous Liner</b>		
				<b>Enclosures</b>		
				<b>DoverPacs</b>		
				<b>Coaxial Neck DoverPac &amp; Enclosure</b>		
						<b>Drum Transfer System</b>
					<b>Glovebags</b>	

Bands vary by Pharmaceutical Manufacturer.  
 Ratings based on independent and customer test data. TWA ratings shown  
 Results can vary by product

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**Thank you. Any Questions?**



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