PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Occupational Health and Industrial Hygiene

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AGENDA 大纲

1. Audit overview – 10 mins
2. Subject overview –40 mins
3. Example audit findings – 30 mins
4. Audience questions – 10 mins

Bio 个人简介

15 years in Pharma & Chemical

PSCI Role: IH sub team member

Company Job Title: Manager, External Supply EHS&S, J&J

Previously working as

- Associate EHS Manager at Roche
- EHS Supervisor at BASF
- EHS Engineer at Shanghai chlorine-alkline chemical

BS in Safety Engineering

Certified Industrial Hygienist

AGENDA 大纲

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1 – AUDIT OVERVIEW

Audit Questions Summary – Occupational Health and Industrial Hygiene

Topic	Question summary
Occupational Health and Industrial Hygiene	• Risk assessments for chemicals handled • Occupational exposure level (OEL) values for APIs and hazardous substances • Exposure control capabilities for pharmaceutical compounds • Risk-based medical monitoring or employee health surveillance • Plan to protect First Aid Responders and Medical Professionals from body fluids • Exposure monitoring for the following health and safety risks • Site procedure to inform employees of the results of exposure evaluations and monitoring • Personal Protective Equipment (PPE) for face, eye, foot, head, body and hand protection • Respiratory protective devices and/or engineering controls • Respiratory protection equipment program appropriateness • Fit testing, training, use, cleaning, inspecting, storing, and maintenance of respirators
Hazard Information	• Safety Data Sheets (SDSs) for all hazardous substances
Biosafety	• Does the site handle Risk Group 2 – 4 organizations and have a Biosafety Program

2 – SUBJECT OVERVIEW

What are the PSCI Health & Safety Principles applicable to IH?

1. Worker Protection
Suppliers shall protect workers from over exposure to chemical, biological, physical hazards and physically demanding tasks in the work place and in any company provided living quarters.

3. Emergency Preparedness and Response
Suppliers shall identify and assess emergency situations in the workplace and any company provided living quarters, and to minimize their impact by implementing emergency plans and response procedures.

4. Hazard Information
Safety information relating to hazardous materials - including pharmaceutical compounds and pharmaceutical intermediate materials - shall be available to educate, train, and protect workers from hazards.

Using the PSCI Questionnaire for IH

- Don't just answer yes/no. If you did not evaluate that question – type in Not Evaluated.
- Identify what they do and let the PSCI company understand ANY concerns with the approach you see.
- Ultimately place in your conclusions about acceptability for the Supplier to be CAPABLE and EFFECTIVE at handling the APIs they are under contract to handle. Be sure in question 66 to document whether the OEL handling approach aligns between the companies. Also document whether in question 67 whether the capability they say they have is there and if it is appropriate for what they are actually handling.
- One of the most common findings is the Supplier doesn't really know whether exposure control is acceptable as there is no monitoring– write the finding "Company has monitoring data for employees but it is limited to (or does not exist) and thus the exposure control strategy cannot be confirmed as adequate. The recommendation might be "secure the exposure assessment data to confirm the existing control strategy of engineering and PPE controls is sufficiently protective.
- ALWAYS – reference what you SAW in the field, not what you read just in a SOP. Be sure to document what you did or did not see on your tour! The actual SCOPE toured is very important for possible sharing of future audit reports between PSCI members. For example we did not see the highly potent handling area or we did not tour buildings 1,2,3.

Using the PSCI Questionnaire for IH

Management System Questions for IH

- 6. Does the facility or company have a process to manage all changes (e.g. chemicals)?
- 9. Does the facility or company maintain documentation for : Injury/Illness logs
- 11. Does the facility have formal processes to assess effectiveness of it's HSE programs?

Safety/Risk Management Questions – for IH

- 49. Indicate the number of significant Health & Safety incidents occurred at this facility over the past three years? if yes – look for evidence of tracking actions.

Some Ideas/Considerations

- Be sure to understand how new unit operations and/or new chemicals are introduced to the facility and if there is a formal change control process for that and for conducting baseline risk assessments.
- Explore how new chemical regulations (vs process) changes are managed – e.g. a new REACH like ban on a chemical.
- Ask about the last 5 years and any chemical exposure events or ergonomic events. If there are none- investigate into reporting of first aids and near misses as this would be somewhat unusual.
- For the self auditing program – confirm that the company is including worker safety / PPE type programs. You don't want centrally written programs by a corporate group that are not verified on the floor at the plant that you are doing business.

Some Ideas/Considerations

- Be sure to cover Chemical exposure to workers or contractors in the scope of this question.

Using the PSCI Questionnaire for IH

Safety/Risk Management Questions – for IH

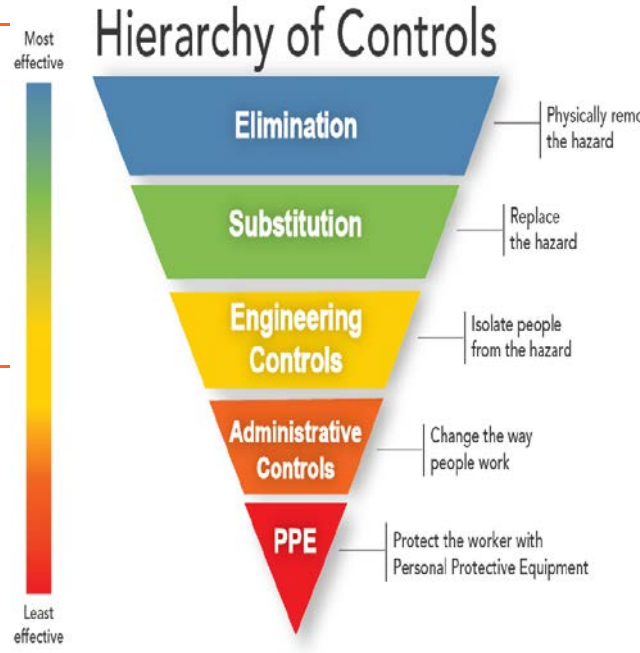
- 50. Does the facility provide HSE training to employees (full time, part time and contract)?

Some Ideas/Considerations

- The only IH specific question is Hazard Communication. There are many other IH related trainings – such as respirator, noise, PPE, asbestos, ergonomics. If you find a significant gap in training for IH be sure to include it either here or in the IH set of questions.

1 – Actual IH Questionnaire questions..

Occupational Health and Industrial Hygiene			
65	Does the facility perform risk assessments for chemicals handled?	Yes ☐ No ☐ Please explain: Do they consider pregnant women?	Yes ☐ No ☐ Comments
66	Has the facility occupational exposure level (OEL) values for all Active Pharmaceutical Ingredients (API) and hazardous substances (including intermediates and solvents)?	Yes ☐ No ☐ NA ☐ If yes, please explain how the OEL values are obtained:	
67	Has the facility established exposure control capabilities for handling pharmaceutical compounds? Please specify the lowest control range of containment for dust/powder handling that has been achieved.	Yes ☐ No ☐ NA ☐ ☐ <1µg/m³ ☐ 1-10 µg/m³ ☐ 10-100 µg/m³ ☐ >100 µg/m³ Comments:	
68	Does the facility perform risk-based medical monitoring or employee health surveillance which includes recording, investigation and follow-up?	Pre-employment physicals: Yes ☐ No ☐ Routine blood monitoring: Yes ☐ No ☐ Routine urinalysis: Yes ☐ No ☐ Lung function testing: Yes ☐ No ☐ Hearing test: Yes ☐ No ☐ Other: Yes ☐ No ☐ If yes, please describe:	



1 – AUDIT OVERVIEW

69¶	Has·the·facility·developed·and·implemented·a·plan·to·protect·First·Aid·Responders·and·Medical·Professionals·from·exposure·to·body·fluids?¤	Yes·☐·No·☐·Please·explain:·°°°°°¶ Does·the·program·include:¶ Training?·Yes·☐·No·☐¶ Exposure·response·kits·regularly·checked?·Yes·☐·No·☐¶ The·offer·of·Hepatitis·B·vaccinations?·¶ Yes·☐·No·☐¤
70¶	Does·the·facility·perform·exposure·monitoring·for·the·following·health·and·safety·risks?¤	Solvent·vapors:·Yes·☐·No·☐·NA·☐¶ Workplace·noise·levels:·Yes·☐·No·☐·NA·☐¶ Pharmaceutical·powders:·Yes·☐·No·☐··NA·☐¶ Radiation·levels:·Yes·☐·No·☐·NA·☐¶ Oxygen-deficient·atmospheres·(e.g.·nitrogen,·inert·gases):·Yes·☐·No·☐·NA·☐¶ Ergonomics·(height·lifting,·clima,·illumination,·vibrations,·...):·Yes·☐·No·☐·NA·☐¶ Other:·Yes·☐·No·☐·¶ If·yes,·please·describe:·°°°°°¤
71¶	Is·there·a·site·procedure·to·inform·employees·of·the·results·of·exposure·evaluations·and·monitoring·results?¤	Yes·☐·No·☐·NA·☐¶ Comments:·°°°°°¤
72¶	Does·the·site·provide·Personal·Protective·Equipment·(PPE)·for·face,·eye,·foot,·head,·body·and·hand·protection?¤	Yes·☐·No·☐¶ Please·explain:·°°°°°¤

1 – AUDIT OVERVIEW

73¶ ¤	Does·the·facility·rely·primarily·on·respiratory·protective·devices·and/or·engineering·controls·to·protect·employees·who·handle·chemicals·to·achieve·exposure·levels·below·the·exposure·limit?¤	Respiratory·protective·devices·Yes·☐·No·☐¶ Engineering·controls·Yes·☐·No·☐¶ ¶ Please·specify·the·types·of·engineering·controls·used·to·manage·identified·chemical·exposure·risks:¶ ¶ Laminar·flow·hoods:·☐·¶ Down·flow·booths:·☐¶ Powder·transfer·systems:·☐¶ Alpha-beta·valves:·☐¶ Split·butterfly·valve:·☐¶ Soft·or·hard·wall·isolators:·☐¶ Local·exhaust·ventilation:·☐¶ Closed·processes:·☐¤
74¶ ¤	Does·the·facility·use·any·of·the·following·respiratory·protection·equipment·for·worker·protection·against·exposure·to·chemicals·or·pharmaceutical·compounds?¤	Supplied·air·breathing·systems·Yes·☐·No·☐¶ Powered·air·purifying·respirators·Yes·☐·No·☐¶ Full·face·respirators·Yes·☐·No·☐¶ Half·face·respirators·Yes·☐·No·☐¶
		Filtering·face·masks·Yes·☐·No·☐¶ Other·Yes·☐·No·☐·-If·yes,·describe:·°°°°°¶ What·criteria·are·used·to·select·respirator·protection·devices?·°°°°°¶ Respiratory·Protection·is·not·used?·☐·¶ Please·explain·if·not·applicable:·°°°°°¤
75¶ ¤	Are·there·provisions·for·fit·testing,·training,·use,·cleaning,·inspecting,·storing,·and·maintenance·of·respirators?¤	Yes·☐·No·☐·NA·☐¶ Please·explain:·°°°°°¤

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Potent and Sensitizing API Compounds

What is a Good IH Program?

- An onsite person who has had training in control of hazardous agents.
- Access to an expert (e.g. certified industrial hygienist, qualified consultant).
- Inventory of hazardous chemicals, in particular potent materials, sensitizers, carcinogens and reproductive hazards.
- Information on chemical agents from customers and suppliers, occupational exposure limits or use of a banding system.
- Access to SDS and communication of risks, procedures and controls to staff using the hazardous chemicals.
- Risk assessments:
  - chemicals used, operations performed, assessment of control measures (including non-production tasks such as maintenance of equipment, handling of waste).
  - physical hazards and exposure controls methods in place.
- PPE Procedures and training on use, storage, and cleaning.
- Exposure sampling and monitoring data as appropriate.
- Risk based health surveillance.
- Incident/exposure records & strong accident investigations.
- Company has default program rules for handling unknown characterized chemicals.
- Worst case scenarios are understood for off-site consequences with training and emergency plans that are practiced….e.g. Ammonia cloud going off site.

WHY is this so critical in Pharma? Because APIs are not Nuisance Dust!!

INDUSTRIAL HYGIENE / WORKER EXPOSURE RED FLAGS

- We know APIs typically do not have regulatory exposure limits – PSCI companies DO NOT treat APIs as NUISANCE DUST. Agree on the required exposure limit and control banding. If none exists – Red Flag.
- Look at SDS between companies – do they agree on OEL and classifications? Differences >20X may be of concern.
- Bulk API /DP (drug product) companies for Pharma MUST have internal processes for setting final API and intermediate control banding and implementing those practices – especially in development and for intermediates.
- Industrial hygiene workplace monitoring needs to CONFIRM their strategy is working, especially when exposure limits are low (< 10 micrograms/m3) and respirator in use is very minimal. No data is a RED FLAG if handling highly potent materials.
- IH Capability in some parts of the world is a challenge. We typically encourage our partners to hire consultants.

First Question to prepare before audit –
Do we agree on Hazards of API?
Do we agree on the Controls Needed?

- API Supplier – Generic
- API Supplier – Proprietary Chemistry as Contract Manufacturer
- Pharma Drug Product site acting as Contract Manufacturing Company

Some Ideas/Considerations

- Review SDSs available– Do they agree on Hazard Classification and Occupational exposure limit?
  - If there is different classification or different OELs, Are the implemented exposure control methods based on the most conservative/lowest OEL?

- In your field visit, verify which are the exposure controls in place. Do they match with the described in the Risk Assessment?
- Request results of IH monitoring data collected.
  - If monitoring has not been conducted, verify exposure control/containment capabilities in your field visit.

A few foundational basics….

- **Occupational Exposure Limit (OELs)**
  - A numerical air concentration limit expressed as PPM or mg/m3 over a stated time duration (8hr, 12hr, 15 min, Ceiling) which nearly all adult workers may be exposed to during their working lifetime without adverse effects. These may be set by a government or a company.
  - Thousands of chemical do NOT have OELs.
  - Can be found on a SDS.

- **Occupational Exposure Banding** – Pharmaceutical Industry Method
  - Classify the Hazard Bands and pick your Default Band: The method a company establishes to setup rules for identifying a control strategy for handling materials with limited toxicology data for safe handling. The bands may be created using rule sets, limited toxicology, and Risk Phrases from the Global Harmonization Standard. Typically found on a SDS.
  - An established set of recommended ENGINEERING and CONTROL strategies for handling chemicals within a chemical exposure band. Companies who set OELs generally have these. NOT typically found on a SDS. You should ask to see this.

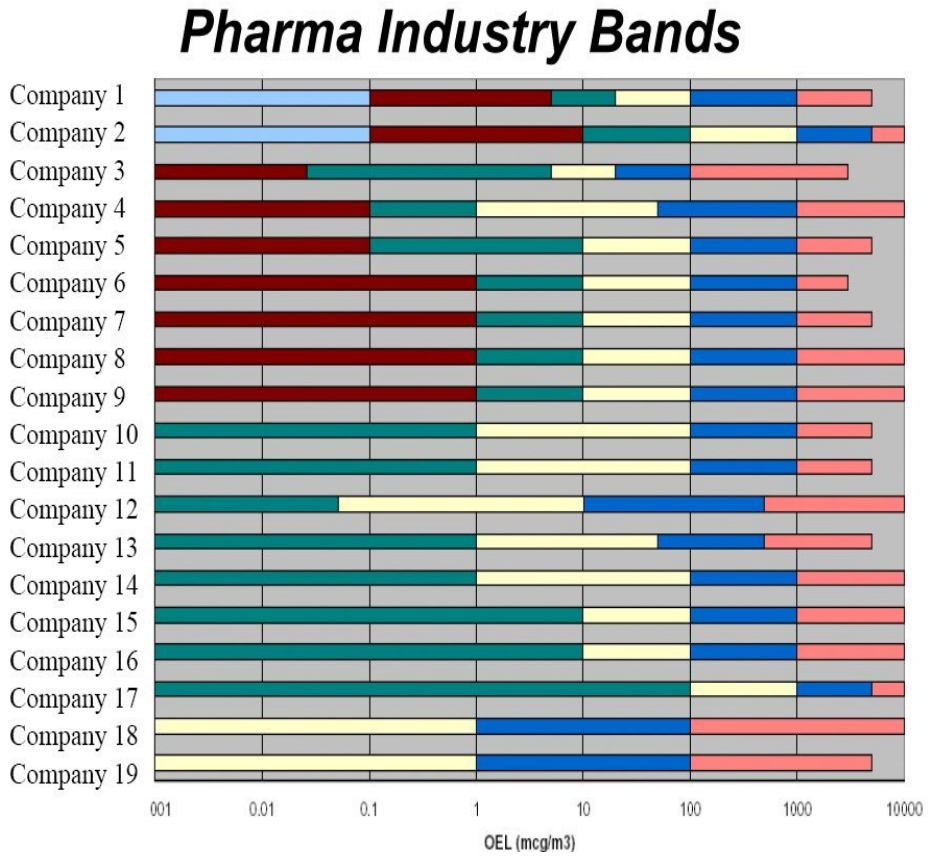
$$\text{OEL } (mg/m^3) = \frac{\text{NOEL } (mg/kg/day) \times \text{BW } (kg)}{V\ (m^3/day) \times S \times UF \times \alpha}$$

- NOEL = the no-observable-effect-level (mg/kg/day)
- BW = average human body weight (50 kg)
- V = volume of air breathed in an 8-hr work day (10 m^3/day)
- S = time, in days, to achieve a plasma steady state
- UF = uncertainty factors
- α (alpha) = % absorbed through inhalation

Managing Potent and Sensitizing Compounds Exposure Control Banding

- Example of exposure control banding:
  - OEB 1 (>1000 ug/m3)
  - OEB 2 (100-1000 ug/m3)
  - OEB 3 (10-100 ug/m3)
  - **OEB 4 (1-10 ug/m3)**
  - **OEB 5 (<1 ug/m3)**
  - **OEB 6 (<0.1 ug/m3)**

Highly Potent Categories



Yes –variation and nomenclature does exist among companies.

Banding Exercise
What OEL Band mass can your eyes no longer see?

Average worker breathes about 17 m^3 in a workday

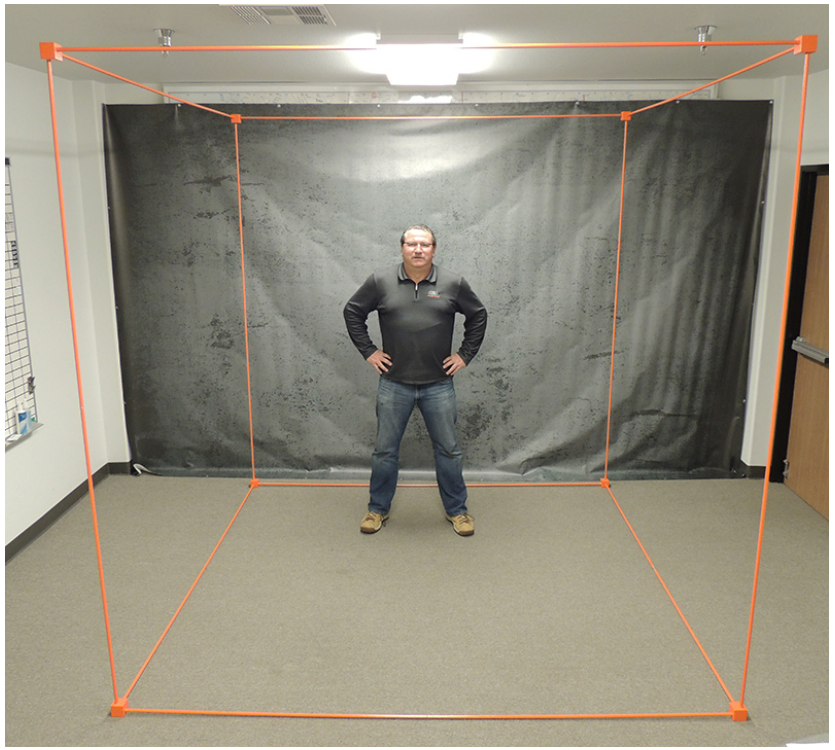
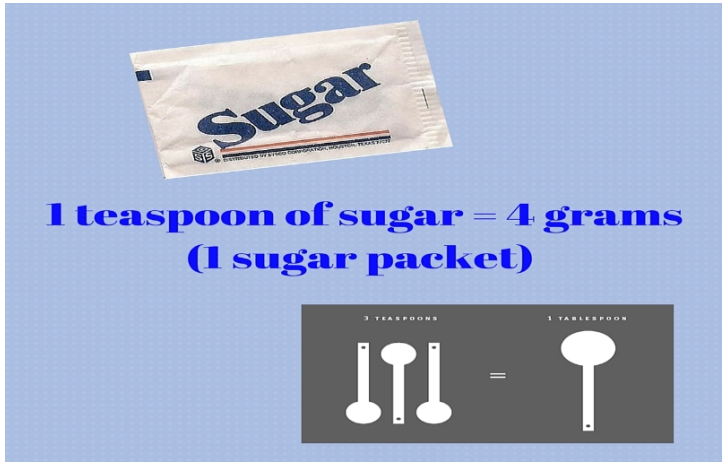


Photo from web reference "IP Powertools – Understanding the OSHA Silica PEL"



Band Range	Mass inhaled over 8hr day
10,000 µg/m^3	4% sugar pack
1,00 µg/m^3	0.4% sugar pack
100 µg/m^3	0.04% sugar pack
10 µg/m^3	0.004% sugar pack
1 µg/m^3	0.0004% sugar pack
0.1 µg/m^3	0.00004% sugar pack

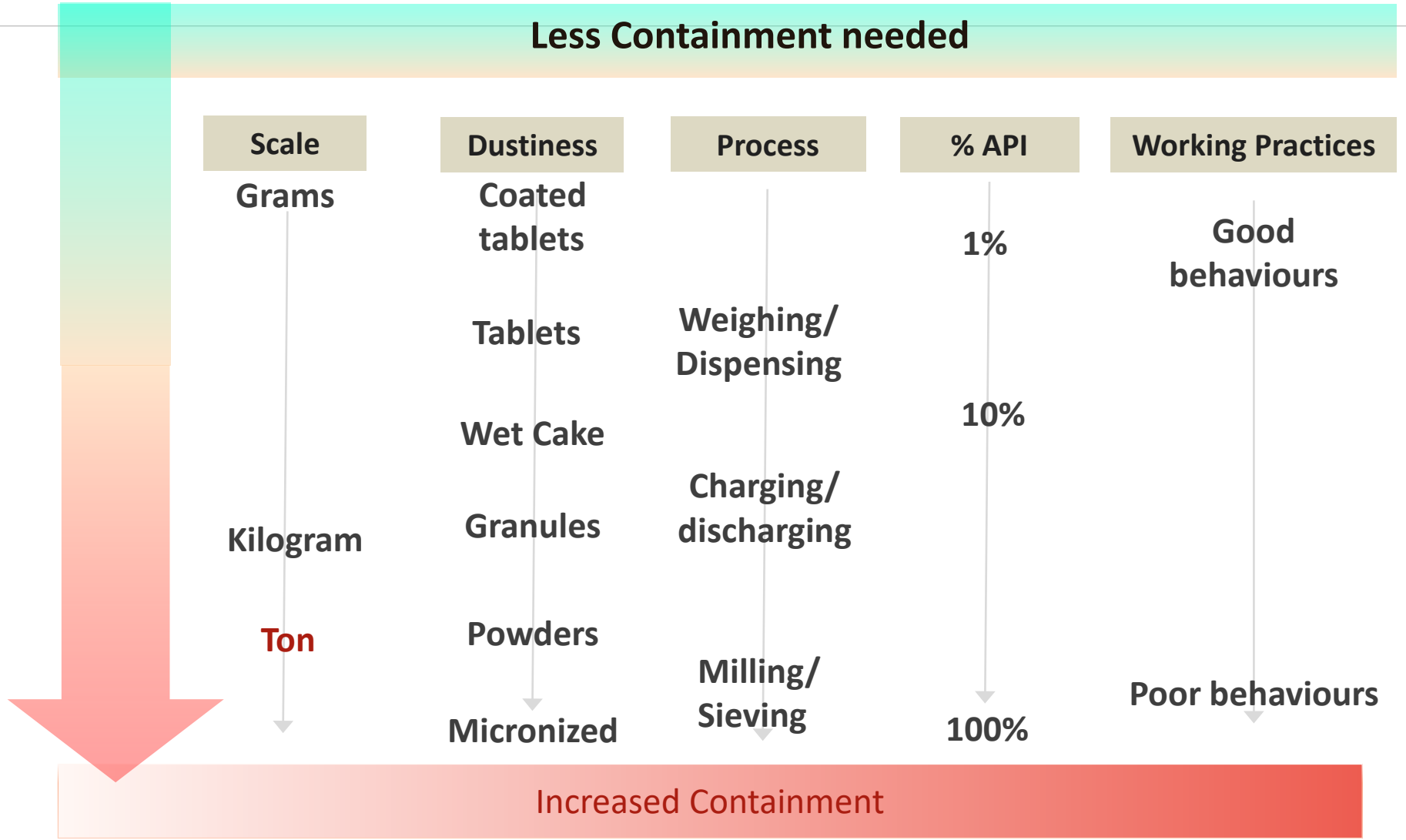
You can't see this exposure

Managing Potent and Sensitizing Compounds Factors Influencing Exposure

If you are Auditing a Supplier making products with an OEL <1 ug/m3 you really need an auditor experienced with exposure control concepts.

It is recommended even for OEL <10 ug/m3.

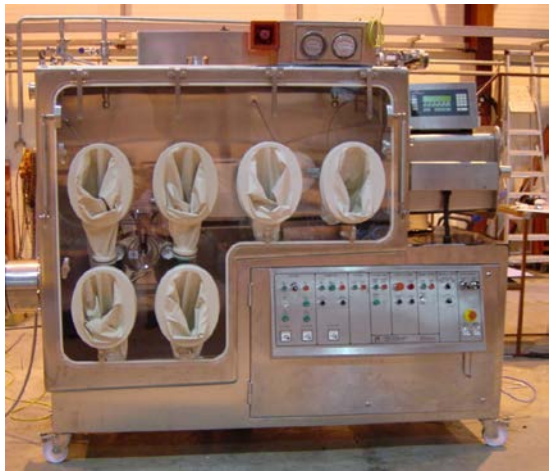
Managing Potent and Sensitizing Compounds Factors Influencing Exposure



Are the controls identified in the Risk Assessment appropriate for the substance OEL or Band and the operation or task observed in your Field visit?

Engineering Control Capabilities from PSCI website

Engineering Control	OEL Capability (µg/m3)*
Walk-in fume hood	< 5000
Laminar flow booth (horiz)	< 500
Laminar flow w/ continuous liner	< 100
Downflow booth	< 100
Downflow booth w/ screen	< 25
Split butterfly valve (SBV)	< 10
Single chamber glovebox (GB)	< 1
SBV w/ purge capability	< 0.5
Glovebox isolator around continuous liner	< 0.1
GB w/ RTP (rapid transfer port)	< 0.05
Multi-chamber GB w/ RTP/ESBV	< 0.01



** operator exposure during unit operation*

When doing a PSCI audit for a member company – Request their banding categories and tools up front to compare supplier actual handling….

Example: Control Banding Implementation

Band	PPE	Facility Design	Engineering Controls	Equipment Cleaning and Maintenance
Level 1	•Gloves •uniforms	•General Ventilation •Shared HVAC •General Filtered Exhaust •Recirculate Permitted •Common Gowning & De-gowning	•Passive Ventilation/Dilution •Open Mat'l Conveying and/or Mat'l Transfers •Open Process Equipment	•Open Process Equipment Transport to Cleaning Area •Manual Cleaning
Level 2	•Respirators •Tyvek coveralls	•Pressure Differential To Selected Adjacencies •Open Process Area •Closed Building •Process segregation with doors •Gowning/De-gowning Room	•Standard Equipment Design (Normally Closed) •Local Exhaust Ventilation •Mat'l Conveying Essentially Open with Hardware Remediation •Pressure Convey •Laminar flow	•Open Process Equipment Cleaned In-Situ
Level 3	•Maximum PF respirator	•HEPA Filtration •Room Finishes & Surface MOC's and Utilities Are Designed for Ease of Cleaning •Process segregation with airlocks •Decon Shower	•Standard Equipment Design with Separate Mechanical Space •Glovebox or Glovebag •Closed Material Conveying •Minimize Make/Break Connections •Split butterfly valves (SBV)	•Provide CIP with Rinse Water Capture •Closed equipment maintenance capability
Level 4	•Seek expert assistance •Respirators not adequate for "open" processing •Redundant PPE with engineering controls	•Seek expert assistance •Dedicated HVAC •HEPA Filtration w/Safe Change •No Exhaust Return •Closed Process Area •Closed Building •Separate Gowning & De-gowning •Automation	•Seek expert assistance •Process Equipment is Designed for Total Containment •Closed Mat'l Transfers with Barrier Add-ons •Vacuum Convey •Minimize Mat'l Conveying Steps •Minimize Material Transfer Connections •Isolator with continuous liner •Enhanced/purgeable SBV	•Seek expert assistance •Minimize Waste via Process and Formula Optimization •Protective barriers for laptops, paperwork, documents

what are your PSCI member company's band cut-off points?

Isolators

High Containment Capability for Potent Substances/APIs.

Flexible- glovebag or room enclosures

Rigid- glovebox

Laminar Flow Booths

When working on Laminar Flow Booths, additional control measures are usually needed to handle potent APIs.

Another important aspect is to ask how filters are changed/replaced? Is it performed in a way that minimizes exposure potential ?

Material Transfers

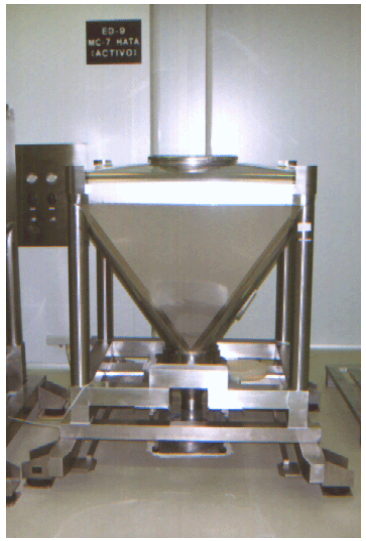
Active- open

Might be acceptable for substances with high OELs, non Potent.

VS

Active- closed

Appropriate for potent substances or substances with low OELs.



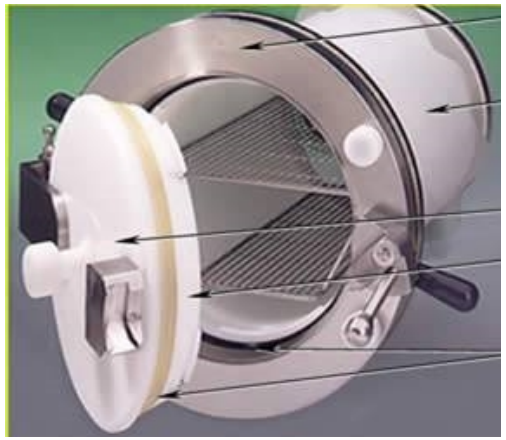
IBC

High containment design but transfer mechanism has to be set in place according to the substance containment level.

FIBC

High containment design for potent and low OELs substances.

Containment Transfer Mechanisms



Alpha/beta flange

Cone valve

Split Butterfly Valve

Containment flap

Continuous liner

Cut & tape bag

Local Exhaust Ventilation (LEV) Case Study

Good vs BAD Design?

- Is it appropriate for the type of operation or substance containment level?
- Does it has the appropriate duct and face velocity?

Request duct and face velocity and compare with industry standard (eg. Industrial Ventilation Manual).

Caution:
When handling Potent APIs, this would not be acceptable. Usually the human eye can not see dusts levels < 10 ug/m3.
Therefore, IH monitoring is necessary to assess containment capability and exposure potential – even on what you think might be well contained

› **Request IH monitoring studies.**

Laboratory Controls

Fume Hood

- Average face velocity 100 fpm
- Max sash height should be demarked
- Alarm (face velocity loss)

Biological Safety Cabinet

- Face velocity varies between 75-100 fpm depending of the cabinet type.
- Alarm (face velocity loss).
- HEPA filtration or ducted models available.
- Filter integrity testing.

Ventilated Enclosure Cabinet for Weighing

Employees must be Trained on how to appropriately use these equipment.

Request performance testing and compare results with industry standard or manufacturer recommendations.

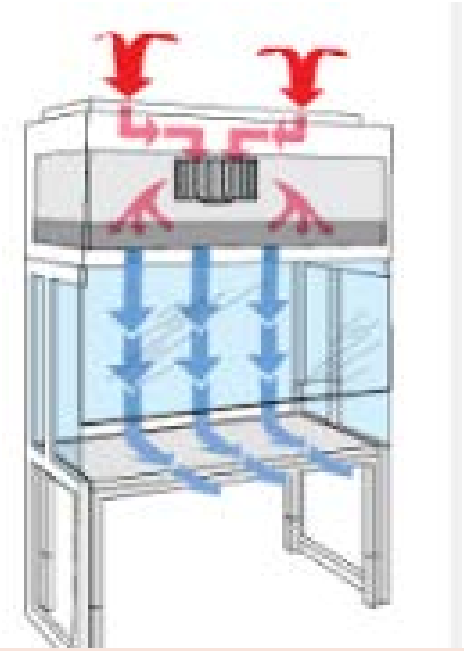
Laboratory Controls

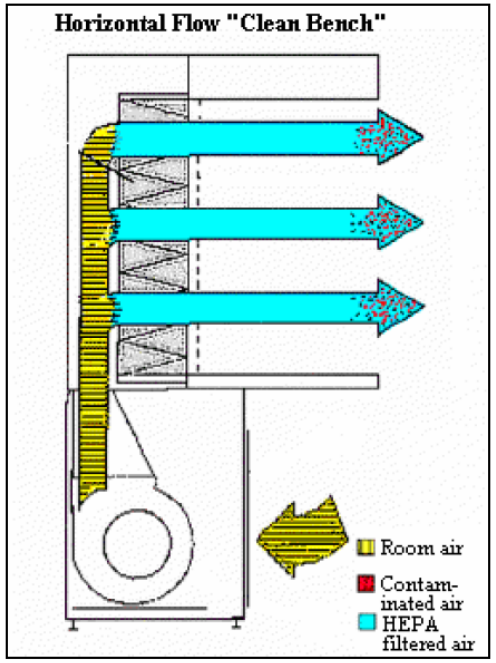
Glove Box

- Provides High Containment capability
- Requires detailed procedure to describe
  - Pre inspection verification
  - Practices for removing API and material (reusable and no reusable) after its use.
- Requires routine maintenance (gloves replacement, filter, pressure test).

Laboratory Controls

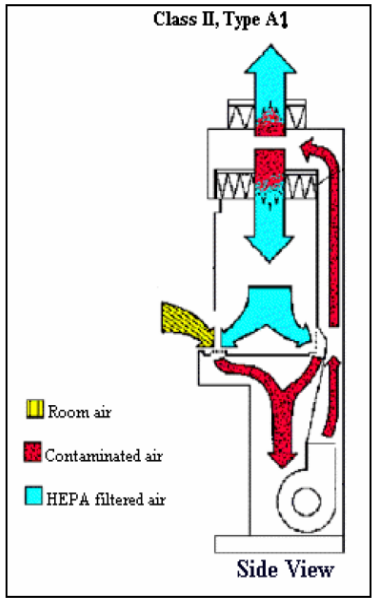
Laminar Airflow Bench





Caution:
Laminar Airflow Workbenches does not provides worker protection. Do not sure for chemicals or Biosafety Level 2 – 4 materials.

Biological Safety Cabinets



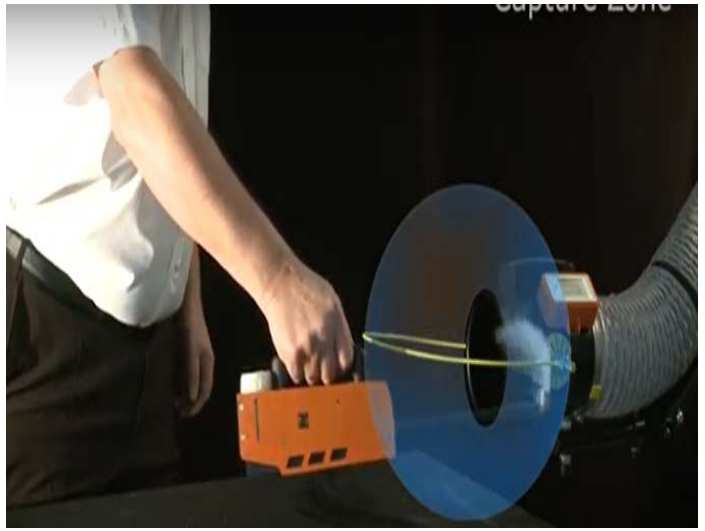
Biological Safety Cabinets Type I or II provides personnel protection. HEPA filters must be tested for efficiency and integrity.

http://www2.tulane.edu/oehs/safety/upload/BSCFactSheet-2.pdf

Engineering Controls Performance Testing

- Proper function of engineering controls depends on adequate maintenance.

Request maintenance records for all engineering control methods and check equipment are being tested in a regular basis and results are compared with industrial standard parameters or manufacturer design parameters.



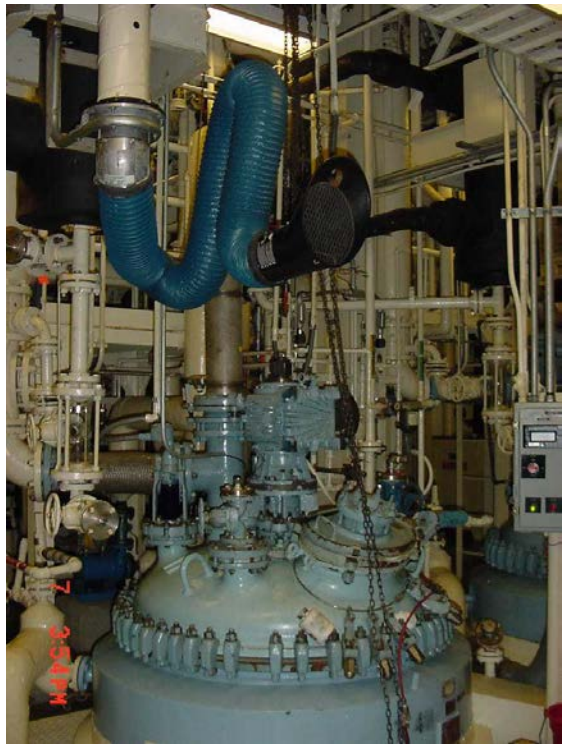
Other IH Considerations in Laboratories

- Chemical Storage by Compatibility (Acids, Bases, Oxidizers, Flammables, Health)
- Flammable Cabinet Storage

- Availability of Eye Wash Safety Showers

Pharma Unit Operations with High Potential for Exposure if not contained

- Reactor charge/material transfer
- Centrifuge unloading of solvent wetcakes
- Unloading Dryers
- Granulation/mixing
- Milling/de-lumping
- Compression
- Dispensing/weighing/repackaging
- Maintenance activities
- Cleaning / Manual Vessel Heel Removal
- Process upsets/spills
- Weighing/Dispensing chemicals



OR

Focus your tour to see these things

IH Monitoring Basics

Does the facility perform exposure monitoring for the following health and safety risks? Mark per category.
Is there a site procedure to inform employees of the results of exposure evaluations and monitoring results?

- Do data/studies ONLY focus on API and not on solvent/gases – Can be BIG issue for wet cakes in API plants.
- Evaluate:
  - # of samples, # of days sampled to understand exposure profile distribution
  - Total Dust vs API dusts at Drug Product Sites – if they are estimating are they using math?
  - Personal Breathing Zone Samples vs Area Samples
  - Short tasks data versus full shift data
  - Training or Technical expertise of the person that
    - collected the samples
    - make study exposure conclusions, and
    - report writer
  - Verify the Math on protection factors
  - No data – they use company's commissioning data on their web site.
- Employees should be informed of monitoring results.

Is it well managed?

Does it seem appropriate?

Most important, use the information to qualify the scope of the data you did see.

Reviewing IH Monitoring Data

During the review of the IH Information and Monitoring Data:

- Be very careful of Units of Measure:
  - mg/m3
  - mcg/m3=µg/m3
  - µg/m3
  - ng/m3

Example:
API Manufacturer Limit : 0.1 mg/m3

PSCI Member Limit: 0.1 mcg/m3

This can be a MAJOR data interpretation mistake on acceptable exposures…it is a 1,000 fold difference.

2nd question – based on controls in place, are people protected?

- If what you saw didn't use the Hierarchy of Engineering Controls, but was more heavily reliant on PPE or work procedures….
- ARE THEY ADEQUATELY PROTECTIVE?

72. Does the site provide Personal Protective Equipment (PPE) for face, eye, foot, head, and hand protection?

- Do PPE and Containment designation comes from a risk or hazard assessment?
- Are PPE and Containment requirements documented in the manufacturing batch record or are employees aware of the requirements by any other formal process?
- Are personnel wearing the correct/required PPE?
- Does the site's Respirator Program appear to be adequately managed?
- If the site is handling highly potent API powders or drug products, have they implemented containment measures to avoid "open handling"? Is there an actual engineering improvement plan? Does the engineering/containment plan comes from a risk assessment or IH monitoring results?
- If the site is handling potent API powders or drug products, have they implemented a comprehensive Industrial Hygiene Monitoring Program (i.e. more than just cursory area samples or particle counting)?

PPE Program should cover the following elements:

- Hazards and PPE types:
  - Head Protection
  - Eye Protection
  - Hearing Protection
  - Respiratory Protection
    - Fit Testing
    - Filters/Cartridges (Use and Replacement)
  - Hands Protection
    - Based on Compatibility Data (Breakthrough time)
  - Body Protection
  - Fee

- Inspection of PPE
- Use of PPE
- Maintenance
- Cleaning
- Storage
- Training

Respirators

- There are two types of Respiratory Protection:
  1. Negative Pressure
  2. Positive Pressure

Negative Pressure

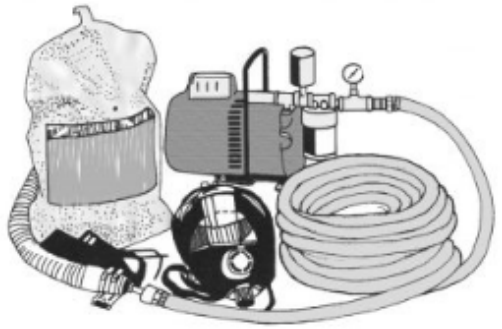
Half Mask Tight Fitting

Medical surgical mask is not a respirator

Full Face Mask Tight Fitting

Positive Pressure

Powered Air Purifying Respirator (PAPR)
Supplied Air Respirator
Self Contained Breathing Apparatus



Respirators

Negative Pressure	Positive Pressure
• Fit Test is conducted prior to assign. 	• Fit Test is not needed.
• Fit Check is conducted prior to use. Explained in Training. • Can not be use with beard or other interferences on the respirator seal. • Training is needed.	• Prior to use inspection is required (physical, battery, airflow, filtration media) • Training is needed.

Use of appropriate filtration media according to the chemicals present.

3rd Question – do we have adequate Respiratory Protection?

The values of the APF in EU and other countries [edit]

Studies of respirator's performance was carried out not very often, and almost all of these studies were conducted in USA (and UK). It is possible that the lack of information about the RPD efficiency in the workplaces, was the reason behind developing these assigned PF in several European countries, whose values differ significantly from the evidence-based values of APFs in the US and UK.

The Assigned Protection Factors for some main RPD types, developed in several EU countries[2] [hide]

RPD type	APF in several EU countries			
	Finland	Germany	Italy	Sweden
FFP2 filtering facepices	10	10	10	10
Elastomeric half masks with P2 filters	10	10	10	10
FFP3 filtering facepices	20	30	30	20
Elastomeric half masks with P3 filters	-	30	30	-
Negative pressure air-purifying respirators with full face mask and P2 filters	15	15	15	15
Negative pressure air-purifying respirators with full face mask and P3 filters	500	400	400	500
Powered Air-Purifying Respirators (PAPRs) with loose-fitting hood or helmet, and THP3 filters	200	100	200	200
PAPRs with full face mask, and TMP3 filters	1000	500	400	1000
SARs with full facepiece and negative pressure demand air supply	500	1000	400	500
Supplied Air Respirators (SARs) with full facepiece and positive pressure demand air supply	1000	1000	400	1000
SCBAs with full facepiece and positive pressure demand air supply	-	≥ 1000	1000	-

If you see dust masks with open handling tasks this could be a red flag…

What is the Level of Protection

- The level of protection for Respirators is defined by the Assigned Protection Factor or Nominal Protection Factor.
- Usually, each Country has established their APF or NPF.
  - APF or NPF x OEL substance= Max Use Concentration

Application:

- Sampling results show a TWA exposure of 350 ug/m3 in 8 hrs
- Respirator being used has a NPF of 10
- OEL for the API is 8 ug/m3 TWA 8 hrs

Is the Respirator appropriate?
> 8 ug/m3 x 10=80 ug/m3 (maximum use concentration).

No, Sampling results (350 ug/m3 TWA) are higher than respirator maximum use concentration. Evidence of employee over-exposure.

Medical Surveillance

68. Does the facility perform risk-based medical monitoring or employee health surveillance which includes recording, investigation and follow-up?

- Regulations can vary on formality of program and scope – know your local countries requirements
- Generally – programs globally exist for respirator protection, noise, some vaccines.
- Is there an occupational physician for the site who understands and sees the workers IH profiles and establishes the medical surveillance program?
- For highly potent compounds – does the site have any special medical surveillance programs, including biological monitoring?
- Has the site experienced high blood results / occupational health events – what is their response action?
- If the material is a sensitizer, has the site established processes to protect people with known allergies?
- How is the site managing reproductive hazards for both men and women?
- What is the frequency of IH Health type events at the site?
- How does the site investigate workplace exposure events?




Is it well managed?

Does it seem appropriate?

Does it cover all hazards that were identified in the visit?

Case Study....potent steroid

- API manufacturer of Generic material did not set their own limits but found a limit on the web from another company and used it.
- **PSCI Member** limit was 500X times lower. Data exchange revealed similar thought process on setting limits but different toxicology data was being used.
  - End Result – companies aligned within 5X on OEL accounting for different safety margin practices.
- Company had no workplace monitoring data to verify they were meeting their previous limit or the new limit. They were in a dedicated suite.
  - API company asked to immediately upgrade from dust masks to PAPR respirators and install better controls.
  - API manufacturer collected IH data to verify that their final PPE/engineering was protective.
  - Engineering controls were implemented in a very focused way reducing costs. Best practice ideas shared between member company and manufacturer.
  - Company applying same approach to all their chemical manufacturing where OELs are not yet established.
  - After visit, manufacture developed a comprehensive banding approach using a consultant.
- DATA IS YOUR FRIEND. In absence – default to more protective PPE & SOPs.

AGENDA 大纲

1. Audit overview – 10 mins
2. Subject overview – 40 mins
3. Example audit findings – 30 mins
4. Audience questions – 10 mins

Industrial Hygiene – What are we after?

PSCI Audit Findings Definitions

Critical Findings:

- Are **very** high risk findings that require immediate action to protect human life, the health of employees or the environment;
- May result in loss of license to operate or serious damage to reputation;
- Require immediate corrective action by the supplier;
- Need to be communicated to the audit sponsor prior to audit report finalization.

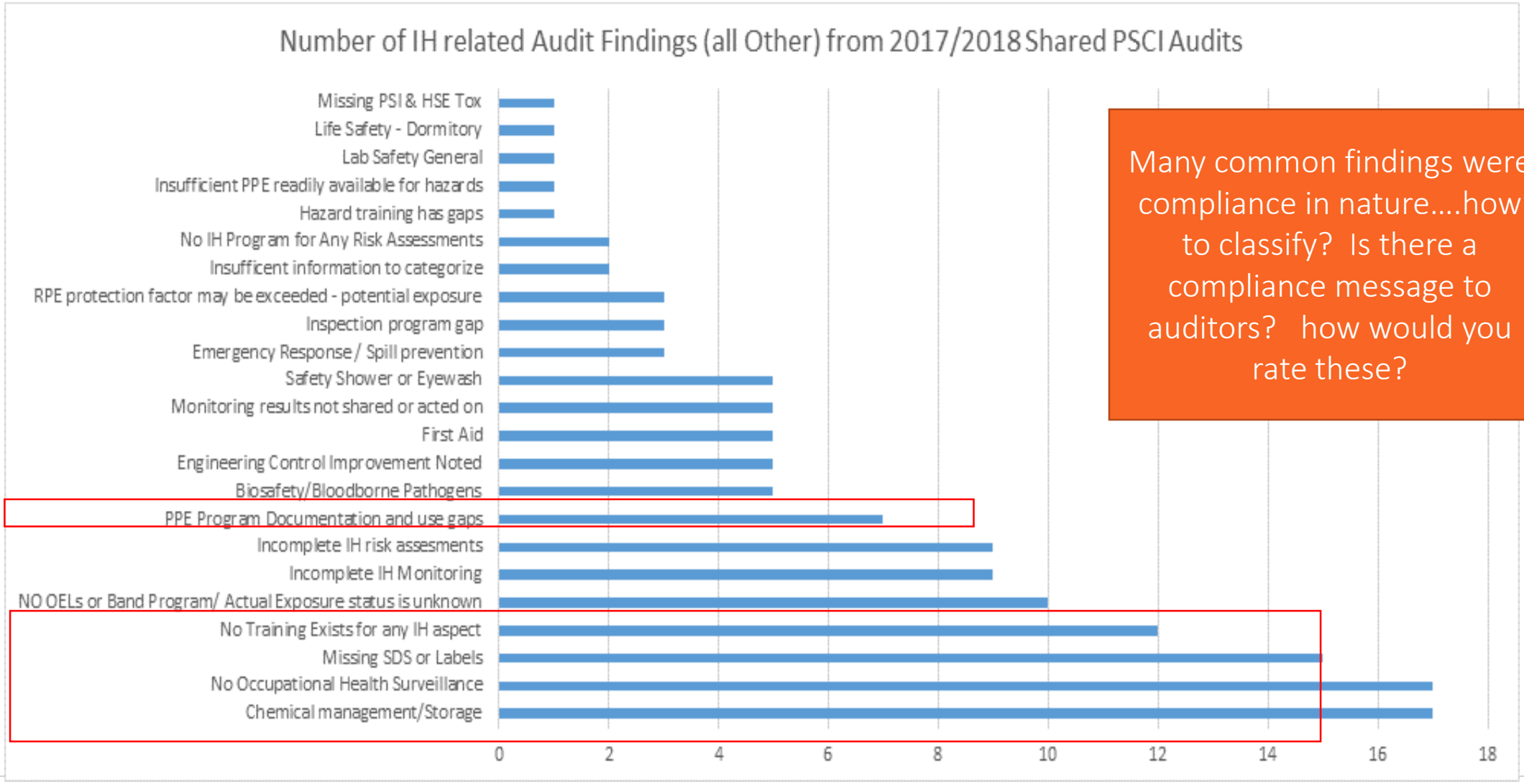
Examples for critical findings:

- Severe violations of human rights or labor rights (e.g. presence of child labor in a facility or forced labor, over-excessive working hours);
- Health and safety issues that can cause immediate life threatening situation or serious injuries to employees and other individuals on site;
- Environmental or safety issues that could result in serious and immediate harm to the community.

Other findings:

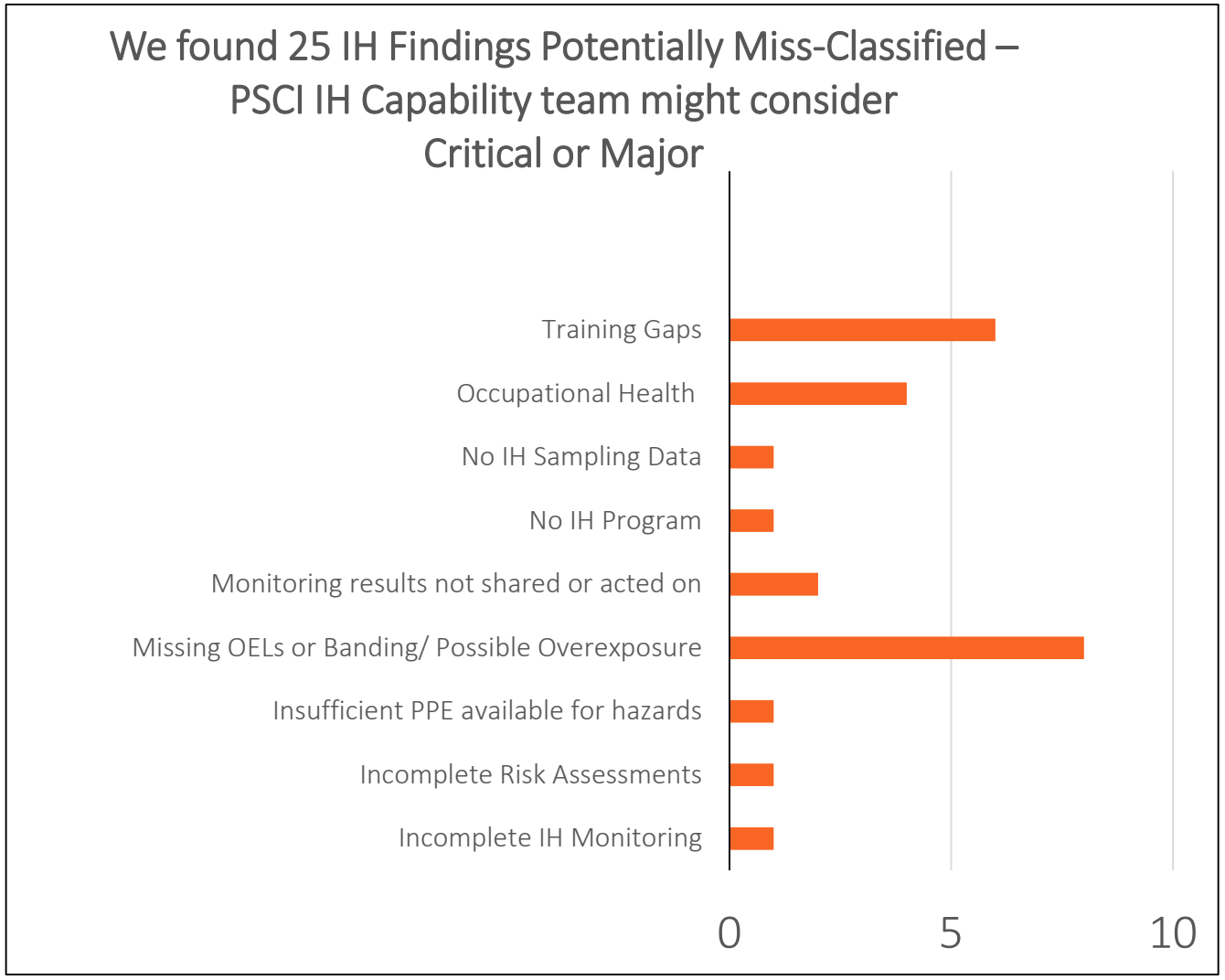
- Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time?

What do we see with Shared PSCI Audits?

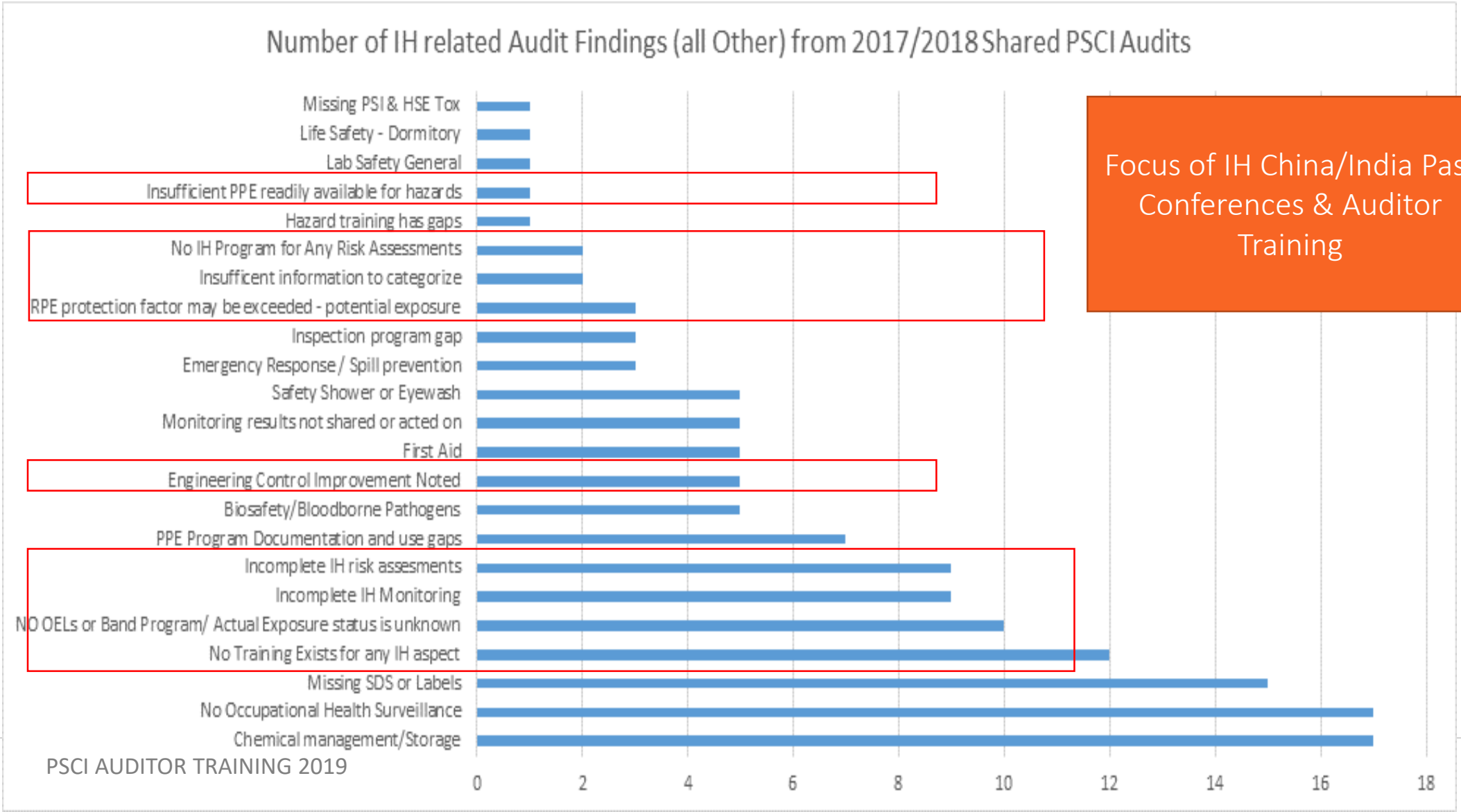


Many common findings were compliance in nature….how to classify? Is there a compliance message to auditors? how would you rate these?

In 587 Findings in 2017/2018 PSCI shared audits – there were no CRITICAL IH findings



What might be serious concerns misclassified?



Focus of IH China/India Past Conferences & Auditor Training

Common Possible Critical Findings - Examples

- The site lacks any data to justify that they know their workers are protected i.e. There is no IH qualitative & quantitative risk assessment is in place where facilities handling multiple API's & chemicals including potent compounds. This combines with limited or no Hazard communication information and observed inadequate PPE/RPE practices- Basic IH program not in place.
- Site handling their API as NUSIANCE DUST 10 mg/m3 because no regulatory limit. No banding approach exists for products without limits. Site has never seen the API – OEL from the PSCI member company SDS. When you compare SDSs available, there is a major difference in classifications, OEL band, and handling. No engineering control or RPE exist.
- Highly potent pharmaceutical being handled (<10 mcg/m3), operation is OPEN , respirator required by SOP but is NOT on the site or completely wrong for the hazard class (e.g. not a respirator or respirator protection factor too low). No segregation and unsure if nearby personnel are also overexposed.
- Observed strong odors during site tour and also observed inadequate knowledge (Adequate training not provided on usage of respiratory protective equipment's) on RPE Selection, storage, cleaning, disposal. e.g. Wearing surgical mask for handling solvents & dust and no other masks available. Also training, use, cleaning, inspection, storage and maintenance of respirators not in place.

Common Possible Critical Findings - Examples

- During tour of area with highly toxic gases and/or solvents – you smell strong odors, experience irritation, see wrong PPE and RPE, and no alarm or shut-offs. Dust masks being used on solvents/gases. Process venting is directed into the room where people work.
- There is no LEV in the centrifuge unloading or dryer loading rooms where wet cakes are being handled. Limited PPE and RPE are being worn.
- IH monitoring (if collected) has had faulty interpretation – there are clear overexposures and no action.
- Limited knowledge on handling of hazardous chemicals like Carcinogens, Teratogens, Mutagens –No program in place.
- Improper chemical storage at many locations & observed chemical spills at many locations.

IH–Common "Other" Findings- Examples

- Combination of all controls appear to be protecting workers but process is HIGHLY dependent on PPE and administrative controls. Engineering improvements to improve control are strongly recommended.
- No marking on the fume hood to demarcate safe working level and also fume hood performance details not available & no place available to handle liquids in the fume hood (placed other equipment's in the fume hood).
- Working cloths not provided/half sleeve aprons provided to all the company employees/visitors however same carry back to home for washing and no working cloths provided to workers.
- Hazard labels not available for all the containers and also provided training on SDS/ Missing Safety Data Sheets
- Site has not assessed exposure risk and potential in lab areas handling materials.
- Site performs QC sampling in warehouse on the open floor for ALL chemicals – regardless of banding
- PPE and IH Program are written centrally by Supplier corporate HSE office – instructions on posters, SOPs, etc., do not match what is available at the actual site. Need confirmation of all SOPs and PPE actual requirements so workers can be protected. No evidence of immediate overexposure concerns.
- Site not doing respirator fit testing.
- Site has not linked occupational workplace exposure to their health surveillance program fully
- IH data collected exists but is very limited, all area samples (no personal results) – data does not show a major issue
- LEV exists, but designs and photos show it is most likely highly ineffective to control risks and no (or very minimal) PPE is being used. The site needs a review of its engineering control strategy and data collected on LEV/exposure performance…no potent compounds.
- Noise data exists but not covered all the process areas of the site.

On Line Control Banding Information and Tools

- COSHH (Control of Substances Hazardous to Health) Essentials (UK HSE, 2006)
  http://www.coshh-essentials.org.uk/
- ILO (International Labour Organization) International Chemical Control Kit (ILO, 2006)
  http://www.ilo.org/public/english/protection/safework/ctrl_banding/index.htm
- AIHA Control Banding Working Group
  http://www.aiha.org/content/insideaiha/volunteer+groups/controlbanding.htm
- NIOSH Control Banding
  http://www.cdc.gov/niosh/topics/ctrlbanding/
- ISPE Volume 7 (2010) “Risk Based Manufacture of Pharmaceutical Products”
- PSCI website – Type in “IH, Banding, or Containment” on the resource link.

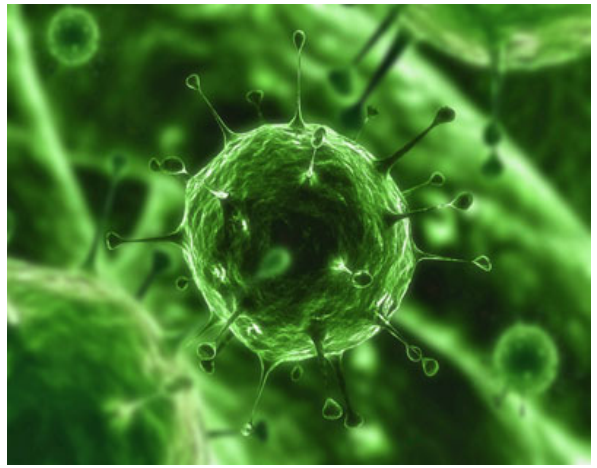
Other SDS Classification Potential Issues you may find

- Material is a Dangerous Good for Shipping and API company is not aware of the toxicology data driving this decision.
- Packaging, Shipping, and handling practices need awareness
- Combustible Dust Classification
- Process Safety Data may not may not be on the SDS depending on the company philosophy.
- Labeling for shipping country does not match the labeling for the receiving country requirements.

Biosafety & Radiation Safety

- Just as there are Control Bands for Chemicals, there are Risk Groups for Biosafety Hazards and the establishment of Biosafety Control Bands (1-4) for Biologicals. Do the companies agree?

- If sites have products with ionizing radiation and/or BSL 3 or 4 operations be sure the correct expert is part of the evaluation. Generally special government licenses may be required.



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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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