Implementing a Comprehensive Industrial Hygiene Program

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Anna Gonzalez, EHS Manager, Bristol Myers Squibb
Matthew Thomas, Global Industrial Hygiene Lead, AstraZeneca
AGENDA

Session 1: Vivian Rivera Turro, Eli Lilly

Session 2: Ana Gonzalez, Bristol Myers Squibb

Session 3: Matthew Thomas, AstraZeneca
Risk Assessment

- A risk assessment for a Task:
  
  Ex. **Preparation of Formulation Batch**
  
  i. Preparation of pre formulation solution
  
  ii. Transfer of formulation solution to formulation tank
  
  iii. Adding Drug Substance to formulation tank

- Risk Based methodology (AIHA, COSHH, Qualitative Chemical Risk Assessment).

- The outcome of each risk assessment is to:
  
  - Characterize and classify employee exposure potential* in one of the exposure categories:
    
    - **Acceptable** (<50% of the OEL)
    
    - **Uncertain** (50-100% of the OEL)
    
    - **Unacceptable** (>100% of the OEL)
      
      *without considering respiratory protection

  - Determine PPE and requirements (filter or cartridge replacement, fit test, etc.)

  - Medical and training requirements

- There are software available in the market to document risk assessments. However, when a software is not available in the company, a simple spreadsheet could be used to gather the information and manage the program.

Each country have their own requirements and/or guidance to conduct risk assessment.
Exposure Assessment Profile Tool

Example

- Similar Exposure Group
- Hazard Characterization

<table>
<thead>
<tr>
<th>Hazard Information</th>
<th>Task Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical, Physical, or Biological Hazard</td>
<td>Site Name, Department, Area, Position</td>
</tr>
<tr>
<td>Drug Substance xxx</td>
<td>Star, Manufacturing, Dispensing, Manufacturing operator</td>
</tr>
<tr>
<td>Reproductive, Liver effects</td>
<td>Primary Hazards, OEL, Frequency, Duration per, Quantity Used, Operation Type, Containment capability</td>
</tr>
<tr>
<td>1 ug/m3 TWA 8 hrs</td>
<td>Daily, 2 hrs, 5 kg, Manual addition, Open-no controls</td>
</tr>
</tbody>
</table>

- Risk Assessment

<table>
<thead>
<tr>
<th>Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>[AIHA Model]</td>
</tr>
<tr>
<td>Hazard</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

- PPE determination, Medical Surveillance, and Training Requirements.
Exposure Assessment Profile Example

- As the risk assessment is completed for each task, site exposure profile is start to be built.
- Multiple tasks will be reflected in the Exposure Assessment Profile.
- The information is ready to be managed:
  - Risk Prioritization

<table>
<thead>
<tr>
<th>Task</th>
<th>Hazard Information</th>
<th>Exposure Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Dispensing</td>
<td>Drug Substance xxx</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Material Dispensing</td>
<td>Chloroform</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Addition of material into formulation tank</td>
<td>Drug Substance xxx</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Preparation of pre formulation solution.</td>
<td>Drug Substance xxx</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Addition of water and materials into pre</td>
<td>Hydrogen Peroxide</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Material Dispensing</td>
<td>Sodium Nitrate</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Material Dispensing</td>
<td>Lactose</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Preparation of pre formulation solution.</td>
<td>Phosgene</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Addition of water and materials into pre</td>
<td></td>
<td></td>
</tr>
<tr>
<td>formulation tank. Mixing and pump</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance task to support operations</td>
<td>Sanding</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
Hierarchy of Controls

- Eliminate or replace hazards
- Design and modify processes or tasks
- Engineering Controls
- Administrative controls
- PPE

Most Effective

Least Effective
**Personal Protective Equipment (PPE)**

- **PPE Communication**
  - Could be done in many ways and some of them have more advantages than others.
  - Some examples:
    - Manufacturing Tickets
    - electronic batch records (eTickets)
    - Procedure and trainings
    - Labels at room entrance
    - Collaboration site or hard copy files in a centralized location, ex. control room

- **PPE Management**
  - Once PPE (make and model) is determined.
  - Partner with Site contacts (Purchasing/Procurement, Supervisors) to ensure that only IH selected equipment is purchased/ordered and new equipment goes through IH evaluation.
  - Other PPE considerations: define safety shoes requirements by area, safety prescriptions for employees needing visual correction or wearing full face respirators.
AGENDA

Session 1: Vivian Rivera Turro, Eli Lilly

Session 2: Ana Gonzalez, Bristol Myers Squibb
  * Training Requirements
  * Medical Surveillance
  * Fit Test

Session 3: Matthew Thomas, AstraZeneca
Speaker Bio - Anna M. González

Anna M. González
EHS Manager for Bristol Myers Squibb

- Based at Lawrenceville, New Jersey, USA
- With BMS for 14 years
- Over 20 years of IH experience including; consulting, chemical manufacturing, pharmaceutical, consumer and research.

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- (609) 252-6640
### Identifying Training Requirements

**Identify Biological, Chemical & Physical Hazards to be included in Hazard Communication Training**

- Examples: Combustibles, Highly Toxic Materials, Biologics, Reproductive Hazards, liquefied gases, noise, etc.

- Other Training needs: Ergonomics, Chemical Compatibility, Lasers, PPE, etc.

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**An example of an Excel based Exposure Assessment Profile has been posted in PSCI Suppliers Link.**

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**Identifying Training Requirements**

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Department</th>
<th>Position</th>
<th>Hazard Type</th>
<th>Hazard Name</th>
<th>Hazard Class</th>
<th>OEL</th>
<th>Frequency</th>
<th>Duration per shift</th>
<th>Quantity Used</th>
<th>Operation Type</th>
<th>Containment Level</th>
<th>Exposure Risk Rating</th>
<th>PPE</th>
<th>Training Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Star Manufacturing Dispensing</td>
<td>Manufacturing operater</td>
<td>Sodium Nitrate</td>
<td>Irritant</td>
<td>1 mg/m³ TWA 8 hrs</td>
<td>2</td>
<td>Once a week</td>
<td>2 hrs</td>
<td>2 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>2</td>
<td>2</td>
<td>Unacceptable</td>
<td>Medium</td>
</tr>
<tr>
<td>Star Manufacturing Dispensing</td>
<td>Manufacturing operater</td>
<td>API xxx</td>
<td>Reproductive, Liver effects</td>
<td>2 ug/m³ TWA 8 hrs</td>
<td>3</td>
<td>Daily</td>
<td>2 hrs</td>
<td>5 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Star Manufacturing Dispensing</td>
<td>Manufacturing operater</td>
<td>Lactose</td>
<td>Irritant</td>
<td>10 ug/m³ TWA 8 hrs</td>
<td>1</td>
<td>Daily</td>
<td>1 hr</td>
<td>20 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Star Manufacturing Dispensing</td>
<td>Manufacturing operater</td>
<td>Sodium Chloride</td>
<td>Irritant</td>
<td>20 ug/m³ TWA 8 hrs</td>
<td>1</td>
<td>Daily</td>
<td>1 hr</td>
<td>50 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Star Manufacturing Dispensing</td>
<td>Manufacturing operater</td>
<td>Magnesium Sterate</td>
<td>Irritant</td>
<td>3 mg/m³ TWA 8 hrs</td>
<td>1</td>
<td>Daily</td>
<td>1 hr</td>
<td>5 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Star Manufacturing Dispensing</td>
<td>Manufacturing operater</td>
<td>Noise</td>
<td>Hearing loss</td>
<td>85 dBA TWA 8 hrs</td>
<td>2</td>
<td>Daily</td>
<td>7 hrs</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>2</td>
<td>4</td>
<td>8</td>
<td>Inconclusive</td>
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<tr>
<td>Star Manufacturing Dispensing</td>
<td>Manufacturing operater</td>
<td>Vibration</td>
<td>Reynolds effects</td>
<td>Daily</td>
<td>1 hrs</td>
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<td>n/a</td>
<td>n/a</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>Inconclusive</td>
<td>Medium</td>
</tr>
<tr>
<td>Star Manufacturing Formulation</td>
<td>Manufacturing operater</td>
<td>API xxx</td>
<td>Reproductive, Liver effects</td>
<td>2 ug/m³ TWA 8 hrs</td>
<td>3</td>
<td>Daily</td>
<td>2 hrs</td>
<td>5 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Star Manufacturing Formulation</td>
<td>Manufacturing operater</td>
<td>Lactose</td>
<td>Irritant</td>
<td>10 ug/m³ TWA 8 hrs</td>
<td>1</td>
<td>Daily</td>
<td>1 hr</td>
<td>20 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Star Manufacturing Formulation</td>
<td>Manufacturing operater</td>
<td>Sodium Chloride</td>
<td>Irritant</td>
<td>20 ug/m³ TWA 8 hrs</td>
<td>1</td>
<td>Daily</td>
<td>1 hr</td>
<td>50 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Star Manufacturing Formulation</td>
<td>Manufacturing operater</td>
<td>Magnesium Sterate</td>
<td>Irritant</td>
<td>3 mg/m³ TWA 8 hrs</td>
<td>1</td>
<td>Daily</td>
<td>1 hr</td>
<td>5 kg</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Star Manufacturing Formulation</td>
<td>Manufacturing operater</td>
<td>Phosgene</td>
<td>Nervous System, Reproductive Hazard</td>
<td>0.1 ppm TWA 8 hrs</td>
<td>4</td>
<td>Once a week</td>
<td>1 hr</td>
<td>50 L</td>
<td>Manual</td>
<td>Enclosed (Glove Box)</td>
<td>4</td>
<td>2</td>
<td>8</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Star Manufacturing Formulation</td>
<td>Manufacturing operater</td>
<td>Hydrogen Peroxide</td>
<td>Corrosive</td>
<td>1 mg/m³ TWA 8 hrs</td>
<td>3</td>
<td>Once a week</td>
<td>3 hrs</td>
<td>1 L</td>
<td>Manual</td>
<td>Open-no controls</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Inconclusive</td>
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<tr>
<td>Star Manufacturing Formulation</td>
<td>Manufacturing operater</td>
<td>Noise</td>
<td>Hearing loss</td>
<td>85 dBA TWA 8 hrs</td>
<td>2</td>
<td>Daily</td>
<td>7 hrs</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>Inconclusive</td>
</tr>
</tbody>
</table>
Medical Surveillance

- Must meet local regulations.
- Can be conducted by on site Medical personnel or outsourced.
- Examples of requirements:
  - Respirator Program
    - Questionnaire
    - Pulmonary Function Test (Spirometry)
  - Hearing Conservation Program
    - Questionnaire
    - Audiometry
  - Sensitizers
    - Questionnaire
    - Physical examination of the skin and respiratory tract
    - Other, as determined by medical staff

  - Some Active Pharmaceutical Ingredients and Hazardous Chemicals may have their own medical surveillance requirements. Review the SDS prior to initial use of the material on site to determine if additional testing is needed.
  - Medical consultations should be available for employees who have had accidental exposures and/or participated of hazardous materials spill clean ups.
  - Special or Particular needs must be considered under this program.
    - Pre-existing conditions
    - Reproductive Health

  - For additional information you can refer to the Medical Surveillance presentation posted on the PSCI Suppliers Link page.
## Medical Surveillance

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Department</th>
<th>Area</th>
<th>Position</th>
<th>Conclusion</th>
<th>Uncertainty</th>
<th>Personal Protective Equipment</th>
<th>Respirator</th>
<th>Fit Test</th>
<th>Medical Surveillance Requirements</th>
<th>Training Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
<td>Medium</td>
<td>Goggles, Nitrile disposable gloves</td>
<td>Respirator</td>
<td>x</td>
<td>Respirator program</td>
<td>PPE, Respirator</td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
<td>Low</td>
<td>Full Face Respirator with HEPA filter</td>
<td>Full Face</td>
<td>x</td>
<td>PPE, Respirator</td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
<td>Medium</td>
<td>Full Face Respirator with HEPA filter</td>
<td>Full Face</td>
<td>x</td>
<td>PPE, Respirator</td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
<td>Medium</td>
<td>Full Face Respirator with HEPA filter</td>
<td>Full Face</td>
<td>x</td>
<td>PPE, Respirator</td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
<td>Medium</td>
<td>Full Face Respirator with HEPA filter</td>
<td>Full Face</td>
<td>x</td>
<td>PPE, Respirator</td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
<td>Medium</td>
<td>Full Face Respirator with HEPA filter</td>
<td>Full Face</td>
<td>x</td>
<td>PPE, Respirator</td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>Hearing protection NRR 33</td>
<td>Respirator program</td>
<td>PPE, Hearing conservation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>Safety glasses</td>
<td>Respirator program</td>
<td>PPE, Respirator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>Goggles, Nitrile disposable gloves</td>
<td>Respirator program</td>
<td>PPE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Low</td>
<td>PAPR respirator with HEPA Filter cartridge</td>
<td>PAPR</td>
<td>Respirator program</td>
<td>PPE, Respirator</td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>PAPR respirator with HEPA Filter cartridge</td>
<td>PAPR</td>
<td>Respirator program</td>
<td>PPE, Respirator</td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>Goggles, Nitrile disposable gloves</td>
<td>PPE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>Nitrile disposable gloves</td>
<td>PPE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>Safety glasses, nitrile gloves</td>
<td>PPE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>High</td>
<td>Hearing protection NRR 33</td>
<td>Hearing conservation</td>
<td>PPE, Hearing conservation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Respiratory Protection Requirements

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Department</th>
<th>Area</th>
<th>Position</th>
<th>Conclusion</th>
<th>Uncertainty</th>
<th>Personal Protective Equipment</th>
<th>Respirator</th>
<th>Fit Test</th>
<th>Medical Surveillance</th>
<th>Training Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
<td>Medium</td>
<td>Goggles, Nitrile disposable gloves</td>
<td>Respirator</td>
<td>Fit Test</td>
<td>Medical Surveillance</td>
<td>Training Requirements</td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
<td>Low</td>
<td>Full Face Respirator with HEPA filter</td>
<td>Full Face</td>
<td>x</td>
<td>Respirator program</td>
<td>PPE, Respirator</td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Unacceptable</td>
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<td>x</td>
<td>Respirator program</td>
<td>PPE, Respirator</td>
</tr>
</tbody>
</table>

- PAPR with loose fitting hoods do not require fit testing, however, employee must be medically approved to wear one and has to be trained in proper use, maintenance and storage of equipment.
Your Exposure Assessment is a live document!

- Your exposure assessment must be updated periodically and when there are any changes that might impact the exposure risk.
- Personal Protective Equipment should be used as the last line of defense or as an interim control measure.
Fit Testing

- Before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the following requirements must be met:
  - Medical surveillance
  - Respirator Training
  - Fit testing with the same make, model, style, and size of respirator that will be used.

- There are two types of Fit testing:
  - **Qualitative fit testing**
  - **Quantitative fit testing**
Qualitative Fit Testing (QLFT)

- **QLFT** involves the introduction of a harmless odoriferous or irritating substance into the breathing zone around the respirator being worn. If no odor or irritation is detected by the wearer, this indicates a proper fit.

- **QLFT** may only be used to fit-test:
  - Negative-pressure, air-purifying respirators, as long as they’ll only be used in atmospheres where the hazard is at less than 10 times the permissible exposure limit (PEL).
  - Tight fitting facepieces used with powered and atmosphere-supplying respirators.
Quantitative Fit Testing

- **Quantitative fit testing** offers more accurate, detailed information on respirator fit. While the wearer performs exercises that could induce facepiece leakage, a fit testing instrument numerically measures the amount of leakage into the respirator. This testing can be done either by generating a test aerosol as a test atmosphere, using ambient aerosol as a test agent, or using controlled negative pressure to measure any leakage.
Additional Resources

Qualitative Fit Test
- 3M Overview of Fit Testing Process
- 3M China
- 3M India

Quantitative Fit Test
- TSI
- AccuTec-HIS
AGENDA

Session 1: Vivian Rivera Turro, Eli Lilly
Session 2: Ana Gonzalez, Bristol Myers Squibb
Session 3: Matthew Thomas, AstraZeneca

IH Risk Analysis & Prioritisation
IH Monitoring Plans
IH Improvement Plans
Speaker Bio – Matthew Thomas

Matthew Thomas
Global Industrial Hygiene Lead for AstraZeneca

- Based at Alderley Park, Cheshire, UK
- In post with AstraZeneca for 5 years
- Nearly 15 years IH consultancy experience including 2 year secondment to AstraZeneca and a further 2+ years with AstraZeneca managing their UK LEV contract
- Wide ranging industry experience including; pharmaceutical, petrochemical, transport, engineering, defence, food, logistics, energy and security

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Industrial Hygiene Risk Prioritisation

- Using your risk assessment or Exposure Assessment Profiling Tool it is possible to plan the prioritisations for your Industrial Hygiene program and drive its maturation.

- Prioritisation allows you to identify the areas for further investigation based on a criteria.

- One approach to applying criteria is from AIHA as follows:-
  - **Acceptable** (<50% of the OEL)
  - **Uncertain** (50-100% of the OEL)
  - **Unacceptable** (>100% of the OEL)
    *without considering respiratory protection*

- Note there are a range of alternative approaches available that will be equally effective.
<table>
<thead>
<tr>
<th>Site Name</th>
<th>Department</th>
<th>Area Position</th>
<th>Hazard Type</th>
<th>Date/Date(s) of Occurrence</th>
<th>Duration per Shift</th>
<th>Exposure Level</th>
<th>Control Strategy</th>
<th>Risk Assessment</th>
<th>Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Star Mfg</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Sodium Nitrate</td>
<td>Irritant</td>
<td>1 mg/m³ TWA 8 hrs</td>
<td>Once a week</td>
<td>2 hrs</td>
<td>2 kg</td>
<td>Manual Open-no controls</td>
</tr>
<tr>
<td>Star Mfg</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>API XXX</td>
<td>Reproductive, Liver effects</td>
<td>2 μg/m³ TWA 8 hrs</td>
<td>Daily</td>
<td>2 hrs</td>
<td>5 kg</td>
<td>Manual Open-no controls</td>
</tr>
<tr>
<td>Star Mfg</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Lactose</td>
<td>Irritant</td>
<td>10 μg/m³ TWA 8 hrs</td>
<td>Daily</td>
<td>1 hr</td>
<td>20 kg</td>
<td>Manual Open-no controls</td>
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<tr>
<td>Star Mfg</td>
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<td>Manufacturing operator</td>
<td>Sodium Chloride</td>
<td>Irritant</td>
<td>20 μg/m³ TWA 8 hrs</td>
<td>Daily</td>
<td>1 hr</td>
<td>50 kg</td>
<td>Manual Open-no controls</td>
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<td>Star Mfg</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Magnesium Sterate</td>
<td>Irritant</td>
<td>3 mg/m³ TWA 8 hrs</td>
<td>Daily</td>
<td>1 hr</td>
<td>5 kg</td>
<td>Manual Open-no controls</td>
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<tr>
<td>Star Mfg</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Noise</td>
<td>Hearing loss</td>
<td>70-80 dBA TWA 8 hrs</td>
<td>Daily</td>
<td>7 hrs</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Star Mfg</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Vibration</td>
<td>Reynolds effects</td>
<td>Daily</td>
<td>1 hrs</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Star Mfg</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>API XXX</td>
<td>Reproductive, Liver effects</td>
<td>2 μg/m³ TWA 8 hrs</td>
<td>Daily</td>
<td>2 hrs</td>
<td>5 kg</td>
<td>Manual Open-no controls</td>
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<td>Star Mfg</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Lactose</td>
<td>Irritant</td>
<td>10 μg/m³ TWA 8 hrs</td>
<td>Daily</td>
<td>1 hr</td>
<td>20 kg</td>
<td>Manual Open-no controls</td>
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<td>Star Mfg</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Sodium Chloride</td>
<td>Irritant</td>
<td>20 μg/m³ TWA 8 hrs</td>
<td>Daily</td>
<td>1 hr</td>
<td>50 kg</td>
<td>Manual Open-no controls</td>
</tr>
<tr>
<td>Star Mfg</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Magnesium Sterate</td>
<td>Irritant</td>
<td>3 mg/m³ TWA 8 hrs</td>
<td>Daily</td>
<td>1 hr</td>
<td>5 kg</td>
<td>Manual Open-no controls</td>
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<tr>
<td>Star Mfg</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Phosgene</td>
<td>Nervous System, Reproductive Hazard</td>
<td>0.1 ppm TWA 8 hrs</td>
<td>Once a week</td>
<td>1 hr</td>
<td>50 L</td>
<td>Manual Enclosed (Glove Box)</td>
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<tr>
<td>Star Mfg</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Hydrogen Peroxide</td>
<td>Corrosive</td>
<td>1 mg/m³ TWA 8 hrs</td>
<td>Once a week</td>
<td>3 hrs</td>
<td>1 L</td>
<td>Manual Open-no controls</td>
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<tr>
<td>Star Mfg</td>
<td>Formulation</td>
<td>Manufacturing operator</td>
<td>Noise</td>
<td>Hearing loss</td>
<td>70-80 dBA TWA 8 hrs</td>
<td>Daily</td>
<td>7 hrs</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>
## Industrial Hygiene Risk Prioritisation

- Identify areas of highest concern - high/very high exposure potentials
- Focus on unacceptable risks
- Aim for lowest uncertainty for maximum benefit

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Exposure Risk Rating</th>
<th>Exposure Potential</th>
<th>Exposure Conclusion</th>
<th>Uncertainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>4</td>
<td>Very High</td>
<td>Unacceptable</td>
<td>Low</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>High</td>
<td>Unacceptable</td>
<td>Medium</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>Very High</td>
<td>Unacceptable</td>
<td>Low</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>High to Very High</td>
<td>Unacceptable</td>
<td>Medium</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>Very High</td>
<td>Unacceptable</td>
<td>Low</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Moderate to High</td>
<td>Inconclusive</td>
<td>Medium</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>Moderate</td>
<td>Inconclusive</td>
<td>Medium</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>Moderate</td>
<td>Inconclusive</td>
<td>Medium</td>
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<td>1</td>
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<td>1</td>
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<td>Moderate</td>
<td>Inconclusive</td>
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<tr>
<td>1</td>
<td>4</td>
<td>Moderate</td>
<td>Inconclusive</td>
<td>Medium</td>
</tr>
</tbody>
</table>
Industrial Hygiene Risk Prioritisation

- Risk prioritisation allows you to look at tasks or processes, to see where the weaknesses are in that process and to plan improvements. Include all steps in a process (including cleaning etc).
- Additional PPE can be used as an interim measure until improvements can be made that manage exposure.
- Hierarchy of control
Industrial Hygiene Risk Prioritisation

- Effective Risk Prioritisation allows you to focus efforts where most needed.
  - Unacceptable vs Trivial risks
  - Timescales for improvement
  - Budget for improvements or for IH monitoring

- Key outcome/main goal is improved protection for your workers

- Allows the creation of:
  - Industrial Hygiene Monitoring Plan
  - Industrial Hygiene Improvement Plan
Industrial Hygiene Monitoring Plan

- IH monitoring plan can include planning for the assessment of any of the IH risks at your site;

- Hazard (potential) vs Risk (likelihood)

- Understand your hazards?
- Understand your risks?
Having a plan allows budgeting in advance.

- Prioritisation for planned monitoring based on risk.
- Set the rules for monitoring.
- When and how frequently monitoring will be undertaken. ↑ risk = ↑ frequency
- Monitoring methodology? Personal and/or area measurements?
- Validated analytical sampling technique is critical (or a surrogate can be used).

- Who will do the monitoring? Internal resource? Consultant resource?

IH monitoring should always be undertaken by competent individuals.
Key Point - API vs general nuisance dust

- **Key message**, within the pharmaceutical production environment, not all powders are the same.
- API is often significantly more potent than the excipients and present a far greater toxicological risk.
- OELs often µg/m³ for API vs mg/m³ for excipients i.e. 1000x or more lower
- At µg/m³ levels, you can’t see the airborne dust. At ng/m³ levels .................
- As part of routine training, ensure that staff are aware of the potencies for the products they are working with, any additional controls in place and what to do in an emergency such as a spillage.

<table>
<thead>
<tr>
<th>Band Range</th>
<th>Mass inhaled over 8hr day</th>
</tr>
</thead>
<tbody>
<tr>
<td>10,000 µg/m³</td>
<td>4% sugar pack</td>
</tr>
<tr>
<td>1,000 µg/m³</td>
<td>0.4% sugar pack</td>
</tr>
<tr>
<td>100 µg/m³</td>
<td>0.04% sugar pack</td>
</tr>
<tr>
<td>10 µg/m³</td>
<td>0.004% sugar pack</td>
</tr>
<tr>
<td>1 µg/m³</td>
<td>0.0004% sugar pack</td>
</tr>
<tr>
<td>0.1 µg/m³</td>
<td>0.00004% sugar pack</td>
</tr>
</tbody>
</table>
Industrial Hygiene Improvement Plan

- Your risk prioritisation also allows you to develop an IH Improvement Plan
- This sets out high level aspirations over the longer term (3, 5 or even 10 years)
- This is an opportunity to plan for fundamental change e.g. RPE Free or PPE Free...........

- Supported by an implementation/transformation plan that sets out on a schedule that will allow the long terms goals to be achieved with actions in the short, medium and long term
- Prioritise improvements to unacceptable risks.
- Obtain leadership buy in.

- Improvements based on cultural/behavioural change or process change/equipment/hardware and can include training, equipment with a prioritisation process and planned budget
Listen to the business in respect of what they want

Management buy in

Developing Governance piece

Training & networking at the forefront of IH representation into the business

All employees and managers aware of the risks related to skin exposure

Online resource

iH monitoring plans in place

No exposure levels above the OEL (taking account of RPE)

Exposures above the OEL (taking account of RPE) to be reported

Bitesize training

Multi function collaboration

Management buy in

PPE & RPE Free Workplace as the default philosophy

IH universally understood and implemented (improve). All levels of the business.

Truly sustainable IH organization

Industry leading mature IH Management Framework (Govern)

Be bold enough to push the limits

Embrace new media to drive the IH message. Tailor comms to the right levels

2019

2020

2021-2024

Desired State 2025

Mature IH Processes
Risk Assessment

Sampling Strategy
Prioritized:
- Air Monitoring Plan
- Noise Monitoring Plan
- Other assessments: Ergonomics

PPE
- Communication
- Fit Test
- Respirator cartridge change
- Purchase administration

Medical Surveillance
- Applicable Panels
- Testing Frequency

Training
- Applicable courses
- Group assignment

Exposure Controls
- Preventive Maintenance
- Prioritized list of containment opportunities

Performance Evaluation
- Metrics
- Self Assessment

IH Integration in Site Management System
- Management Review of Program Metrics:
  - Exposure Assessment, Medical Surveillance, Self Assessment and Audit Outcome
  - Setting up Priorities, action plans, and resources (human and economical).
  - Containment opportunities

VIRTUAL SUPPLIER CONFERENCE SEP-OCT 2020
To ask questions, please go to [https://app.sli.do/](https://app.sli.do/) and enter the event code: #PSCIIndia
Thank you for working with the PSCI

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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.