PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Introduction and Industrial Hygiene Maturity Model

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PSCI IH Sub Team Members

AGENDA

Industrial Hygiene Maturity Model Overview

Implementing a Comprehensive IH Program

Speaker Bio

- Vivian Rivera Turro

- Certified Industrial Hygienist (CIH).
- Corporate Industrial Hygienist for Eli Lilly & Co.
- Based at Indiana, US.
- 5 years in Corporate role supporting manufacturing sites globally.
- 15 years of IH experience working in API, Dry Product, and Biotech Manufacturing.

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Industrial Hygiene Maturity Model

- IH Maturity Model is built in 4 Levels:

Starting	Developing	Implementing	Leading

  - Will help to implement every element of the IH program.
  - Could be used to self assess your implementation position and give you direction where to go.
- This version is primarily focused in Chemical Exposure and the basis of hearing conservation program.
- The IH Maturity Model covers:
  - Chemical Management
  - Risk Assessment
  - Quantitative Exposure Assessment
  - PPE
  - Medical Surveillance
  - Exposure Control/Containment.
- Next versions will include implementation aspects related to physical and biological hazards.

IH Maturity Model

- This version also introduces the aspect of Management System focused to Industrial Hygiene:
  - Designation of a person to administer the IH Program
  - Training for Management and functions that supports the program.
  - IH Procedures and Compliance with local regulations.
  - Involvement in change management.
  - Program performance, metrics, and site management review.
  - Self assessment process to identify gaps and areas for continuous improvement.
- Implementation will be supported with References, Resources, and Tools that we will be posting in PSCI Link page.
  - Example: A risk assessment has been documented for each process or task using a Risk Based methodology. (Tool name)

Implementing a Comprehensive IH Program

- IH Program consist of several elements.
- PSCI IH Team reviewed 2019 PSCI Assessment Results:
  - Common and wide variety of observations in different elements of IH Program.
- As a result, the IH Sub Team decided to provide a holistic overview of the implementation of the IH Program.
  - Risk Assessment is the basis of program implementation and how should be used to successful implement all other elements in a cascading mode.
- Lead to:
  - successful implementation of all elements,
  - management oversight and planning, and
  - long term sustainability.

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Presentation #2

Implementing a Comprehensive Industrial Hygiene Program

Panel Presentation:

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

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
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Presentation #2
Section 1

Panel Presentation: Implementing a Comprehensive Industrial Hygiene Program

Speaker:

Vivian Rivera Turro, Eli Lilly

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

Each country have their own requirements and/or guidance to conduct risk assessment.

Low Risk
Medium Risk
High Risk

  - 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.

Exposure Assessment Profile Tool

Example

If interested

PSCI IH Team is posting a Template of an Excel based Exposure Assessment Profile in PSCI Suppliers Link.

- Similar Exposure Group
- Hazard Characterization
- Risk Assessment
- PPE determination, Medical Surveillance, and Training Requirements.

Similar Exposure Group			
Site Name	Department	Area	Position
Star	Manufacturing	Dispensing	Manufacturing operator

Hazard Information			Task Description				
Chemical, Physical, or Biological Hazard	Primary Hazards	OEL	Frequency	Duration pe	Quantity Used	Operation Type	Containment capability
Drug Substance xxx	Reproductive, Liver effects	1 ug/m3 TWA 8 hrs	Daily	2 hrs	5 kg	Manual addition	Open-no controls

Risk Assessment (AIHA Model)					
Hazard	Exposure Risk Rating	Exposure Potential	Exposure Conclusion	Uncertainty	IH Monitoring (Study #)
3	4	Very High	Unacceptable	Low	

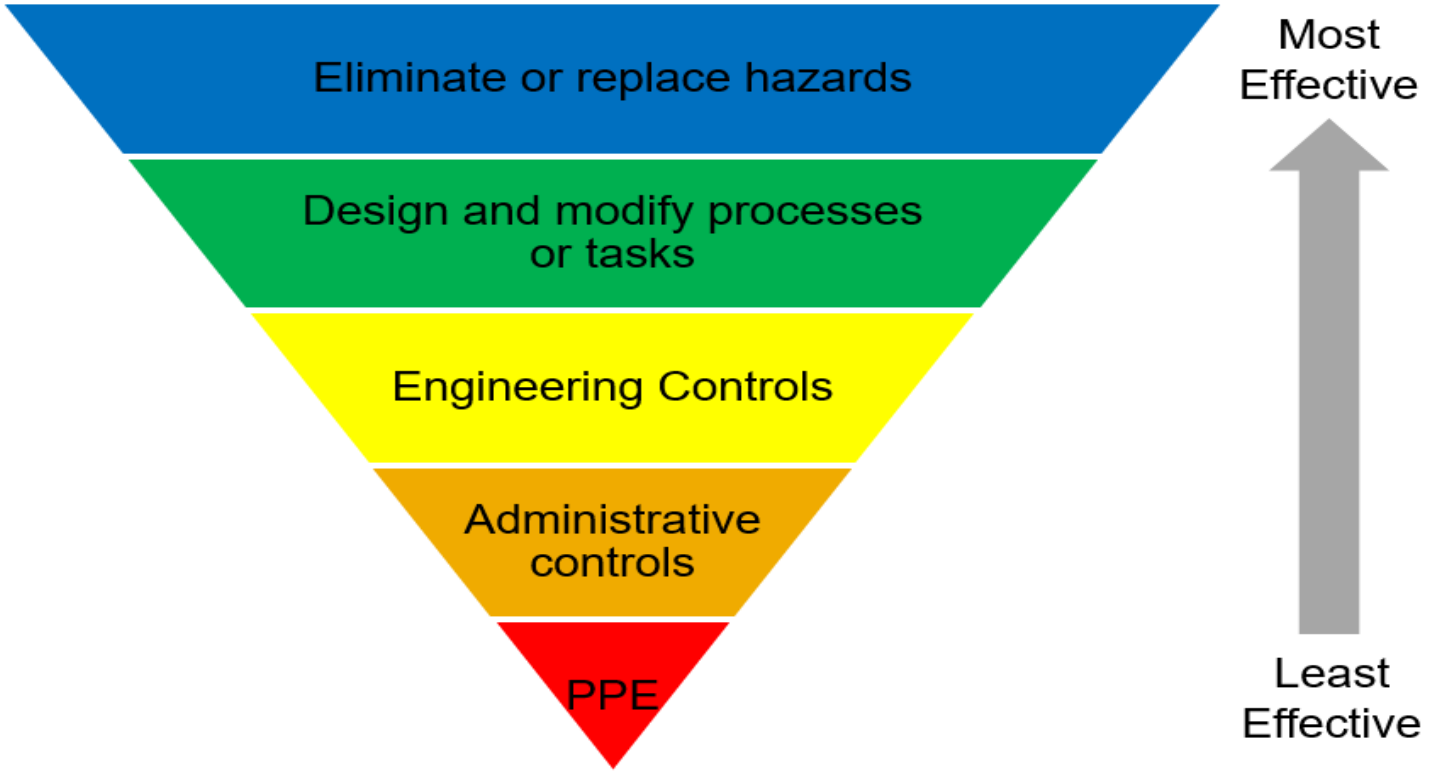
PPE Determination		Medical Surveillance Requirements	Applicable Trainings
Personal Protective Equipment	Fit Tes	Medical Panel	Training
PAPR Respirator with HEPA filter		Respirator program	CLP/GHS (HazCom), PPE, Respirator
Full Face Respirator with organic filters	x	Respirator program	CLP/GHS (HazCom), PPE, Respirator, Fit Test

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

	Hazard Information	
Task	Chemical, Physical, or Biological Hazard	Exposure Conclusion
Material Dispensing	Drug Substance xxx	Unacceptable
Material Dispensing	Chloroform	Unacceptable
Addition of material into formulation tank	Drug Substance xxx	Unacceptable
Preparation of pre formulation solution. Addition of water and materials into pre	Hydrogen Peroxide	Unacceptable
Material Dispensing	Sodium Nitrate	Inconclusive
Material Dispensing	Lactose	Inconclusive
Preparation of pre formulation solution. Addition of water and materials into pre formulation tank. Mixing and pump	Phosgene	Acceptable
Maintenance task to support operations	Sanding	Acceptable

Hierarchy of Controls



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.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
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Presentation #2
Section 2

Implementing a Comprehensive Industrial Hygiene Program

Speakers:

Anna González, Bristol Myers Squibb

AGENDA

Training Requirements

Medical Surveillance

Fit Test

Speaker Bio

- 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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Identifying Training Requirements

If interested

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

Similar Exposure Group				Hazard Information								Risk Assessment		Risk Prioritization							
Site Name	Department	Area	Position	Chemical, Physical, or Biological Hazard	Primary Hazards	L	Frequency	Duration per shift	Quantity Used	Operation Type	Containment Level	Hazard	Exposure Risk Rating	Exposure Judgment	Conclusion	Uncertainty	Personal Protective Equipment	Respirator	Fit Test	Medical Surveillance Requirements	Training Requirements
Star	Manufacturing	Dispensing	Manufacturing operator	Sodium Nitrate	Irritant	ng/m3 TWA 8 hrs	Once a week	2 hrs	2 kg	Manual	Open-no controls	2	2	4	Unacceptable	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Dispensing	Manufacturing operator	API xxx	Reproductive, Liver effects	g/m3 TWA 8 hrs	Daily	2 hrs	5 kg	Manual	Open-no controls	3	4	12	Unacceptable	Low	Full Face Respirator with HEPA filter	Full Face	x	Respirator program	PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Lactose	Irritant	ug/m3 TWA 8 hrs	Daily	1 hr	20 kg	Manual	Open-no controls	1	4	4	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Sodium Cloride	Irritant	ug/m3 TWA 8 hrs	Daily	1 hr	50 kg	Manual	Open-no controls	1	4	4	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Magnesium Stereate	Irritant	ng/m3 TWA 8 hrs	Daily	1 hr	5 kg	Manual	Open-no controls	1	2	2	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Noise	Hearing loss	dBA TWA 8 hrs	Daily	7 hrs	n/a	n/a	n/a	2	4	8	Inconclusive	Medium	Hearing protection NRR 33			Hearing conservation	PPE, Hearing conservation
Star	Manufacturing	Dispensing	Manufacturing operator	Vibration	Reynolds effects		Daily	1 hrs	n/a	n/a	n/a	2	1	2	Inconclusive	Medium	Safety glasses				PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Chloroform	Teratogen	ppm TWA 8 hrs	Daily	< 1 hr	0.1 grams	Manual	SemiOpen-LEV	4	2	8	Inconclusive	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	API xxx	Reproductive, Liver effects	g/m3 TWA 8 hrs	Daily	2 hrs	5 kg	Manual	Open-no controls	3	4	12	Inconclusive	Low	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Lactose	Irritant	ug/m3 TWA 8 hrs	Daily	1 hr	20 kg	Manual	Open-no controls	1	4	4	Inconclusive	Medium	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Sodium Cloride	Irritant	ug/m3 TWA 8 hrs	Daily	1 hr	50 kg	Manual	Open-no controls	1	4	4	Inconclusive	Medium	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Magnesium Stereate	Irritant	ng/m3 TWA 8 hrs	Daily	1 hr	5 kg	Manual	Open-no controls	1	2	2	Inconclusive	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Phosgene	Nervous System, Reproductive Hazard	ppm TWA 8 hrs	Once a week	1 hr	50 L	Manual	Enclosed (Glove Box)	4	2	8	Inconclusive	Medium	Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Hydrogen Peroxide	Corrosive	ng/m3 TWA 8 hrs	Once a week	3 hrs	1 L	Manual	Open-no controls	3	3	9	Inconclusive	Medium	Safety glasses, nitrile gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Noise	Hearing loss	dBA TWA 8 hrs	Daily	7 hrs	n/a	n/a	n/a	2	3	6	Inconclusive	High	Hearing protection NRR 33			Hearing conservation	PPE, Hearing conservation

- 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.

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

Similar Exposure Group				Risk Prioritization						
Site Name	Department	Area	Position	Conclusion	Uncertainty	Personal Protective Equipment	Respirator	Fit Test	Medical Surveillance Requirements	Training Requirements
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Low	Full Face Respirator with HEPA filter	Full Face	x	Respirator program	PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Inconclusive	Medium	Hearing protection NRR 33			Hearing conservation	PPE, Hearing conservation
Star	Manufacturing	Dispensing	Manufacturing operator	Inconclusive	Medium	Safety glasses				PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Inconclusive	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Low	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	Safety glasses, nitrile gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	High	Hearing protection NRR 33			Hearing conservation	PPE, Hearing conservation

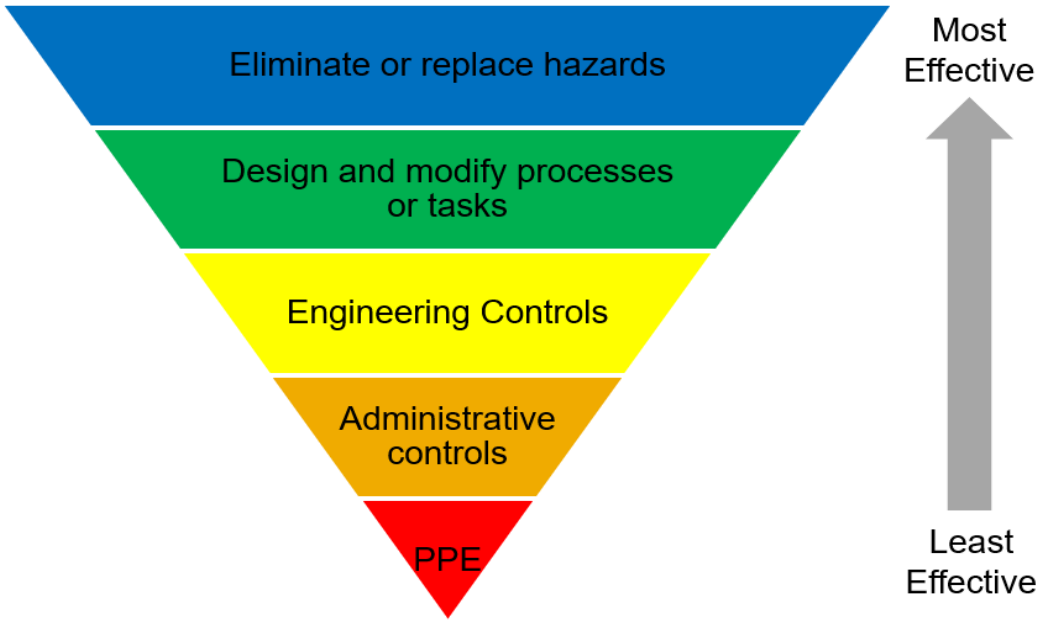
Respiratory Protection Requirements

Similar Exposure Group				Risk Prioritization						
Site Name	Department	Area	Position	Conclusion	Uncertainty	Personal Protective Equipment	Respirator	Fit Test	Medical Surveillance Requirements	Training Requirements
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Low	Full Face Respirator with HEPA filter	Full Face	x	Respirator program	PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Inconclusive	Medium	Hearing protection NRR 33			Hearing conservation	PPE, Hearing conservation
Star	Manufacturing	Dispensing	Manufacturing operator	Inconclusive	Medium	Safety glasses				PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Inconclusive	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Low	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	Medium	Safety glasses, nitrile gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Inconclusive	High	Hearing protection NRR 33			Hearing conservation	PPE, Hearing conservation

- 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

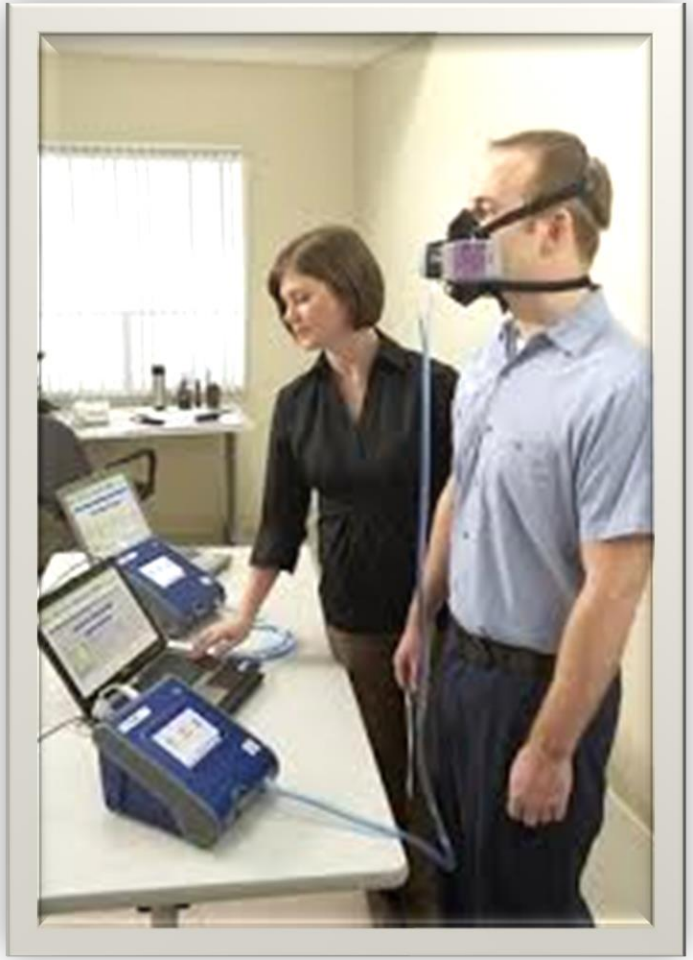
- Before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the following requirements must be met:
  - Medical surveillance
  - Respirator Training
  - Fit testing with the same make, model, style, and size of respirator that will be used.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



Additonal Resources

Qualitative Fit Test

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

Quantitative Fit Test

- TSI
- AccuTec-HIS

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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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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
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Industrial Hygiene – Section 3 Risk Prioritisation

Matthew Thomas
Global Industrial Hygiene Lead
AstraZeneca

AGENDA

IH Risk Analysis & Prioritisation

IH Monitoring Plans

IH Improvement Plans

Speaker Bio

- 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.

Industrial Hygiene Risk Register

Similar Exposure Group				Hazard Information								Risk Assessment		Risk Prioritization							
Site Name	Department	Area	Position	Chemical, Physical, or Biological Hazard	Primary Hazards	OEL	Frequency	Duration per shift	Quantity Used	Operation Type	Containment Level	Hazard	Exposure Risk Rating	Exposure Judgment	Conclusion	Uncertainty	Personal Protective Equipment	Respirator	Fit Test	Medical Surveillance Requirements	Training Requirements
Star	Manufacturing	Dispensing	Manufacturing operator	Sodium Nitrate	Irritant	1 mg/m3 TWA 8 hrs	Once a week	2 hrs	2 kg	Manual	Open-no controls	2	2	4	Unacceptable	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Dispensing	Manufacturing operator	API xxx	Reproductive, Liver effects	2 ug/m3 TWA 8 hrs	Daily	2 hrs	5 kg	Manual	Open-no controls	3	4	12	Unacceptable	Low	Full Face Respirator with HEPA filter	Full Face	x	Respirator program	PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Lactose	Irritant	10 ug/m3 TWA 8 hrs	Daily	1 hr	20 kg	Manual	Open-no controls	1	4	4	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Sodium Cloride	Irritant	20 ug/m3 TWA 8 hrs	Daily	1 hr	50 kg	Manual	Open-no controls	1	4	4	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Magnesium Stereate	Irritant	3 mg/m3 TWA 8 hrs	Daily	1 hr	5 kg	Manual	Open-no controls	1	2	2	Unacceptable	Medium	Full Face Respirator with HEPA filter	Full Face	x		PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Noise	Hearing loss	85 dBA TWA 8 hrs	Daily	7 hrs	n/a	n/a	n/a	2	4	8	Inconclusive	Medium	Hearing protection NRR 33			Hearing conservation	PPE, Hearing conservation
Star	Manufacturing	Dispensing	Manufacturing operator	Vibration	Reynolds effects		Daily	1 hrs	n/a	n/a	n/a	2	1	2	Inconclusive	Medium	Safety glasses				PPE, Respirator
Star	Manufacturing	Dispensing	Manufacturing operator	Chloroform	Teratogen	0.2 ppm TWA 8 hrs	Daily	< 1 hr	0.1 grams	Manual	SemiOpen-LEV	4	2	8	Inconclusive	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	API xxx	Reproductive, Liver effects	2 ug/m3 TWA 8 hrs	Daily	2 hrs	5 kg	Manual	Open-no controls	3	4	12	Inconclusive	Low	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Lactose	Irritant	10 ug/m3 TWA 8 hrs	Daily	1 hr	20 kg	Manual	Open-no controls	1	4	4	Inconclusive	Medium	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Sodium Cloride	Irritant	20 ug/m3 TWA 8 hrs	Daily	1 hr	50 kg	Manual	Open-no controls	1	4	4	Inconclusive	Medium	PAPR respirator with HEPA Filter cartridge	PAPR		Respirator program	PPE, Respirator
Star	Manufacturing	Formulation	Manufacturing operator	Magnesium Stereate	Irritant	3 mg/m3 TWA 8 hrs	Daily	1 hr	5 kg	Manual	Open-no controls	1	2	2	Inconclusive	Medium	Goggles, Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Phosgene	Nervous System, Reproductive Hazard	0.1 ppm TWA 8 hrs	Once a week	1 hr	50 L	Manual	Enclosed (Glove Box)	4	2	8	Inconclusive	Medium	Nitrile disposable gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Hydrogen Peroxide	Corrosive	1 mg/m3 TWA 8 hrs	Once a week	3 hrs	1 L	Manual	Open-no controls	3	3	9	Inconclusive	Medium	Safety glasses, nitrile gloves				PPE
Star	Manufacturing	Formulation	Manufacturing operator	Noise	Hearing loss	85 dBA TWA 8 hrs	Daily	7 hrs	n/a	n/a	n/a	2	3	6	Inconclusive	High	Hearing protection NRR 33			Hearing conservation	PPE, Hearing conservation

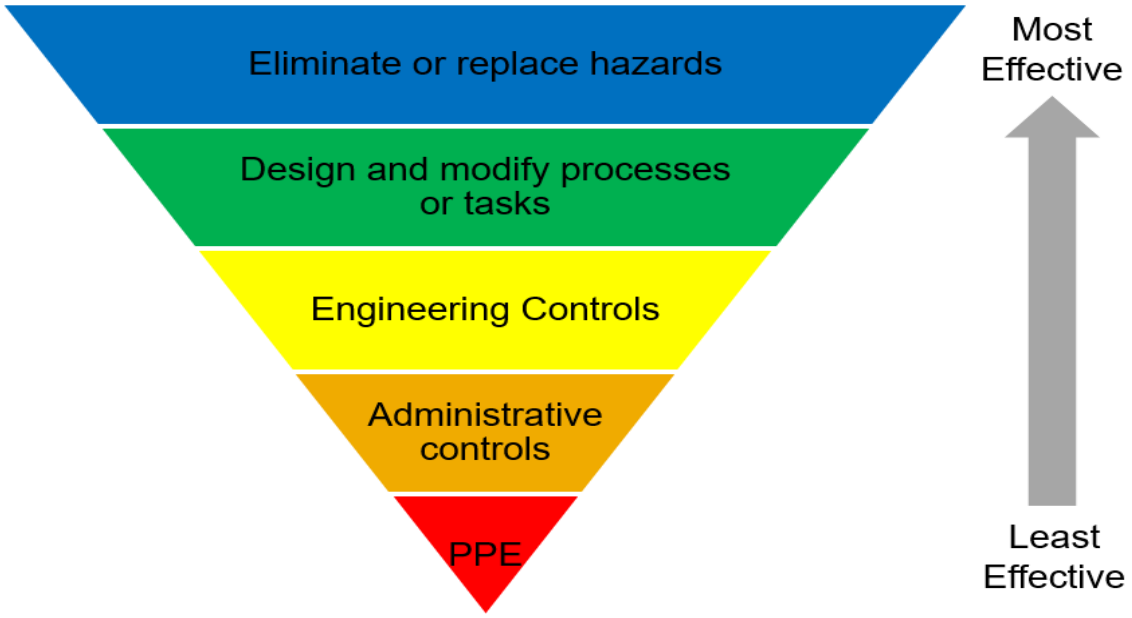
Industrial Hygiene Risk Prioritisation

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

Risk Assessment (AIHA Model)				
Hazard	Exposure Risk Rating	Exposure Potential	Exposure Conclusion	Uncertainty
3	4	Very High	Unacceptable	Low
4	2	High	Unacceptable	Medium
3	4	Very High	Unacceptable	Low
3	3	High to Very High	Unacceptable	Medium
4	3	Very High	Unacceptable	Low
2	2	Moderate to High	Inconclusive	Medium
1	4	Moderate	Inconclusive	Medium
1	4	Moderate	Inconclusive	Medium
1	2	Moderate	Inconclusive	Medium
1	4	Moderate	Inconclusive	Medium
1	4	Moderate	Inconclusive	Medium

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

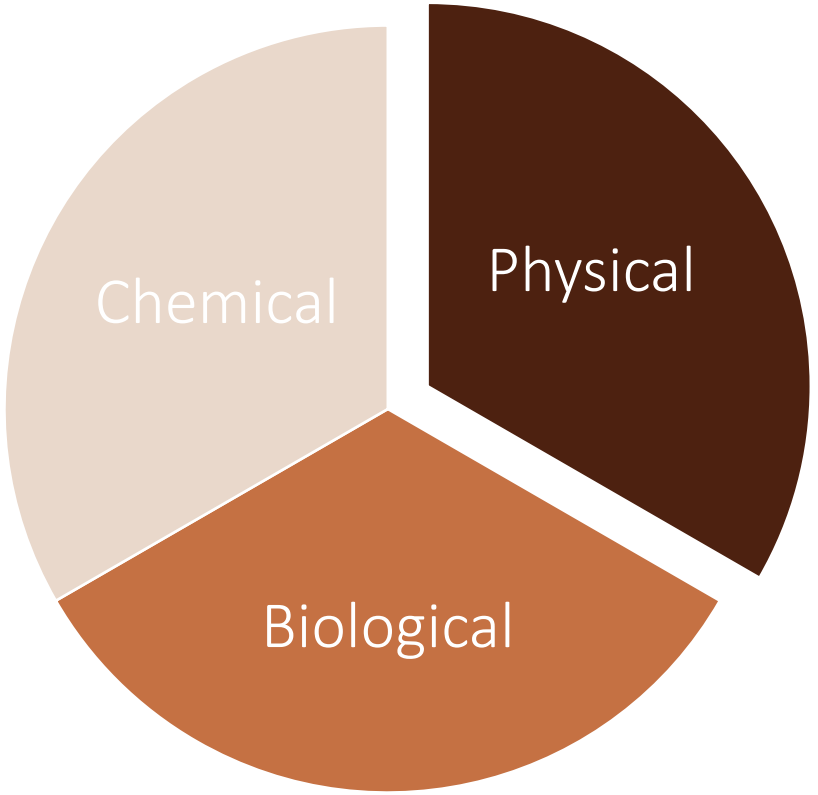
- Allows the creation of:-
  - ➢Industrial Hygiene Monitoring Plan
  - ➢Industrial Hygiene Improvement Plan

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?



Industrial Hygiene Monitoring Plan

- 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/m^3 for API vs mg/m^3 for excipients i.e. 1000x or more lower
- At µg/m^3 levels, you cant see the airborne dust. At ng/m^3 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.

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

Industrial Hygiene Improvement Plan

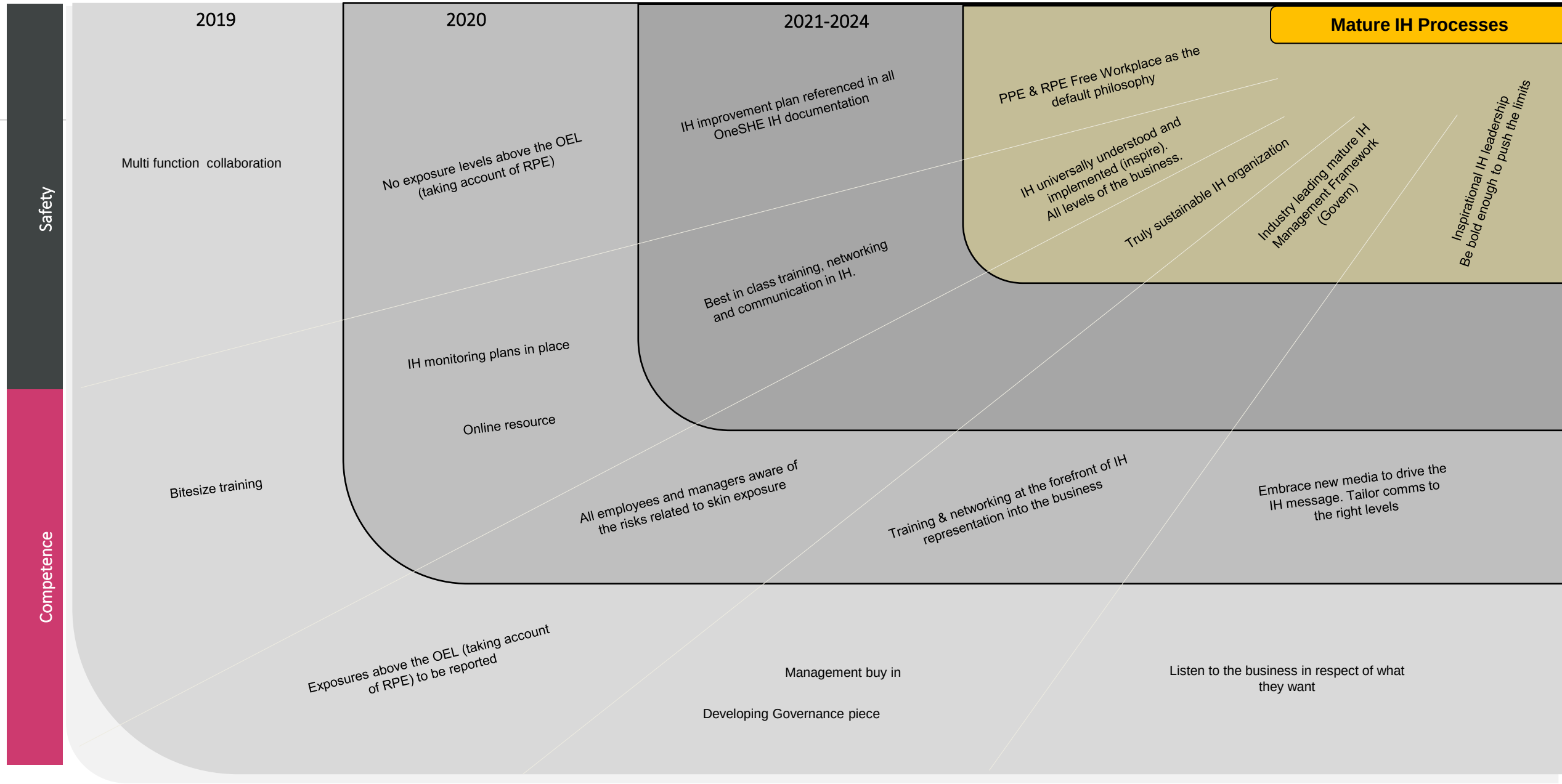
- Your risk prioritisation also allows you to develop an IH Improvement Plan
- This sets out high level aspirations over the longer term (3, 5 or even 10 years)
- This is an opportunity to plan for fundamental change e.g. RPE Free or PPE Free…….

- 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

Transformation Map

Desired State 2025



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Risk Assessment

Sampling Strategy	PPE	Medical Surveillance	Training	Exposure Controls	Performance Evaluation
Prioritized: • Air Monitoring Plan • Noise Monitoring Plan • Other assessments: Ergonomics	• Communication • Fit Test • Respirator cartridge change • Purchase administration	• Applicable Panels • Testing Frequency	• Applicable courses • Group assignment	• Preventive Maintenance • Prioritized list of containment opportunities	• 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
  - Action Plan for Local expense, Capital Expenses, Business Plan.

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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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