Session 4 – Safety, Process Safety Management, and Industrial Hygiene

Disclaimer: Compliance with local requirements is the responsibility of companies and their local business areas. The information in these presentations is not intended to supersede, take the place of, or conflict with, local government requirements.
Practicalities

- Switch to audio feed only for better connection
- Breaks
- We’ll be using Sli.do for Q&As and polls, please follow the link under the Q&A tab on Livestream webpage (Sli.do event code: #PSCIIndia)
- Feedback survey
ANTI-TRUST STATEMENT

While some activities among competitors are both legal and beneficial to the industry, group activities of competitors are inherently suspect under the antitrust/anti-competition laws of the US, UK and other countries in which our companies do business. Agreements between or among competitors need not be formal to raise questions under antitrust laws, but may include any kind of understanding, formal or informal, secretive or public, under which each of the participants can reasonably expect that another will follow a particular course of action or conduct. Each of the participants in this meeting is responsible for seeing that topics which may give an appearance of an agreement that would violate the antitrust laws are not discussed. It is the responsibility of each participant in the first instance to avoid raising improper subjects for discussion, such as those identified below.

It is the sole purpose of this meeting to provide a forum for expression of various points of view on topics described in the agenda and participants should adhere to that agenda. Under no circumstances shall this meeting be used as a means for competing companies to reach any understanding, expressed or implied, which tends to restrict competition, or in any way to impair the ability of members to exercise independent business judgment regarding matters affecting competition.

Topics of discussion that should be specifically avoided are:

i. Price fixing;

ii. Product discounts, rebates, pricing policies, levels of production or sales and marketing terms customer and territorial allocation;

iii. Standards setting (when its purpose is to limit the availability and selection of products, limit competition, restrict entry into an industry, inhibit innovation or inhibit the ability of competitors to compete);

iv. Codes of ethics administered in a way that could inhibit or restrict competition;

v. Group boycotts;

vi. Validity of patents;

vii. On-going litigation;

viii. Specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information.
Electrical Safety & LoTo

Roberta Haski  
HSE Adviser, Elanco Asia- Pacific  
Japan, ANZ

Rajiv Narang  
Associate Director Safety, Health & Environment – Corporate  
Centrient Pharmaceuticals
Speaker Bio – Roberta Haski

ROBERTA HASKI

Company Role
2015 - present  HSE Adviser, Elanco Asia- Pacific, Japan, ANZ
2012 – 2015  Legal work and practice
Prior to 2012  Pharmaceutical
Variety of positions in HSE and HR senior management at global company, university, hospital.
2011:  Variety of consulting work.
2011:  Admitted to practice law, graduated JD from UTS
2007  MLLR – Sydney Uni
Prior to 2007  MSc – UNSW
BSc – Sydney Uni
Speaker Bio – Rajiv Narang

RAJIV NARANG

Company Role

Present
Associate Director Safety, Health & Environment – Corporate
Centrient Pharmaceuticals (previously known as DSM Sinochem Pharmaceuticals)

2015 / 2016
Special assignment as Corporate Safety, Health and Environment auditor with DSM Netherlands Corporate.

1996 – 2017
Various roles in Safety, Health and Environment

1986 – 1996
Various roles in Production

1986
Graduation from Punjab University, Chandigarh
Examples of High Risk Safety Programs
What we explore today

ELECTRICAL SAFETY
IN THE WORKPLACE
‘Electricity is not just a lifeline, it can also take away life when handled improperly’

*Electrical faults* seem to be the major reason for industrial disasters in the country as 56 per cent of incidents are reportedly caused by them. *Overheating, ageing of the material and use of sub-standard quality of electrical gadgets* have been the main factors contributing to the increasing fire accidents in industries in the past four years.

V. Srinivas, member of the Fire and Security Association of India (FSAI) National Executive Board.
Why Focus on Electrical Safety / LoTo?

Why Focus on Electrical Safety / LoTo?

- High Risk Work or SIF (Serious Injuries or Fatalities) programs;
- High risk work – but risks can be controlled;
- One of main causes of serious injuries & fatalities in the workplace;
- Applicable to all workplaces;
- Applicable to own and contractor employees and third party vendors.
- Focus of regulatory requirements;
- PSCI focus;
- Information readily available for workplace improvements
# PSCI Questionnaire – Q55, Q56

## Q55

<table>
<thead>
<tr>
<th>Does the facility have a safe work permit system for the following?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hot Work: Yes  No  NA</td>
</tr>
<tr>
<td>Confined Space Work: Yes  No  NA</td>
</tr>
<tr>
<td><strong>Energy Isolation or Lock Out/Tag Out:</strong> Yes  No  NA</td>
</tr>
<tr>
<td>Line Breaking: Yes  No  NA</td>
</tr>
<tr>
<td>Work at Height: Yes  No  NA</td>
</tr>
<tr>
<td>General Permit: Yes  No  NA</td>
</tr>
<tr>
<td>Other: Yes  No</td>
</tr>
</tbody>
</table>

Please describe:

<table>
<thead>
<tr>
<th>Yes  No  Comments</th>
</tr>
</thead>
</table>

## Q56

<table>
<thead>
<tr>
<th>Has the facility developed and implemented an Electrical Safety Program that includes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Installation of lockable disconnects interlocks, and emergency stop devices? Yes  No</td>
</tr>
<tr>
<td>Labeling of switches, outlets, breakers, panels, and disconnects? Yes  No</td>
</tr>
<tr>
<td>Designating keep clear areas around electrical equipment for safe work practices? Yes  No</td>
</tr>
<tr>
<td>Electrical cabinets are locked? Yes  No</td>
</tr>
<tr>
<td>Arc Flash Analysis? Yes  No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes  No  Comments</th>
</tr>
</thead>
</table>

VIRTUAL SUPPLIER CONFERENCE SEP-OCT 2020
<table>
<thead>
<tr>
<th>Q79</th>
<th>Does the facility perform risk assessment related to the explosion of flammable liquids, vapors, powders, and gases in processing operations (including storage, transfer and charging)?</th>
</tr>
</thead>
</table>
|     | Does it include the following steps?  
|     | • Assessment of the hazards (Minimum Ignition Energy, Kst classification rating, Impact sensitivity etc.) of the handled combustible dusts and powders  
|     | Yes  No  
|     | • Hazardous area classification (zones according EU-ATEX and Classes according to US-NFPA) including documentation (drawing) and is the equipment appropriate for respective zoning?  
|     | Yes  No  
|     | • Installation of special electrical equipment for flammable vapors, gases, combustible dusts, and wet areas?  
|     | Yes  No  
|     | • Periodic testing of grounding and bonding circuits, lightning arresters, and electrical distribution equipment?  
|     | Yes  No  
|     | • Maintenance/calibration done for critical safety equipment (e.g. sensors, instruments, valves, interlocks, reactors, condenser etc.) at suitable intervals.  
|     | Yes  No  
|     | • Assessment of the hazards due to mechanical ignition sources?  
|     | Yes  No  
|     | • What types of engineering controls are used to prevent explosions or damage to personnel, equipment, or buildings?  
|     | Yes  No  
|     | • Nitrogen as inerting gas:  
|     | Yes  No  
|     | • Use of forced ventilation:  
|     | Yes  No  
|     | • Oxygen level monitoring in process equipment:  
|     | Yes  No  
|     | • Grounding/bonding systems:  
|     | Yes  No  
|     | • Anti-static treated working surfaces:  
|     | Yes  No  
|     | • Maintain temperatures below flash points:  
|     | Yes  No  
|     | • Equipment that holds hazardous material has suitable basis of safety (e.g. inertion, ignition source prevention)?  
|     | Yes  No  
|     | • Other, please describe:  
|     | Yes  No |
Electrical Safety – Common Observations

- Site has not identified high risk electrical work;
- Site is unaware / not complying applicable legal requirements for electrical work;
- Site is lacking electrical safety programs, or major parts of programs;
- Lock out, Tag Out, (LoTo) not applied (or not fully applied).
- No documented programs – or worse – what is documented is not what is implemented;
- Workers not trained in these programs;
- Programs not applied to third party contractors;
- High voltage areas not secured for unauthorized access;
- No special procedures for high voltage.
- No Arc Flash Analysis is available.
- Changes done in electrical system are not governed through Management of Change.
- Emergency stops when necessary not available, not identified or not readily accessible to operators.
Electrical Safety – Common Observations contd..

- Field Observations;
  - No tagging of electrical equipment.
  - Damaged Cables, Damaged grounding
  - Resistance for grounding is higher than threshold.
  - No maintenance program for checking effectiveness of grounding.
  - Electrical equipment installed (including in Ex-Zone) don’t comply to standard OR not maintained.
  - Electrical work done by non-certified electricians.
  - Open / accessible electrical terminals.
  - No PPE’s / damaged PPE’s used.
  - LoTo is not followed by electricians while doing maintenance work.
  - Use of temporary installations / connections.
Case Studies
Employee sustained broken shoulders when testing an incorrectly wired appliance

- An employee sustained a 240-volt electric shock that broke both shoulders whilst attempting to test a newly manufactured appliance that had been incorrectly wired to the mains lead.
  - Suitable precautions had not been taken to prevent electrical injury to employees engaged in testing work on electrical appliances.
  - Employees were exposed to live wires at 240 Volts ac,
  - there was exposed metal in the test area,
  - there was no procedure to pre check of mains lead prior to live test and
  - no risk assessment for electrical testing work.
Employee received a shock whilst insulating live wires

- An employee received a 650 Volt ac. electric shock when he picked up a cable lying on the ground that was connected to a generator and began to apply insulating tape to exposed wires.
  - No procedure to work on electrical equipment.
  - No Risk assessment.
  - No Power-Off
A worker was injured when working in a live electrical panel

- An employee was instructed to carry out work on an electrical control panel to reverse the phases and reverse the conveyor that had blocked. The panel was still live and electrical shorting resulted in arcing and caused burns to his face and arms.
  - Worker was not an electrician and had not received training in electrical work
  - No risk assessment
  - No Lock Out Tag Out procedure
A contractor was electrocuted while servicing an Air Conditioner at office

- A contractor was carrying out servicing of an office air conditioners, when someone accidently switched on the MCP causing electric shock to the working person.
  - No Lock Out Tag Out procedure applied for office work
Consequence of Electrical Incidents

- Electric shock / Electrocution
- Fires / Explosion
- Arc Flash / Burns

**Arc Flash / Arc Blast**

- Sudden release of electrical energy through air when a high-voltage gap exists and there is a breakdown between conductors
- Gives off thermal radiation (heat) and bright, intense light that can cause burns, temperatures as high as 35,000°F
- High-voltage arcs can also produce considerable pressure waves by rapidly heating the air and creating an Arc blast
Common Electrical Hazards

Contact with overhead power lines:

- Overhead and underground power lines carry extremely high voltage
- Risks
  - Electrocution (main risk)
  - Burns and falls

Incidents:
- Worker electrocuted when the ladder came in contact with overhead power lines
- Worker electrocuted when mast came in contact with high voltage overhead lines
Common Electrical Hazards

Damaged or bare wires / Damaged Tools

- Fault current may travel through a body, causing electrical burns or death, if
  - Power supply is not grounded
  - Path has been broken
  - There are live parts or bare wires

- Extreme conditions and rough treatment can change electrical equipment from safe to hazardous
Common Electrical Hazards

Unsafe Practices

- Wires crossing through doors
- Wires entangled through steel structure / scaffold
- Temporary repairs
- Overloading, temporary connections
- Construction site is a major challenge
Common Electrical Hazards
Electrical Safety

Specialized Electrical Work;
- Use good quality certified electrical equipment suitable for the work requirement and conditions.
- Installation must fully comply to electrical rules / standards.
- Involve Specialized people to design.
- Don’t carry alterations / modification in original design of equipment.

For Ex Areas;
- Ex Zones have special requirements, generally covered under Process safety.
- Follow ATEX / other equivalent standards to identify applicable zones.
- Install equipment in line with applicable zone.
- Grounding and bonding plays important role.
- Maintenance is crucial.

In Day to Day work;
- Refer next slides..
Electrical Safety - basic requirements

- Work by Qualified and trained electricians.
- Use good quality certified electrical equipment suitable for the work requirement and conditions.
- Installation must fully comply to electrical rules / standards.
- All electrical appliances must be tagged / labelled.
- Grounding plays a crucial role, hence need extra attention.
- All electrical installations must be fully protected for unauthorized access.
- Carryout Risk assessment / Electrical hazard identification.
- Fully apply work permit procedure and Lock-Out, Tag-Out, Try-Out.
- Working on High Voltage require specialized People and Special work permit.
- Choose specialized Personal Protective Equipment for working at electrical installation.
- Changes in electrical system also need Management of Change.
- Precheck before startup (after every maintenance) has no substitute.
Electrical Safety – Portable equipment

- Very commonly used both at workplace and home;
- Identify which portable electrical equipment is to be used where, and needs to be maintained. Include in your maintenance plan and checked by trained person.
- Examples of best practice – test and tag; ERB interlocked circuit breaker receptacles.
- Provide training and information for all users to help carry out user checks including what to do if they find a fault;
- Use of damaged equipment can be risky, and may lead to Electric shock, Short circuit etc.
- Decide what to do about ‘unauthorised equipment’ brought in by employees;
Electrical Safety – Grounding and Bonding

Grounding and Bonding plays a crucial role in electrical safety. If equipment is improperly grounded or bonded, it could result in damage to the equipment, electrical shock, injury, and/or electrostatic discharges that could ignite flammable atmospheres leading to fire or explosion.

**Grounding:**
- Is the method where you connect metal parts of the equipment to the earth to limit the voltage-to-ground on the metal parts.

**Bonding**
- Is the method where you connect metal parts of one equipment to other equipment to reduce the potential voltage difference.
Best Practice – Electrostatic Hazards

- Ground all metal equipment! to avoid **ELECTROSTATIC HAZARDS** e.g. Drums (metal), tote bins, dump chutes, buckets, utensils (scoops), metal wands, etc. Be aware painted / corroded terminals / parts can make grounding / bonding ineffective.

- Operator must use antistatic clothing, PPE’s e.g. gloves, Shoes etc. and floor must be conductive. OR use electrostatic wrist bands.

- Practical limit for resistance to ground of metal items is <10 ohms. Must be checked periodically.

- When portable devices e.g. clamps / wires are used for Grounding / Bonding of mobile equipment, routine checks should be performed on grounding systems including **Before** operations are started.

- Connecting / disconnecting portable ground connections during process can be dangerous. Must be removed only **After** operations have ceased.
Arc Flash – Risk Assessment

- A specialized activity to be done by expert.
- This analysis determines the flash potential boundary and potential thermal exposure to personnel working on or near exposure live parts.
- It recommends special Personal Protective clothing required for various scenarios to protect people working in risk boundary.
- Equipment may be labeled with the results of the arc flash hazard analysis and shock protection analysis.

<table>
<thead>
<tr>
<th>Incident Energy (cal/cm²)</th>
<th>Incident Energy to Flash Point (cal/cm²)</th>
<th>Hazard Risk Category</th>
<th>Clothing Description</th>
<th>Clothing Layers</th>
<th>Required Minimum Arc Rating of PPE (cal/cm²)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>4.0</td>
<td>1</td>
<td>FR Shirt &amp; Pants</td>
<td>1</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>4.0</td>
<td>8.0</td>
<td>2</td>
<td>Cotton Underwear FR Shirt &amp; Pants</td>
<td>1 or 2</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>6.0</td>
<td>25.0</td>
<td>3</td>
<td>Cotton Underwear FR Shirt &amp; Pants + FR Coverall</td>
<td>2 or 3</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>25.0</td>
<td>40.0</td>
<td>4</td>
<td>Cotton Underwear FR Shirt &amp; Pants + Multi-Layer Flash Suit</td>
<td>3 or more</td>
<td>40</td>
<td></td>
</tr>
</tbody>
</table>
Electrical Safety – LoTo

- Lockout Tagout and Tryout must be followed including when work is done by certified and trained electricians.
- When working on live circuits is allowed, must be made clear in the procedures duly supported with risk assessment and required controls.

Step 1: Prepare for shutdown
- Get all required tools and LOTO gear

Step 2: Notify affected workers
- Machine is being locked out

Step 3: Shutdown equipment
- Follow standard shutdown procedure

Step 4: Isolate equipment
- Physically turn off all energy isolation devices

Step 5: Apply LOTO
- One lock per energy source per authorized employee

Step 6: Release stored energy
- Bleed, purge systems per LOTO procedure

Step 7: Verify zero energy condition
- Test controls and return to “OFF” position
Best Practice – LoTo

Use LoTo diagram, help people to know exact location and flow of actions before start of the work.
Electrical Safety – What to do?

Check

- Have you applied electrical safety practices?
- Is your electrical installation as per applicable standards?
- Have you done electrical risk assessment and have defined procedures?
- Do you have certified / trained electricians.
- Do they follow safe work practices?
- Do you periodically check earthing / grounding?
- Do you inspect your installation periodically?
- Do you follow Management of Change for changes in electrical systems?
- Do you have procedures to test equipment before taking it on-line?
Electrical Safety – Personal Protection

Inspection of Insulating Equipment Before Use

Inspect insulating equipment for damage before each use and immediately following any incident. Insulating gloves shall be given an air test, along with the inspection.

1. Hold the Glove with thumbs and fore fingers as illustrated.
2. Twirl the glove around quickly to fill with air.
3. Trap the air by squeezing the gauntlet with one hand. Use the other hand to squeeze the palm, fingers and thumb in looking for weaknesses and defects.
4. Hold the glove to the face to detect air leakage or hold it to the ear and listen for escaping air.
References

India

- THE INDIAN ELECTRICITY ACT, 1910
- THE INDIAN ELECTRICITY RULES, 1956
- GUIDE FOR SELECTION AND INSTALLATION OF ELECTRICAL EQUIPMENT IN HAZARDOUS AREAS (OTHER THAN MINES) - IS 5571 : 2009

International standards:

- Electrical Safety Rules - NFPA 70E
To ask questions, please go to [https://app.sli.do/](https://app.sli.do/) and enter the event code: #PSCIIndia
PSM Maturity Model

Dr. Daniel Rehm
Lead HSE Advisor Elanco External Manufacturing (EEM) EMEA&API
Elanco Animal Health Inc.
AGENDA

Introduction

PSM Maturity Model

PSM Primers
PSM Team

- Daniel Rehm (Elanco) Lead
- Kumarkrishna Bhattacharjee (Novartis)
- Da Ming Bai (Elanco)
- Vijay Bendi (J&J)
- Germano D`Arasmo (Gilead)
- Giovanni Desanti (FIS)
- Simon Hodgson (Carnstone)
- Mark Hoyle (AstraZeneca)
- Andreas Ludwig (Boehringer Ingelheim)
- Denis Prat (Sanofi)
- Pierre Reuse (Lonza)
- Wenquan Yuan (Pfizer)
Speaker Bio – Daniel Rehm

- Daniel is Lead HSE Advisor in the Elanco External Manufacturing EMEA &API Hub Basel, Switzerland
- PhD in Chemistry from Humboldt University in Berlin, Germany with 16 years of experience in Chemical Industry, Insurance and Pharmaceutical Industry. Functional experience in R&D, HSE, Engineering and Manufacturing
- Working in Elanco for 5 year.
- Additional work as Loss Prevention Manager and Tech Transfer Project Lead
- Team lead of the PSM sub-team of the PSCI Capability Committee

Dr. Daniel Rehm

Elanco Animal Health Inc.
Mattenstrasse 24A, 4058 Basel, Switzerland
+41 61 6 85 6347 (office) | +41 79 640 4487 (mobile)
rehm_daniel@elanco.com
Introduction

- Maturity models for different topics are been created
- Each maturity model has 4 levels from **Starting out** to **Leading**

<table>
<thead>
<tr>
<th>Starting out</th>
<th>Developing</th>
<th>Implementing</th>
<th>Leading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1: Primers</td>
<td>Level 2: Tools &amp; techniques</td>
<td>Level 3: Specialised content</td>
<td>Level 4: Expert access</td>
</tr>
</tbody>
</table>

- The maturity models shall help the suppliers to identify their current standing and where are areas of improvement
## PSM Maturity model: Management

<table>
<thead>
<tr>
<th>Management</th>
<th>Starting out Level 1: Primers</th>
<th>Developing Level 2: Tools &amp; techniques</th>
<th>Implementing Level 3: Specialised content</th>
<th>Leading Level 4: Expert access</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assign an appropriately qualified PSM person with defined responsibility (Process Safety) and necessary resource to fulfil the role.</td>
<td>Risk evaluation and prioritization (safety systems, emergency equipment)</td>
<td>Develop substitution program for most dangerous chemicals (Inherent safety practices)</td>
<td>Investigate PSM incidents, implementation of corrective actions + sharing learning information on PSM studies, provided to all employees</td>
</tr>
<tr>
<td></td>
<td>• Risk evaluation and prioritization (safety systems, emergency equipment)</td>
<td>• Develop substitution program for most dangerous chemicals (Inherent safety practices)</td>
<td>• Contractor programs in place with respect to PSM</td>
<td>• Benchmark PSM program, best practices + implement</td>
</tr>
<tr>
<td></td>
<td>• Contractor programs in place with respect to PSM</td>
<td>• Implement an internal audit system</td>
<td>• Implement an internal audit system</td>
<td>• External PSM program Audit</td>
</tr>
</tbody>
</table>

### Management Objectives:
- Assign an appropriately qualified PSM person with defined responsibility (Process Safety) and necessary resource to fulfil the role.
- Risk evaluation and prioritization (safety systems, emergency equipment).
- Develop substitution program for most dangerous chemicals (Inherent safety practices).
- Contractor programs in place with respect to PSM.
- Implement an internal audit system.
- Investigate PSM incidents, implementation of corrective actions + sharing learning information on PSM studies, provided to all employees.
- Benchmark PSM program, best practices + implement.
- External PSM program Audit.
## PSM Maturity model: Risk Assessment

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th>Starting out</th>
<th>Developing</th>
<th>Implementing</th>
<th>Leading</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 1: Primers</td>
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<td>Level 3: Specialised content</td>
<td>Level 4: Expert access</td>
</tr>
<tr>
<td>Basic PSM training for EHS, Engineers and Management:</td>
<td>• Train PHA (HAZOP / What-if) techniques by example</td>
<td>• Include critical safety parameters in Operational instructions</td>
<td>• Fully integrate PSM in every business decision:</td>
<td></td>
</tr>
<tr>
<td>○ Understanding of chemical reaction and fire/explosion hazards</td>
<td>• Conduct PHA in suitable team</td>
<td>+ communicate with affected employees</td>
<td>○ periodically update PSPI information, PSPI database</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PHA available for most hazardous processes</td>
<td>• PHA available for all processes</td>
<td>○ periodic update all PSM related trainings</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>○ periodic inspection, review and improvement of all process safety (program &amp; field)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>○ periodically update PHA studies</td>
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<td>○ implement a document retention policy</td>
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<td></td>
<td></td>
<td></td>
<td>○ participate in national and international PSM congresses, training events</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>○ membership of PSM organizations (CCPS, etc.), literature, ...</td>
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</tbody>
</table>

- Basic PSM training for EHS, Engineers and Management:
  - Understanding of chemical reaction and fire/explosion hazards

- Train PHA (HAZOP / What-if) techniques by example
  - Conduct PHA in suitable team
  - PHA available for most hazardous processes

- Include critical safety parameters in Operational instructions
  - Communicate with affected employees
  - PHA available for all processes

- Fully integrate PSM in every business decision:
  - Periodically update PSPI information, PSPI database
  - Periodic update all PSM related trainings
  - Periodic inspection, review and improvement of all process safety (program & field)
  - Periodically update PHA studies
  - Implement a document retention policy
  - Participate in national and international PSM congresses, training events
  - Membership of PSM organizations (CCPS, etc.), literature, ...
# PSM Maturity Model: PSI/MoC/Training

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<th>Level 4: Expert access</th>
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</thead>
<tbody>
<tr>
<td><strong>PSI</strong></td>
<td><strong>MoC</strong></td>
<td><strong>Training</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Understand the need for process safety information to support decisions | Management of Change (MoC) procedure | Basic PSM training for EHS, Engineers and Management:  
  - Fundamentals of PSM  
  - PSM elements  
  - ATEX or NFPA  
  - Flammable & explosive materials  
  - Static electricity  
  - Understanding of dust explosion hazards | Basic PSM training for shift supervisor and operator  
  - Competency Management System –Safety Critical Task assessment and documentation of competence for operators | Proactive (forward) safety studies and in house PSI monitoring capabilities |
| Gather appropriate Process Safety Information required to assist PHA | MoC procedure & practice | Full PSM training for EHS, Engineers, shift supervisor and operator | MoC included in external PSM program Audit |
| Appropriate Process Safety Information for all processes available | MoC process fully implemented with involvement of PSM expert | Continuous monitoring and update of training program (track record) and competency assessments on Safety Critical Tasks (reviewed on a suitable timeline (e.g. every 3 years or when a change is made) |                        |

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## PSM Maturity model: Fire Protection

| Fire Protection | Starting out  
Level 1: Primers | Developing  
Level 2: Tools & techniques | Implementing  
Level 3: Specialised content | Leading  
Level 4: Expert access |
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Fire water supply/ hydrant system</td>
<td>• Trained people on site for first response</td>
<td>• Fire protection program started</td>
<td>• Automated extinguishing systems in all high risk areas and warehouses</td>
<td></td>
</tr>
<tr>
<td>• Fire detection in all areas - Automatic smoke detection &amp; fire alarm in high risk areas</td>
<td>• Fire protection program started</td>
<td>• Adequate fire water, fire pump(s), hydrants and enough foam generating liquid provided (based on calculation)</td>
<td>• Automated extinguishing systems in all high risk areas</td>
<td>• The facility is equipped with an on-site fire station and fire truck (for larger facilities)</td>
</tr>
<tr>
<td>• Hot work permit in place</td>
<td>• Fire extinguishers are available at strategic locations and inspected periodically (ensure employees know how to use extinguisher)</td>
<td>• Fire extinguishers are available at strategic locations and inspected periodically (ensure employees know how to use extinguisher)</td>
<td>• Automated extinguishing systems in all high risk areas</td>
<td></td>
</tr>
<tr>
<td>• Maintenance/inspection program for equipment (spare back-up pump, jockey pump, valves locked open)</td>
<td>• Fire extinguishers are available at strategic locations and inspected periodically (ensure employees know how to use extinguisher)</td>
<td>• Fire extinguishers are available at strategic locations and inspected periodically (ensure employees know how to use extinguisher)</td>
<td>• Automated extinguishing systems in all high risk areas</td>
<td></td>
</tr>
<tr>
<td>• Passive fire protection (fire doors, walls etc.)</td>
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</tbody>
</table>

**VIRTUAL SUPPLIER CONFERENCE SEP-OCT 2020**
# Process Safety Primers

- Already available

<table>
<thead>
<tr>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>Dust explosion protection</td>
</tr>
<tr>
<td>PHA</td>
</tr>
<tr>
<td>GHS</td>
</tr>
<tr>
<td>Static Electricity</td>
</tr>
<tr>
<td>Not Described Situations</td>
</tr>
</tbody>
</table>

- in Preparation

<table>
<thead>
<tr>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>Fire detection</td>
</tr>
<tr>
<td>MoC</td>
</tr>
<tr>
<td>Tank farm safety</td>
</tr>
<tr>
<td>Boiler safety</td>
</tr>
<tr>
<td>Basic PSI</td>
</tr>
<tr>
<td>ATEX</td>
</tr>
</tbody>
</table>
Risk Assessment pitfalls

Kumarkrishna Bhattacharjee (Novartis)
Vijaya Kumar Bendi (Johnson & Johnson)
PSCI PSM Sub-Team
Kumarkrishna Bhattacharjee
Head- Supplier HSE assurance and risk, India Region
Novartis  India pvt ltd.
kumarkrishna.bhattacharjee@novartis.com

- Chemical Engineer (B.E), PGCBM-XLRI
- 19+ years of diverse and multidisciplinary experience in field of manufacturing (API), process engineering, process development, technology transfer and Health, Safety and Environment.
- Previous experiences – Associate director, Process safety management – Corporate SH&E Drreddy’s, Process engineer, AstraZeneca, Bangalore.
- PSCI Role : Process safety management subcommittee member, India Subcommittee member.
Speaker Bio – Vijaya Kumar Bendi

Vijaya Kumar Bendi
Manager, External Supply EHS&S
Johnson & Johnson Pvt. Ltd.
vbendi@its.jnj.com

- M.Sc. (Environmental Chemistry) M. Tech. (Environmental Management), Diploma in Ind. Safety
- >14 years of multidisciplinary experience in EHS&S in various industries (Pharmaceutical, Consumer & Medical devices)
- Support EHS&S for J&J External Suppliers in India & South East Asia - EHS&S Onsite Assessments, Technical / Capability Building visits
- Core team member of J&J PSM Team
- PSCI Role: PSM sub team member
AGENDA

Recent incidents in Indian Context
Case Study
Risk Assessment
Common gaps and pitfalls of inadequate risk assessments
Good risk assessment
Conclusion
# Some Recent Incidents – India

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Incident</th>
<th>Consequences</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-May-2020</td>
<td>Vizag</td>
<td>Styrene Leak</td>
<td>12 citizens losing their lives and 585 citizens being hospitalized, causing loss of livestock and vegetation.</td>
<td>Risk Assessment/SOP failure</td>
</tr>
<tr>
<td>03-June-2020</td>
<td>Dahej, Bharuch</td>
<td>Boiler Explosion</td>
<td>8 dead, 50 injured</td>
<td>Risk Assessment/SOP failure</td>
</tr>
<tr>
<td>13-Jan-2020</td>
<td>Tarapur, Boisar</td>
<td>Explosion during testing of new reactor</td>
<td>8 killed &amp; 6 injured</td>
<td>Risk Assessment/No factory license</td>
</tr>
<tr>
<td>07-May-2020</td>
<td>Cuddalore</td>
<td>Boiler Explosion</td>
<td>8 workers injured 6 losing their lives &amp; 17 injured</td>
<td>Risk Assessment/PSSR</td>
</tr>
<tr>
<td>01-July-2020</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-June-2020</td>
<td>Parawada, Vizag</td>
<td>Gas leak</td>
<td>2 dead &amp; 4 fall sick</td>
<td>Risk Assessment/PSSR</td>
</tr>
<tr>
<td>13-Apr-2020</td>
<td>Tarapur, Boisar</td>
<td>Explosion</td>
<td>2 killed &amp; 1 injured</td>
<td>Risk Assessment/PSSR</td>
</tr>
<tr>
<td>17-Aug-2020</td>
<td>Tarapur, Boisar</td>
<td>Reactor Explosion</td>
<td>2 killed &amp; 4 critically injured</td>
<td>Risk Assessment/Pressure build up in reactor</td>
</tr>
<tr>
<td>12-June-2020</td>
<td>Ankleshwar</td>
<td>Reactor explosion</td>
<td>1 killed &amp; 5 injured</td>
<td>Risk Assessment/Pressure build up in reactor</td>
</tr>
</tbody>
</table>

* Source: Collected recent accidents from internet
Case Study - LG Polymers

Description of the event:

- **When**: In the early hours of 7th May 2020, an accident of uncontrolled release of Styrene vapour occurred at LG Polymers India Pvt. Ltd. (LG Polymers) at Vizag from one of the Styrene storage tanks (M6).

- **Type of industry**: LG Polymers manufacturing of Polystyrene (General purpose PS & High impact PS), Expandable Polystyrene (EPS) & engineering plastic compounds - expanded the manufacturing capacities from time to time.

- **Impact**: The hazardous Styrene vapours spread beyond the factory premises, affecting the populace of five villages / habitations. This led to 12 citizens losing their lives and 585 citizens being hospitalized, besides causing loss of livestock and vegetation.

Source: High Power Committee Report
Case Study - LG Polymers

Some properties of Styrene:

- Colorless liquid at normal temperature
- Highly Flammable with Explosive range: 1.1 to 7%, Flash point: 31°C, Boiling point: 145°C, Density: 0.906 g/mL at 20 °C; Vapor Density: 3.6 (air -1)
- Highly reactive and can polymerize (exothermic reaction) - The rate of polymerisation increases with increase in temperature and results in runaway reaction at 65°C
- Polymerisation is controlled in normal circumstances by adding low temperature inhibitor substance like p-tert-butyl catechol (TBC). At higher temperatures, only high temperature inhibitors like Tertiary Dodecyl Mercaptan (TDM) and n-dodecyl mercaptan (NDM) etc. can inhibit the polymerisation of Styrene
- Time weighed average for 8 hours a day: 50 ppm; Short-term Exposure Limit (STEL) of maximum 15 minutes: 100 ppm; Immediate Danger to Life & Health (IDLH): 700 ppm. (ACGIH recommends TLV 10 ppm)
- Causes severe eye, skin and respiratory irritation, CNS depression, nausea, vomiting etc. on short term exposure

Source: High Power Committee Report
Case Study - LG Polymers

Styrene storage M6 Tank with 1937 MT storage had started uncontrolled release of Styrene vapors from the top of the tank through the Flame arrestor / Vent (N6) and Dip hatch vent (N1), which spread beyond the factory boundary, affecting the neighboring areas & habitations.

Fault Tree Diagram

Source: High Power Committee Report
Case Study - LG Polymers

Reasons for the release of Styrene Vapour - Investigation report revelations/findings

There are number of contributory factors which led to the accident – in this presentation mainly we are highlighting some reasons link to the risk assessment

- Seriousness in execution of warm shut-down and warm restart: Pre-Startup Safety Review (PSSR) has not conducted prior to startup of a processing/manufacturing plant to ensure that installations meet the original design or operating intent, to catch, re-assess any potential hazard due to changes during the lockdown period, has not been done

- Redundant instruments/Accessories not provided for critical parameters

- Electrostatic discharge hazard assessment not in place - Bonding and grounding of Styrene storage tanks and pipelines, and inspection of these system on a periodical basis are also missing in the plant.

- Thorough trainings on Process safety management not in place/ process safety measures not followed

- No thorough HAZOP/ risk assessment carried out for M6 Tank before it was installed, commissioned, modified and converted from molasses storage tank to Styrene storage tank

Source: High Power Committee Report
Introduction - Risk assessment

- Process industries are vulnerable to the risk of Process safety incidents due to use of Hazardous chemicals and process conditions if not controlled suitably.
- Process safety incidents such as explosion, Fire, toxic release (Impacting community) etc. results into loss of business (shut down of facility), Reputation loss (loss in business) and Regulatory violation (shut down).
- These are caused due to either or many of these gaps such as
  - Inadequate job knowledge or insufficient training
  - Inadequate understanding of process safety information
  - Inadequately designed equipment or modification of equipment with inadequate safety knowledge.
  - Inadequate inspection and maintenance
  - Incomplete or obsolete operating and emergency procedures
  - Inadequate supervision
- It is very important that proper Management process is set to Prevent, Mitigate and Respond to such incidents.
- One of the important step in above management process is Risk Assessment which combines science, skill and Judgement to systematically identify (know your hazardous), evaluate (find scenarios) and develop method (prevent &/or mitigate) to control Hazards.
- Different type of risk assessments are available which are What if analysis, What if with checklist, HAZOP, FMEA, ETA, FTA etc.
Risk assessment

Pitfalls of inconsistent/incomplete Risk assessments as observed from audits

- Risk assessment with out process safety information
  - No/inadequate information on Hazards of material (in normal and challenged condition), process technology and equipment results in incomplete risk analysis and Risk assessment
  - This in turn fails to identify potential risk and hence right control in place
- Risk assessments focusing only on work place safety (e.g. Personal injuries like trip, falls, cuts etc.)
  - Wrong impression to management that process risk assessments are identified and addressed.
  - Organization is exposed to probability of process safety incidents.
- Inadequate identification of risk
  - Due to lack of understanding of Hazardous event and process safety information, which in turn is due to inadequate skills, expertise and insufficient resource allocation, results in incomplete risk assessment.
  - E.g. 1. unable to identify risk of decomposition of reaction mass near operating temperature, risk of non-sequential addition of chemicals or reagent can result in fire/explosion. 2. ignition sensitivity and dust cloud explosion risk of formulation mixture etc.
- Inadequate identification of controls commensurate with risk
  - Risk identified having high consequences and probability with weak controls implemented such as only training & administrative control like instruction in SOP etc., may result in incidents.
  - Right control/s based on risk shall be implemented, for example passive controls, active controls, redundant controls etc, based on risk.
Risk assessment

Pitfalls of inconsistent/incomplete Risk assessments as observed from audits

- Inadequate system to implement identified recommendations or controls
  - Failure of management to allocate budget and resource to implement recommendations like engineering controls can result in incident when event occurs without preventive and mitigation system in place

- Inadequate or improper upkeep of controls over life cycle of process
  - Not identifying list of process safety critical equipment and absence of robust preventive maintenance program can result in failure of control and resulting in incident.

- Outsourcing risk assessment and considering it as one time activity
  - Conducting risk assessment as one time activity just to meet requirement of audit clearance and not making as part of management system can result in process safety incident during such time such as implementation of change, introduction of new process and modification of facility etc.

- Risk assessment without considering risk to/from neighbouring industry
  - Incidents at neighbouring industry impacts operations of site at close vicinity and vice-versa
  - Risk assessment if do not identify such risk result into shut down and loss of life. For example risk assessment considering facility siting identifying largely populated office near fire zone of risky process of neighbouring site and impact of site on nearby population (temporary/permanent)

- Not making risk assessment as part of input to Onsite emergency plan
  - Hazardous event scenario identified during risk assessment shall become part of onsite emergency plan and drill. During real event absence of such drill results into large scale damage
# Good risk Assessment

<table>
<thead>
<tr>
<th>Good / Adequate Risk assessment</th>
<th>Inputs for adequate Risk assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ Identifies hazardous processes and materials handled and used in process</td>
<td>➢ Collection and evaluation of process safety data, physical properties, safety data, thermal data etc.</td>
</tr>
<tr>
<td>➢ Provides outline for understanding the hazardous events and responses to them.</td>
<td>➢ Definition of safe process conditions and critical limits</td>
</tr>
<tr>
<td>➢ Identifies unknown hazardous event.</td>
<td>➢ Systematic search for deviations from normal operating conditions</td>
</tr>
<tr>
<td>➢ Assigns severity and probability to hazardous event and identifies risk profile.</td>
<td>➢ Right Interpretation of data</td>
</tr>
<tr>
<td>➢ Identifies action to eliminate or reduce risk (ALARP) involved with known and unknown hazardous event.</td>
<td>➢ Clearly defined assessment criteria</td>
</tr>
<tr>
<td>➢ Provide input to disaster risk management</td>
<td>➢ Professional experience</td>
</tr>
<tr>
<td></td>
<td>➢ Identify Process improvement measures</td>
</tr>
<tr>
<td></td>
<td>➢ Define technical measures</td>
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<tr>
<td></td>
<td>➢ Integrate into Plant management</td>
</tr>
<tr>
<td></td>
<td>➢ Management of change</td>
</tr>
<tr>
<td></td>
<td>➢ Test of controls and management system</td>
</tr>
</tbody>
</table>
Conclusions – LG Polymers

- The uncontrolled Styrene vapour release from the M6 Tank at LG Polymers Visakhapatnam, qualifies as a major accident under MSIHC Rules, 1989.

- If facility would have conducted good risk assessment - would have addressed
  - Poor design of tank
  - Inadequate refrigeration and cooling system
  - Absence of circulation & mixing systems
  - Inadequate measurement parameters
  - Poor safety protocol
  - Minimized impact of its operations on the neighboring community by good preparation (conducts dispersion study)
  - Insufficient knowledge of the chemical properties of Styrene (mainly how it behaves with increasing temp.), especially during storage under idle conditions and total breakdown of the emergency response procedures

Source: High Power Committee Report
Conclusions – LG Polymers

It is difficult to predict catastrophic incidences but using systematic approach of hazard identification, assessment of risk and providing controls can prevent or mitigate such incidents.

Source: High Power Committee Report
BREAK 1

Conference resumes at 15:15. Please come back in 15 minutes.

If your question could not be addressed, please feel free to email it to info@pscinitiative.org and the relevant speaker will provide an answer in writing.
Process Risk Assessment

Case Study – Divi’s

Rao Divi  
Process Risk Assessment  
Divi’s Laboratories Limited

Srinivas Maddineni  
Corporate Head – EHS  
Divi’s Laboratories Limited
AGENDA

Process Risk Assessment - Introduction

Process Risk Assessment approach at Divi’s

Case Study 1: Safe charging of powder material into process vessel through open manhole

Case Study 2: Nitration reaction safety

Conclusion
Speaker Bio – Rao Divi

Rao Divi
Director, Divi’s Laboratories Limited

- 50+ years experience
- Currently administers all aspects of manufacturing including Production, Engineering, Environment, Health, Safety and Sustainability management along with construction of new projects.
- Executed large defense and civil construction contracts in Saudi Arabia, Iraq and Kuwait.
- Worked as Executive Director of SADAH General Trading and Construction Co, Kuwait.
Speaker Bio – Srinivas Maddineni

Srinivas Maddineni
Corporate Head - EHS, Divi’s Laboratories Limited

- 25+ years of multi disciplinary experience in Manufacturing of APIs, Bulk Drug Intermediates, Environmental Health, Safety & Sustainability.
Process Risk Assessment (PRA) - Introduction

- A technique for proactive identification and addressing of process and material risks.
- While recognising that the risk can never be eliminated, effective reduction of process and/or material risks shall be the prime moto.
- Effective risk assessment depends on the approach followed.
- Here, we highlight PRA approach being followed at Divi’s.
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

Activity Description

Hazard Identification

Hazard Analysis and Process Optimization

Cause, Consequence and Severity Assessment

Risk Mitigation & Control Measures

Residual Risk level estimation

Facilitation / Installation

Pre-start up reviews / Clearances

Monitoring & Periodical reviews for Continual Improvement
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

1. Hazard Identification
2. Hazard Analysis and Process Optimization
3. Cause, Consequence and Severity Assessment
4. Risk Mitigation & Control Measures
5. Residual Risk level estimation
6. Facilitation / Installation
7. Pre-start up reviews / Clearances
8. Monitoring & Periodical reviews for Continual Improvement

- Material
- Process
- Equipment
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

- Material and reactivity hazards
- Process and reactivity hazards

Material and reactivity hazards:
- Fire
- Explosion
- Thermally instable
- Polymerization
- Air/light/water sensitivity
- Impact due to material toxicity
- Impact due to material sensitivity
- Corrosive
- Eco-toxicity
- Reactivity hazards pertaining to other materials involved

Process and reactivity hazards:
- Exothermic
- Gas liberation
- Thermally instable
- High adiabatic temperature raise
- High criticality index
- Hazardous by-products
- High pressure reaction steps
- Critical reactions
- Accumulation energies
- Unexpected intrusions
- Incompatibilities addition
- Wrong reagents addition
- Parameters deviation

Capabilities / Practices:
- Preliminary ‘MSSDS’ i.e., Material Specific Safety Data Sheet by considering complete Material Safety information.
- If data is not available for any material, in-house Chemical Hazard Evaluation Lab studies will be carried out.
- Outsourcing for material testing as per the requirement.
- Benchmarking practices at renowned manufacturers through plant visits and technical reviews.
- Design qualification team experts considers data from the CHEL studies in selection of equipment compatible to the process / material.
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

- Activity Description
- Hazard Identification
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- Monitoring & Periodical reviews for Continual Improvement

Laboratory Capabilities at DIVIS
- Differential Scanning Calorimeter (DSC)
- Rapid Screening Device (RSD)
- Thermal Screening unit (TSU)
- Reaction Calorimeter (RC)
- Easymax HFCal
- Vent Size Package (VSP2)
- Accelerated Rate Calorimeter (ARC)
- Modified Hartmann tube
- Minor-2
- Godbert Greenwald apparatus
- Fall Hammer
- Powder Resistivity cell
- Charge Decay Analyzer
- ABEL flash point apparatus
- Ignition temperature oven
- Liquid concentration apparatus
- Conductivity cell
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

- Base Risk Level Estimation
- Process Hazard Analysis
- Supporting Risk Assessments

1. Activity Description
2. Hazard Identification
3. Hazard Analysis and Process Optimization
4. Cause, Consequence and Severity Assessment
5. Risk Mitigation & Control Measures
6. Residual Risk level estimation
7. Facilitation / Installation
8. Pre-start up reviews / Clearances
9. Monitoring & Periodical reviews for Continual Improvement

Process Hazard Analysis:
- HIRA
- QRA
- HAZOP
- Chemical workplace / IH assessment
- SIL assessments for automation processes

Supporting Assessments:
- Environmental Impact assessment
- Safe Venting requirements assessment
- Utilities and Services adequacy assessment
- Ignition assessments
- Industrial Hygiene assessments
- Storage conditions reviews / assessment
- EHS Validations (PPE, Glove box, Scrubber,..)
- Dust Hazard Analysis
- Dispersion modeling / consequence analysis
- Layers Of Protection Analysis (LOPA)
- Hazardous Area / Zone Classification
- Safe shutdowns and prestart ups
- Containment requirements
- Detection systems
- Fire safety reviews
- Layout review
- Emergency handling capabilities assessment & review

Layers of Protection Analysis

1.6: On Site, Community Emergency Preparedness
1.7: Specific Emergency Preparedness
1.6: Administrative Controls
1.5: Detection Systems, Alarms, Interlocks
1.4: Facility Design
1.3: Engineering Controls
1.2: Process Design
1.1: Process Chemistry

PSCI VIRTUAL SUPPLIER CONFERENCE SEP-OCT 2020
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

- Eliminate: Avoid the hazardous chemicals, process equipment; extent possible
- Minimize: Reduce inventories of hazardous materials on site
- Substitute: Replace hazardous substances, equipment or operations with less hazardous ones whenever possible
- Moderate: Use less aggressive operating conditions
- Simplify: Only use necessary operations. Remove issues by design not by the addition of consequential process operations
- Engineering Controls
- Administrative or Managerial controls
- PPE

Inherent risk reduction through Green Chemistry principles.

Hierarchy of controls

- Inherent risk reduction through Green Chemistry principles
- Feasible / Benchmarking controls

Activity Description

Hazard Identification

Hazard Analysis and Process Optimization

Cause, Consequence and Severity Assessment

Risk Mitigation & Control Measures

Residual Risk level estimation

Facilitation / Installation

Pre-start up reviews / Clearances

Monitoring & Periodical reviews for Continual Improvement
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

Activity Description

Hazard Identification

Hazard Analysis and Process Optimization

Cause, Consequence and Severity Assessment

Risk Mitigation & Control Measures

Residual Risk level estimation

Facilitation / Installation

Pre-start up reviews / Clearances

Monitoring & Periodical reviews for Continual Improvement

- Identifying the risks and determining the controls is the backbone for any assessment.
- Use of Inherently Safer Design (ISD) principles seeks to avoid hazards rather than controlling them with add-on protective equipment.
- Adopting control measures and benchmarking practices varies from organization to organization depending on feasibility and economic viability. Arriving ALARP strategy is the key while deriving controls.
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

Activity Description

Hazard Identification

Hazard Analysis and Process Optimization

Cause, Consequence and Severity Assessment

Risk Mitigation & Control Measures

Residual Risk level estimation

Facilitation / Installation

Pre-start up reviews / Clearances

Monitoring & Periodical reviews for Continual Improvement

 Hazard Assessment

• Pilot scale
• Commercial scale
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

Activity Description

Hazard Identification

Hazard Analysis and Process Optimization

Cause, Consequence and Severity Assessment

Risk Mitigation & Control Measures

Residual Risk level estimation

Facilitation / Installation

Pre-start up reviews / Clearances

Verification of the plant with 33 independent checklists

Monitoring & Periodical reviews for Continual Improvement
Process Risk Assessment approach at Divi’s

PROCESS RISK ASSESSMENT FLOW

- Activity Description
- Hazard Identification
- Hazard Analysis and Process Optimization
- Cause, Consequence and Severity Assessment
- Risk Mitigation & Control Measures
- Residual Risk level estimation
- Facilitation / Installation
- Pre-start up reviews / Clearances
- Monitoring & Periodical reviews for Continual Improvement

> Real time monitoring of process risks and KPIs is much needed.
Process Risk Assessment approach at Divi’s

Does more data lead to more worries?
Process Risk Assessment approach at Divi’s

Does more data lead to more worries?

Fact is that more data gives more Risk visibility!!
Process Risk Assessment approach at Divi’s

Does more data lead to more worries?

Fact is that more data gives more Risk visibility !

Clear Risk visibility is a prerequisite for implementing good and effective control measures.
Case Study 1: Safe charging of powder material into process vessel through open manhole
CASE STUDY 1:

SAFE CHARGING OF POWDER / SOLID MATERIAL INTO PROCESS VESSEL THROUGH OPEN MANHOLE

**ORIGIN:** Flash-fire occurred from reactor while charging solid material into an empty and cleaned reactor. Most probable root cause was identified as “Electrostatic discharge from Material/ Bag / Tools/ Practices or Short Circuit”

**Practices prevailing during the incident – already at Benchmarking level!**

- Charging solids first into cleaned vessel and then solvent
- Nitrogen inertion,
- Anti-static liners,
- Positive air suits for the people.
Process Risk Assessment Case study

Key CAPA adopted:

- Flammable Dust cloud avoiding by closed charging of material through Glove Box, Hopper, Man way purge Hopper, FIBC Type C bags, Process changes, Slurry transfers.
Process Risk Assessment Case study

Key CAPA adopted (Continued):

Charging through Hopper

Charging through Manway purge hopper

Charging through Isolator

Charging through PTS
Process Risk Assessment Case study

CAPA implementation status:

- Total 46 CAPAs identified from this incident for this single activity.

- **Key CAPA:**
  - No open charging of solids in the vessels.
  - Intensification of batch to batch cleaning practices.
  - Oxygen, Static values and Flammable concentration levels monitoring.
  - Included 3 Nitrogen swing in addition to the Vacuum inertion.
  - Fire resistant coatings to structures, all metal pipelines/ fixtures and electrical/mechanical accessories.
  - Anti –Static liners for material packing.
  - Testing of solid materials for dust properties.
  - Anti-Static flame retardant PPE.
  - Online earthing continuity monitor for the equipment to ensure the grounding of the vessel, bag & person.
  - Key CAPA included in batch records as instructions.

- ~530 manhole charging operations are reviewed against the CAPA; CAPA adopted for the required ~251 operations.
Process Risk Assessment Case study

- ALARP approach is clearly defined for the open manhole charging operations as below.

1. Reactor Cleaning.
2. Checking for Cleanliness.
3. Flammable concentration measuring.
4. Vacuum and Nitrogen pressure swings.
5. O2 ensuring.
6. Arranging Hopper on Reactor manhole with earthing continuity.
7. Arranging SS Plate In front of manhole with grounding.
8. Arranging the Enclosure.
9. Ensuring the Grounding.
10. Ensuring the earthing continuity in online earth monitoring unit.
11. Shifting the Material on trolley with rubber hand grips.
12. Personnel under Flame retardant suit for charging material.
13. Discharging the static voltage by providing grounding to the SS bin and placing the SS bin on grounded metal plate.
14. Checking the static voltage of material.
15. Arranging Multi static discharge Rod into material.
16. Checking the static values during /After discharging the static from material.
17. Material charging through SS bin by wearing Flame retardant suit & by standing on SS grounded plate under the enclosure.
Process Risk Assessment Case study

Current Material Charging Philosophy at Divi’s:

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>EQUIPMENT</th>
<th>CHARGING METHODOLOGIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid Material Charging</td>
<td>Reactor / Vessel</td>
<td>• Monorail through Hopper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Jib crane through Hopper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Isolator</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Glove Box</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hopper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Powder Transferring System</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Manway Nitrogen Purge Hopper</td>
</tr>
</tbody>
</table>

Selection philosophy for material charging, follow Preferred option of above listed by following the top to bottom hierarchy by considering the Material Properties, Process Parameters and Facility Design.

Safe Approach for Material Charging: Solid first and Flammable mass next.
Case Study 2: Nitration Reaction Safety
## CASE STUDY 2: NITRATION REACTION SAFETY

<table>
<thead>
<tr>
<th>Prior to technical PRA</th>
<th>After technical PRA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activity Description</strong></td>
<td></td>
</tr>
<tr>
<td>Dissolve the compound in sulphuric acid, cool down the mixture to ~22°C and add nitric acid for NLT 3hrs. After addition, raise reaction mass temperature to ~45°C and maintain for NLT 10hrs</td>
<td>Dissolve the compound in sulphuric acid, raise the mixture temperature to ~45°C and add nitric acid for NLT 3hrs. After addition maintain the batch at ~45°C for NLT 2hrs</td>
</tr>
<tr>
<td><strong>Risk:</strong> Interrupted power, agitation, cooling may lead to thermal runaway</td>
<td></td>
</tr>
<tr>
<td><strong>Process critical parameter</strong></td>
<td></td>
</tr>
<tr>
<td>Heat of reaction – 292kJ</td>
<td></td>
</tr>
<tr>
<td>Thermal accumulation at the end of addition - 40%</td>
<td></td>
</tr>
<tr>
<td>As higher accumulation percentages indicates high severity levels, we choose to redesign the process.</td>
<td>This reaction should be performed at an optimized temperatures through a well screened studies because there are more potential hazard and side-reactions at above 50 °C.</td>
</tr>
<tr>
<td><strong>Process critical parameter</strong></td>
<td></td>
</tr>
<tr>
<td>Heat of reaction – 249 kJ</td>
<td></td>
</tr>
<tr>
<td>Thermal accumulation at the end of addition - ~3.5%</td>
<td></td>
</tr>
</tbody>
</table>
## CASE STUDY 2: NITRATION REACTION SAFETY

<table>
<thead>
<tr>
<th>Prior to technical PRA</th>
<th>After technical PRA</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Graph 1" /></td>
<td><img src="image2.png" alt="Graph 2" /></td>
</tr>
</tbody>
</table>

- Nitric acid addition
- qr_hf
- Thermal Accumulation
- Tj
- Tr

---

This image illustrates the process risk assessment case study for nitration reaction safety. The graphs compare the process before and after the technical PRA, highlighting changes in key parameters such as nitric acid addition and thermal accumulation.
### Process Risk Assessment Case study

Few case studies resulted in advancements achieved with Process Risk Assessment are given below,

<table>
<thead>
<tr>
<th>Subject</th>
<th>Traditional Method</th>
<th>Divi’s Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solids separation by filtration</td>
<td>Centrifuges are used</td>
<td>Filtrations through ANFs</td>
<td>~320 are being used in the plant, whereas centrifuges are less than 20 only</td>
</tr>
<tr>
<td>Powders drying</td>
<td>In TDRs / FBDs</td>
<td>Wet slurry transfers / ANFDs / SFDs / Nitrogen jet mills</td>
<td>TDR / FBD used only for pilot scale or aqueous based powders</td>
</tr>
<tr>
<td>Gas cylinders handling</td>
<td>Handling of cylinders</td>
<td>In-house Hydrogen, Oxygen generation plants</td>
<td>~ 1,20,000 cylinders handling eliminated per year</td>
</tr>
<tr>
<td>Cleaning of vessels</td>
<td>Open vessel cleaning by hose pipes</td>
<td>Closed EHS-CIP (EHS Clean in place) is being practiced</td>
<td>Risky open cleaning activities are facilitated with EHS-CIP in 800 vessels</td>
</tr>
<tr>
<td>Liquid materials in drums</td>
<td>Procuring in drums</td>
<td>Eliminated drums handling by procuring in tankers</td>
<td>~1,40,000 drums eliminated per year</td>
</tr>
<tr>
<td>Sampling from vessels</td>
<td>Collection of samples in open manner</td>
<td>Closed sampling systems are facilitated for vessels</td>
<td>Risky open sampling activities are facilitated with closed sampling points in all the vessels</td>
</tr>
</tbody>
</table>
Conclusion

- Plants need to be prepared for any unexpected / unforeseen risks apart from the anticipated risks which are already taken care.

- Despite of providing the life saving drugs around the globe, major challenge for the industry is effectively controlling the process risks as many of the process risks may extend to surrounding community.

- Thorough Process Risk Assessments results in **ASSURED BUSINESS CONTINUITY**.

- The growth of any organization depends on how these process risks are managed!!!
Process Risk assessment

Case Study – Dr Reddy’s

Ravi J. R.
Lead Program Manager – Audit & Compliance, Operational Excellence Group
Dr. Reddy’s Laboratories Limited
AGENDA

Speaker Introduction
About Dr.Reddy’s
Dr.Reddy’s SH&E Policy and Principals
Risk Management at Dr.Reddy’s
Governance Mechanism
Speaker Bio – Ravi J. R.

Ravi J. R., Dr Reddy’s Laboratories Limited
Lead Program Manager Audit and Compliance, Operational Excellence Group

- EHS professional with more than 30 years experience in Safety, Health, Environment Management and Sustainability
- Worked in various sector industries like Metal finishing, Pesticide and Pharmaceuticals
- Successfully handled Six Sustainability reporting projects and designed and implemented SH&E Web enabled Workflow management
- Trained Corporate trainer for Behaviour based safety and Incident Investigation, Contractor safety management
- Graduate in Chemistry with post diploma in Environment management and Industrial safety and currently working as Lead Program Manager for Audit and compliance

Contact Information:
Dr. Reddy’s Laboratories Limited,
Global Manufacturing operations
FTO-2, Bachupally Village,
Medchal Malkajgiri Dist.,
Hyderabad – 500090, Telangana State India
Phone - +91 9701501858
Mail: ravijr@drreddys.com
Driven by the Belief that Good Health Can’t Wait.
20000+ people | 40 nationalities | 200+ products | 30 countries

One Purpose
We accelerate access to affordable and innovative medicines

because

Good Health Can’t Wait.
SH&E risk assessment

- All work place hazards requires to be identified, assessed for significant risk related to Safety, Health & Environment.
- Site should monitor the implementation of defined control measure’s to mitigate the impact of “Identified significant risk”.
The process of risk assessment broadly involves

- Identifying the hazards present
- Assessing the risks they pose, taking into account the effectiveness of controls and precautions already in place.
Overview of Risk Assessment Process

**Process Development team**
- Provide MSDS
- Safety /Health data on materials.
- Identify process wastes.

**Scale up team**
- Identify Safety/ Health hazards.
- Assess environmental impacts.

**SHE review Team**
- Hazard analysis.
- Recommend process safeguards/
- Environmental discharge control measures
Ensure inherently safe processes transferred from R&D

Facilitate risk reduction measures For new processes

Identify hazards and reduce risk in existing processes
To Implement a structured and systematic method to

Identify **SHE impacts** arising out of manufacturing

- Operating Personnel
  - Occupational Health Issues
  - Physical Injuries

- Equipment and buildings
  - Dust explosions
  - Fires

- Environment
  - Ecological impacts due to release of process wastes

Facilitate deployment of appropriate MEASURES to protect....

- Operating Personnel
  - API & Chemical exposures leading to health impairment.
  - Potential injuries from machines.

- Equipment and buildings
  - Potential "Dust cloud" ignition.
  - Solvent ignition.

- Environment
  - Release of VOC’s + API’s through equipment vents.
  - Release of chemicals + API’s through waste water.
Expected Outcome

- Embed “SHE” into manufacturing processes
- Prevention through Design – (PtD)
- Eliminate Hazards at each stage of process development life cycle
- Inherently SAFE manufacturing processes
Our Approach for Process Risk Assessment

- When feasibility of any product starts then the respective Scientist must reach out to the process safety team of R&D to carry out the desktop screening studies.
- Based on requirement the process safety team should carry out the desktop screening studies such as;
  - theoretical heat of reaction calculations, chemical compatibility,
  - fall hammer test / oxygen balance for those molecules which are associated with phosphors (e.g. Nitro, azide, peroxides).
- During/after optimization of a product the respective Scientist shall reach out to the process safety team for the complete process safety evaluation before going for scale-up batches.
- Process safety team must carry out all the required experiments in order to identify the chemical reaction hazards associated with that particular chemical process. Also if the existing chemical process is not safe for scale-up within the proposed operating conditions then the process safety team needs to provide proper support and guidance to the chemistry team to come up with an inherently safe process.
- Upon completion of all the experiments process safety team needs to compile all the data and share the information to the concerned team in the form of a Hazard Evaluation Report (HER).
Implications for Scale-Up

➢ A batch reaction is essentially a reaction with 100% accumulation.
➢ Once a batch reaction is started, if the cooling fails, all of the heat from the reaction can be released.
➢ Need to know the total heat generated
  – Adiabatic temperature rise
  – Consequences
    • Can this reach boiling point/decomposition

➢ Request for Adiabatic Calorimetry test data to assess the consequences of runaway reaction (ARC etc.)
Dr. Reddy’s Safety lab Infrastructure & Capability

Desk Screening Tools
- Soft wares
- CHETAH
- Physprops
- Books & Journals
  - Brethericks Handbook
  - Saxs dangerous properties of ind. Materials
  - …

Thermal Screening & evaluation Tools
- Differential Scanning Calorimeter (DSC)
- Thermal Screening Unit (TSU)
- Accelerating rate Calorimeter (ARC)
- Reaction Calorimeter (RC)

Powder Explosion testing tools
- Minimum Ignition Energy (MIE)
- Dust Explosion Screening (DES)
- Minimum Ignition Temperature (MIT)
- Burning Behavior (BB)
- Bulk Powder Resistivity (BPR) -(Breakdown)
- Fall Hammer Test
- Charge decay time analyzer (CDTA)
Thermal screening & evaluation tools

Data Obtained:
- Thermal Stability
- Amount and rate of Pressure rise
- Amount of gas evolved
- Characteristics of desired reaction
- Characteristics of decomposition reaction

Obtained data is used in designing a safe chemical process and safe scale-up
Powder explosion testing tools

Data obtained:
Fire and Explosion characteristics of powders

Obtained data is helpful in safe handling of powders during processing in plant

Minimum Ignition Energy & DES
Minimum Ignition Temperature
Fall Hammer

Burning Behavior
Layer Ignition temperature

Bulk Powder Resistivity
Charge decay time analyzer

Data obtained:
Fire and Explosion characteristics of powders

Obtained data is helpful in safe handling of powders during processing in plant
Safety data flow from R&D to Manufacturing

Safety lab will release the Hazard evaluation report (HER) after studies.

Scientist prepares the Process Safety Information (PSI) data.

Both (HER & PSI) the documents will be shared to Manufacturing during Tech Transfer/Process transfer.

Detailed PSI & Process Hazard Analysis (PHA) reports preparation in Manufacturing site by dedicated, trained & certified PSM Ambassadors.

PSSR (Pre startup safety review) for execution facility before batch start up.
PHA Ambassador program

With an objective of developing in-house capabilities in a rigorous and systematic approach to identifying, evaluating, and controlling the process hazards, a team of more than 80 members were identified from all the Business Units and made them PSM ambassadors.

**Result**
- Methodical 3 day Master Train the Trainer (MTT) program was organized covering 92 employees from Hyderabad & Visakhapatnam.
- These MTTs have trained 1939 employees at their respective sites covering all the departments.
- MTTs have reviewed hazardous processes in their sites covering 143 processes across all sites.
Risk Assessment Governance

- MSI
- Management Systems
- Operational Discipline
- Statutory Compliance

- ✓ One score that represents Safety & Health performance of unit
- ✓ Focus on field implementation and Sustenance
- ✓ Easy to track
- ✓ BU Specific Parameters
- ✓ Robust governance mechanism
Risk Assessment Governance

API BU has accorded 20% weightage for High Hazard Process Risk assessment

Culture
- Visible management Felt Leadership
- Consequence Management
- Capability building through trainings

Management Systems
- CSM & Permit to work
- Process Risk Assessment
- Occupational Health
- Road Safety
- Incident Investigation
- Laboratory Safety Management

Operational control
- Mandatory System Checks
- Legal compliance

Parameters drawn from existing Safety Standards
Process Risk assessment

Case Study – Granules

Dealing Emergencies / Fire at Neighbouring Industries & Vice Versa

Srinivas Nagalla
Head-Corporate EHS
M/s. Granules India Limited
AGENDA

About Granules India Limited

Emergency preparedness at Granules India

Dealing emergencies at neighbouring industries

Extending support for fire fighting in neighbouring industry
Speaker Bio – Nagalla Srinivas

Nagalla Srinivas
Head-Corporate EHS
Granules India Ltd.
Srinivas.Nagalla@granulesindia.com

- M.Sc., M. Tech – Environmental Management, Diploma in Ind. Safety and Ind. Hygiene
- 25 years of multidisciplinary experience in EHS in pharmaceutical industry (R & D, API & Intermediates manufacturing and formulations)
About Granules India Limited

Business Divisions
- Core Business
- Emerging Business
- US Generics

Revenue Mix & Global Reach
- Over 80% of revenues through exports, through regulated markets like USA, Europe and Canada
- 60+ countries
- 250+ customers

Regulatory Approvals
- USFDA, EDQM, EU GMP, COFEPRIS, INFARMED, TGA, WHO GMP, CDCSO, KFDA, DEA, CFDA, TFDA, MHRA, MCC, Health Canada, HALAL

Building Blocks & People Strength
- Regulatory Compliance
- Operational Efficiency
- Customer Centricity
- Scale of Operation & 3029 people as on 31st March, 2020

Product Verticals
Vertically integrated across value chain

Granules India
Incorporated in 1991, this is the only listed entity.
1 FD site, 02 PFI sites, 04 API Sites & 01 intermediate site

Granules USA
100% subsidiary, for front-end marketing in the U.S
01 FD site

Granules Pharmaceuticals
100% subsidiary with manufacturing setup at Chantilly, USA focused on advanced formulation development.

Granules Europe
100% subsidiary, for front-end marketing in Europe.

"To be the global leader in pharmaceutical manufacturing by process innovation and unparalleled efficiencies."
Emergency preparedness at Granules India

We at Granules India, work proactively developing an effective onsite emergency plan and strictly adhere to mock drills and fire drills.

Key areas:
❖ Incident control organogram & responsibilities
❖ Categorization of emergencies
❖ Emergency response team
❖ Fire fighting systems
❖ Occupational health centre
❖ Agreement with hospitals
❖ Emergency shutdown & general start up procedures
❖ Agreement with vendors to supply water on need basis
❖ Risk evaluated through process reviews and significant risks with effective control measures(incl. MOC/PHA/PSSR/JSA)
❖ Periodic review & updation of OSEP (incl. offsite emergencies)
Emergency Preparedness at Granules India

**Comm. & ERT**
1. Periodic & refresher trainings – In-house / external
2. Emphasize employee participation

**Fire Prevention**
1. Inertization practices
2. Hazardous Area Classification
3. Work Permit system
4. Flame arresters to process equipment vents
5. Management of Change & process hazard analysis
6. PSSR & routine inspections
7. ESD controls (Earth rite system, Continuous Earth Monitoring System, etc.,)

**Fire Suppression**
1. Fire Hydrant system
2. Emergency trolley
3. Fire extinguishers
4. Sprinklers
5. Wet risers
6. Fire retardant PPE (Suits, SCBA, etc.,)
7. Auto Modular fire extinguishers
8. ARFFF & AFFF

**Team Buildup**
1. Fire Prevention
2. Comm. & ERT
3. Fire Suppression
4. Communication & Coordination
Dealing Emergencies at Neighbouring Industries

Are we prepared for the fire??

How about offsite/neighbouring industries?

Have you ever faced any emergencies pertain to neighbouring industries
Dealing Emergencies at Neighbouring Industries

Objective

• Rescue the threat casualties and safeguard the people
• Minimize damage to property and environment

During Emergency

• To combat and contain the disaster.
• To evacuate & protect the affected areas.
• Coordination & communication.
• To inform the public for necessary self-protection measures

Post Emergency

• To rehabilitate displaced victims
• Ensure the emergency is under control
• Treatment of affected people at OHC/nearby hospitals

Offsite Emergency Plan

Deciding Factors

- Mutual aid agreement between neighboring industries
- Contact details of key personnel of neighbouring Industries
- Information about the abutting industries operations and storage of materials of higher threshold volumes

How effective we are in combating the emergencies??
Dealing Emergencies at Neighbouring Industries

Two emergencies occurred in last one year and we provided necessary support to subdue the emergency by combating fire in war footing basis without affecting personnel & property.

Paparazzi were prompt in capturing the scenario and published in tabloids applauding the Granules team for supporting neighbouring industry in this critical time.
Extending support for Fire Fighting in neighbouring industry

Case Study-1
Reactor Explosion near site-1

✓ Initial observation from security and prompt communication to site team alerted the management and activated the ERT.
✓ On getting concurrence with the neighboring industry, our ERT and EHS personnel rushed to incident spot and skillfully acted on the incident.
✓ Senior management coordinated with abutting industries and analyzed the situation to arrange for necessary support.
✓ HR team were quick in coordinating with water suppliers and managed to reach the spot in time.
✓ Wind direction created a ruckus at one point of time in both the incidents.
✓ ERT members swiftly and dexterously initiated the precautionary measures; wetted our common boundaries, switched off power, utilities, relocated the solvent drums, activated MCP and evacuated our site people.
✓ In complete coordination with fire tender team our ERT members have meticulously brought the fire under control.
✓ In view of any sudden outburst of fire again, ERT & EHS personnel maintained adequate stock of fire extinguishing equipment and the accessories.

Case Study-2
Fire broke out near site-2
Extending support for Fire Fighting in neighbouring industry

Case Study -1

- **Observed smoke at neighboring Industry**
- **Communication** to authorized & concerned personnel
- **Coordination** with neighboring industry and assessing impact

Case Study -2

- **Fire tenders & water tankers**
- **Rescue, fire fighting & providing first aid**
- **Alert site members, activation of ERT, provide fire extinguishing accessories**

- **Coordination & communication with external parties**
- **Coordination with neighboring industry and assessing impact**
- **Communication to authorized & concerned personnel**
Take home

- Significant points to be considered while dealing emergencies at neighbouring Industries
  - Active mutual aid programme
  - Contact details of key personnel of neighbouring industries
  - Maintain updated information of the neighbouring industries hazardous materials storage and operations.
  - Know your neighboring industries fire protection capabilities
  - Incorporate the changes in on-site emergency plan wrt. offsite/neighbouring industries accident history.
  - Annual / periodic schedule on collective mock drill between hazardous chemical industries with common boundary
Discussion Forum

- Line of control (LOC) for our ERT to enter the neighbouring industry.
- What should be included in mutual aid agreement to further strengthen it?
BREAK 2

Conference resumes at 16:15. Please come back in 10 minutes.

If your question could not be addressed, please feel free to email it to info@pscinitiative.org and the relevant speaker will provide an answer in writing.
Introduction and Industrial Hygiene Maturity Model

Vivian Rivera Turro
Industrial Hygiene Senior Associate Consultant
Eli Lilly & Co.
AGENDA

Industrial Hygiene Maturity Model Overview

Implementing a Comprehensive IH Program
Speaker Bio – Vivian Rivera Turro

Vivian Rivera Turro
Industrial Hygiene Senior Associate Consultant
Eli Lilly & Co.

- 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.

- riverav@lilly.com
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.
### October Calendar

#### Industrial Hygiene Webinars

<table>
<thead>
<tr>
<th>Date</th>
<th>Course Title</th>
<th>Partner</th>
<th>Additional Information/Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 20</td>
<td>Industrial Hygiene Fundamentals Series</td>
<td>Safebridge</td>
<td><a href="https://www.safebridge.com/training/159466/industrial-hygiene-fundamentals-series">https://www.safebridge.com/training/159466/industrial-hygiene-fundamentals-series</a></td>
</tr>
</tbody>
</table>
To ask questions, please go to https://app.sli.do/ and enter the event code: #PSCIIndia
Implementing a Comprehensive Industrial Hygiene Program

Vivian Rivera Turro, Industrial Hygiene Senior Associate Consultant, Eli Lilly & Co.
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
- Risk Assessment
- PPE determination, Medical Surveillance, and Training Requirements.

### Similar Exposure Group

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Department</th>
<th>Area</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
</tr>
</tbody>
</table>

### Hazard Characterization

<table>
<thead>
<tr>
<th>Drug Substance xxx</th>
<th>Reproductive, Liver effects</th>
<th>1 ug/m³ TWA 8 hrs</th>
<th>Daily</th>
<th>2 hrs</th>
<th>5 kg</th>
<th>Manual addition</th>
<th>Open-no controls</th>
</tr>
</thead>
</table>

### Risk Assessment

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Exposure Risk Rating</th>
<th>Exposure Potential</th>
<th>Exposure Conclusion</th>
<th>Uncertainty</th>
<th>IH Monitoring (Study #)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>4</td>
<td>Very High</td>
<td>Unacceptable</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

### PPE Determination

<table>
<thead>
<tr>
<th>PPE Determination</th>
<th>Fit Test</th>
<th>Medical Surveillance Requirements</th>
<th>Applicable Trainings</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAPR Respirator with HEPA filter</td>
<td></td>
<td>Respirator program</td>
<td>CLP/GHS (HazCom), PPE, Respirator</td>
</tr>
<tr>
<td>Full Face Respirator with organic filters</td>
<td></td>
<td>Respirator program</td>
<td>CLP/GHS (HazCom), PPE, Respirator, Fit Test</td>
</tr>
</tbody>
</table>
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

### Exposure Assessment Profile Example

<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>Hydrogen Peroxide</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Addition of water and materials into pre</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>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.
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

<table>
<thead>
<tr>
<th>Hazard Information</th>
<th>Risk Assessment</th>
<th>Risk Prioritization</th>
<th>Training Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical, Physical, or Biological</strong></td>
<td><strong>Low</strong></td>
<td><strong>2 hrs</strong></td>
<td><strong>Full Face Respirator with HEPA filter</strong></td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td><strong>Medium</strong></td>
<td><strong>1 hr</strong></td>
<td><strong>Full Face Respirator with HEPA filter</strong></td>
</tr>
<tr>
<td><strong>Dispensing</strong></td>
<td><strong>Medium</strong></td>
<td><strong>2 hrs</strong></td>
<td><strong>PAPR respirator with HEPA Filter cartridge</strong></td>
</tr>
<tr>
<td><strong>PPE, Respirator</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hearing conservation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Goggles, Nitrile disposable gloves</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respirator</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PAPR</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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.

---

If interested
An example of an Excel based Exposure Assessment Profile has been posted in PSCI Suppliers Link.
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>Similar Exposure Group</th>
<th>Risk Prioritization</th>
<th>Personal Protective Equipment</th>
<th>Respirator</th>
<th>Fit Test</th>
<th>Medical Surveillance Requirements</th>
<th>Training Requirements</th>
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</thead>
<tbody>
<tr>
<td>Site Name</td>
<td>Department</td>
<td>Area</td>
<td>Position</td>
<td>Conclusion</td>
<td>Uncertainty</td>
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<td>PPE, Respirator</td>
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<td>Full Face Respirator with HEPA filter</td>
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<td>Star Manufacturing</td>
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<td>Goggles, Nitrile disposable gloves</td>
</tr>
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<td>Formulation</td>
<td>Manufacturing operator</td>
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<td>PAPR respirator with HEPA Filter cartridge</td>
</tr>
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<td>High</td>
<td></td>
<td>Hearing protection NRR 33</td>
</tr>
</tbody>
</table>
Respiratory Protection Requirements

- All employees that work in areas requiring the use of a tight fitting respirator will require Fit Testing.
- 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.

<table>
<thead>
<tr>
<th>Similar Exposure Group</th>
<th>Risk Prioritization</th>
<th>Personal Protective Equipment</th>
<th>Respirator</th>
<th>Fit Test</th>
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<td>Manufacturing operator</td>
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<td>Manufacturing operator</td>
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<td>Manufacturing operator</td>
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<td>Low PAPR respirator with HEPA Filter cartridge</td>
</tr>
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<td>Manufacturing operator</td>
<td>Inconclusive</td>
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<td>Medium PAPR respirator with HEPA Filter cartridge</td>
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<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>Medium PAPR respirator with HEPA Filter cartridge</td>
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<td>Dispensing</td>
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<td>Manufacturing operator</td>
<td>Inconclusive</td>
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<td>Nitrile disposable gloves</td>
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<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>Medium</td>
<td>Safety glasses, nitrile gloves</td>
</tr>
<tr>
<td>Star</td>
<td>Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>Inconclusive</td>
<td>High</td>
<td>Hearing protection NRR 33</td>
</tr>
</tbody>
</table>

PSCI VIRTUAL SUPPLIER CONFERENCE SEP-OCT 2020

@PSCInitiative
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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- (+44) 07469 408913
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

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Department</th>
<th>Function</th>
<th>Position</th>
<th>Exposure Type</th>
<th>Frequency</th>
<th>Duration per shift</th>
<th>Quantity Used</th>
<th>Operation Type</th>
<th>Containment Level</th>
<th>Hazard Information</th>
<th>Risk Prioritization</th>
<th>Risk Assessment</th>
<th>Exposure Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Star Manufacturing</td>
<td>Dispensing</td>
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<td>Manual</td>
<td>Open - no controls</td>
<td>Irritant</td>
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<td>Unacceptable</td>
<td>Medium</td>
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<tr>
<td>Star Manufacturing</td>
<td>Dispensing</td>
<td>Manufacturing operator</td>
<td>API xxx</td>
<td>Chemical, Physical, or Biological</td>
<td>Open</td>
<td>2 hrs</td>
<td>5 kg</td>
<td>Manual</td>
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<td>Reproductive, Liver effects</td>
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<td>Low</td>
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<tr>
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<td>Chemical, Physical, or Biological</td>
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<td>1 hr</td>
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<td>Manual</td>
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<td>Sodium Cloride</td>
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<td>1 hr</td>
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<td>Open - no controls</td>
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<td>Inconclusive</td>
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<td>5 kg</td>
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<td>Open - no controls</td>
<td>Irritant</td>
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<td>Inconclusive</td>
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<td>Auditory</td>
<td>Daily</td>
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<td>Hearing loss</td>
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</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>
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<td>3</td>
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<td>4</td>
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<td>2</td>
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<td>Moderate to High</td>
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</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?
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. \( \uparrow \text{risk} = \uparrow \text{frequency} \)
- 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.

### Band Range | Mass inhaled over 8hr day
--- | ---
10,000 µg/m³ | 4% sugar pack
1,000 µg/m³ | 0.4% sugar pack
100 µg/m³ | 0.04% sugar pack
10 µg/m³ | 0.004% sugar pack
1 µg/m³ | 0.0004% sugar pack
0.1 µg/m³ | 0.00004% sugar pack

1 teaspoon of sugar = 4 grams (1 sugar packet)
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.
Not available
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

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**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
To ask questions, please go to https://app.sli.do/ and enter the event code: #PSCIIndia
Thank you for working with the PSCI

To help the PSCI capability building work better for you, please follow the link (https://www.surveymonkey.com/r/7NWTQTT) under the Survey tab on the livestream webpage to provide your feedback. Thank you!
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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.