

# Process Risk assessment at Dr.Reddy's

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TITLE : Lead Program Manager – Audit & Compliance , Operational Excellence Group

COMPANY : 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

Q&A



# Speaker Bio

- 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 .



## Contract Information :

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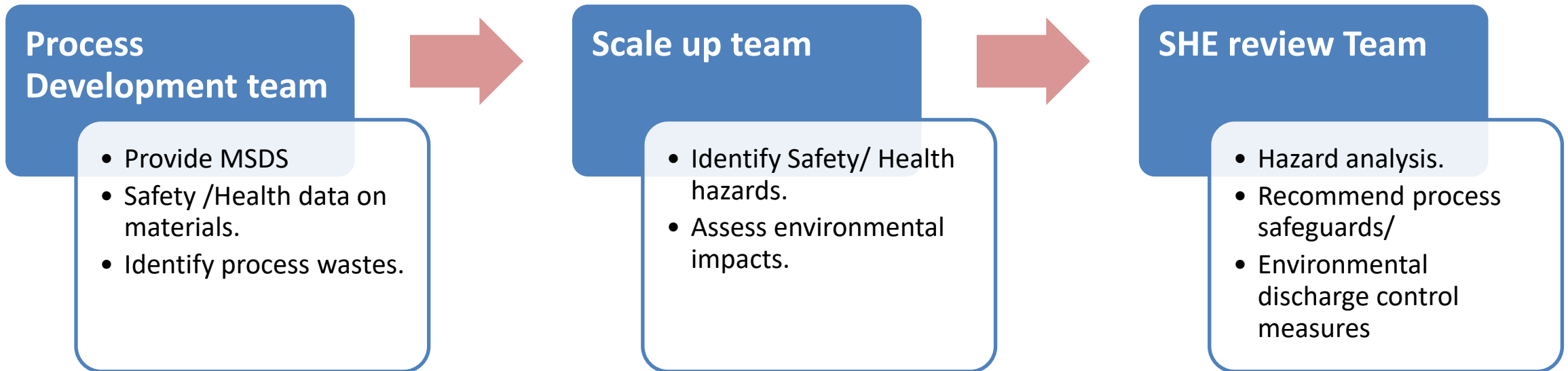
# SH&E risk assessment

- ❑ 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".

# SH&E risk assessment

- 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.

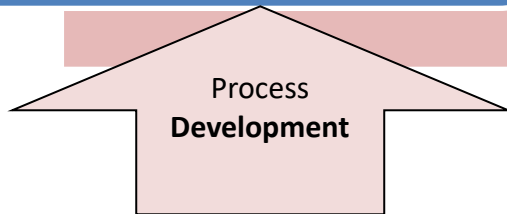
# Overview of Risk Assessment Process



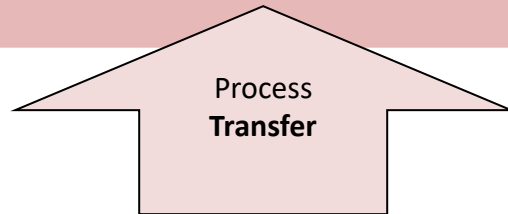


# Dr.Reddy's SH&E Review Guideline

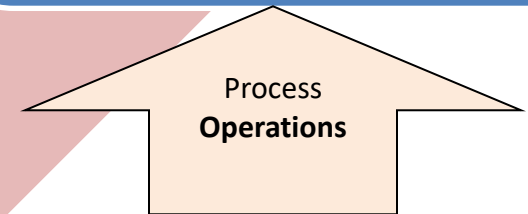
*Ensure inherently safe processes transferred from R&D*



*Facilitate risk reduction measures For new processes*



*Identify hazards and reduce risk in existing processes*

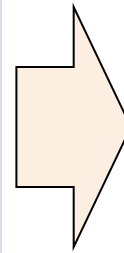


# SH&E risk assessment

To Implement a structured and systematic method to

## Identify SHE impacts arising out of manufacturing

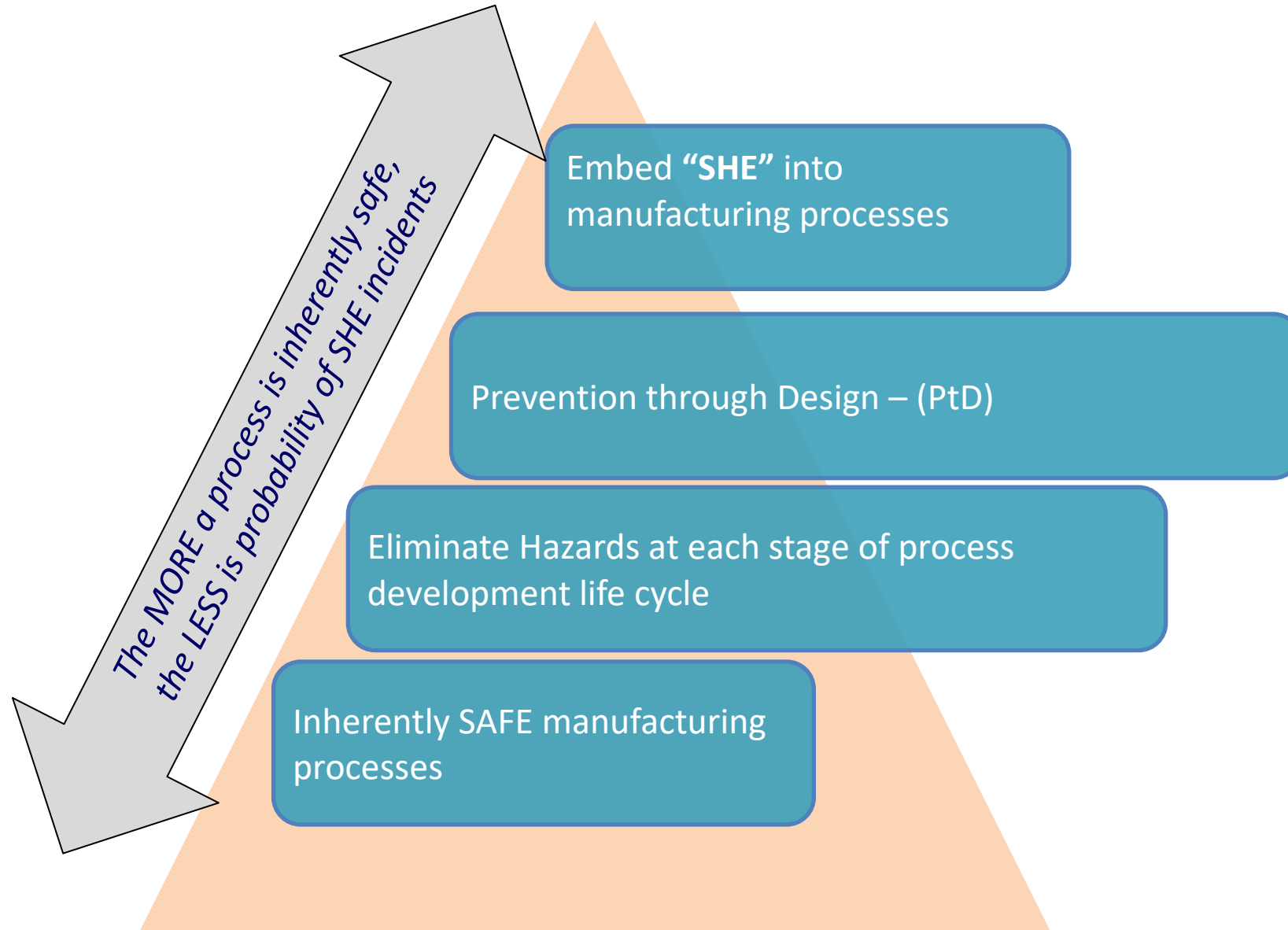
- Operating Personnel
  - *Occupational Health Issues*
  - *Physical injuries*
- Equipment and buildings
  - *Dust explosions*
  - *Fires*
- Environment
  - *Ecological impacts due to release of process wastes*



## 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



# 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
  - Saxe's 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



Differential scanning Calorimeter



Accelerating Rate Calorimeter

## Data Obtained:

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



Thermal screening Unit



Reaction calorimeter

Obtained data is used in designing a safe chemical process and safe scale-up

# Powder explosion testing tools



Minimum Ignition Energy & DES



Minimum Ignition Temperature



Fall Hammer

Data obtained:

Fire and Explosion characteristics of powders

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



Burning Behavior



Layer Ignition temperature



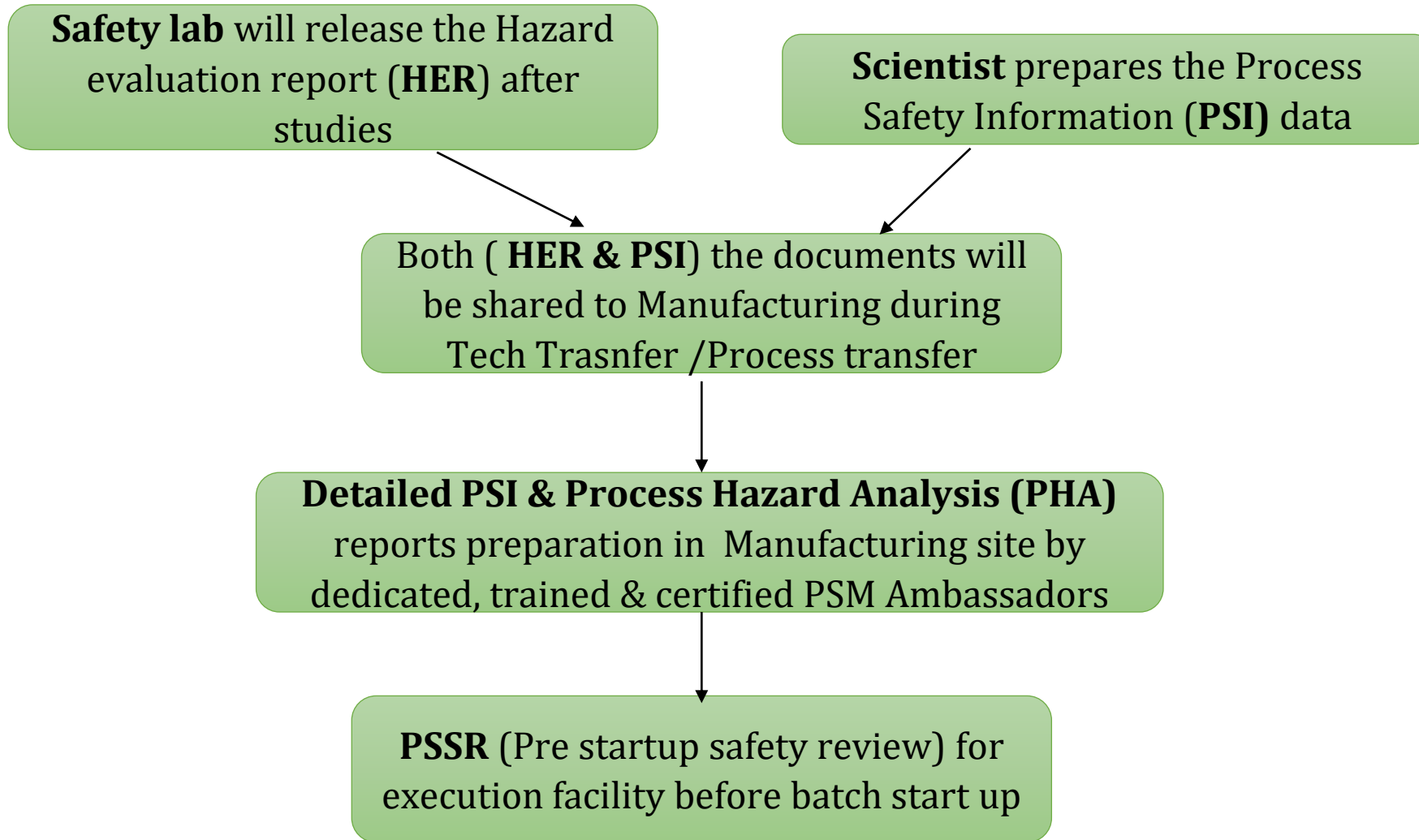
Bulk Powder Resistivity



Charge decay time analyzer



# Safety data flow from R&D to Manufacturing

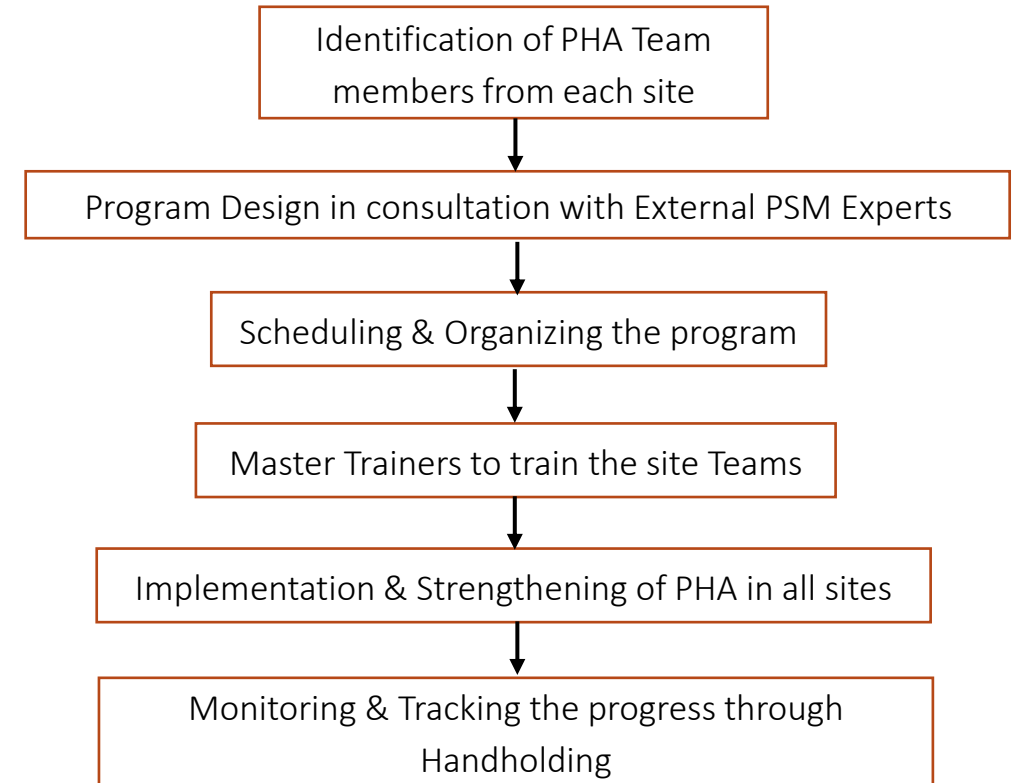


# PHA Ambassador program

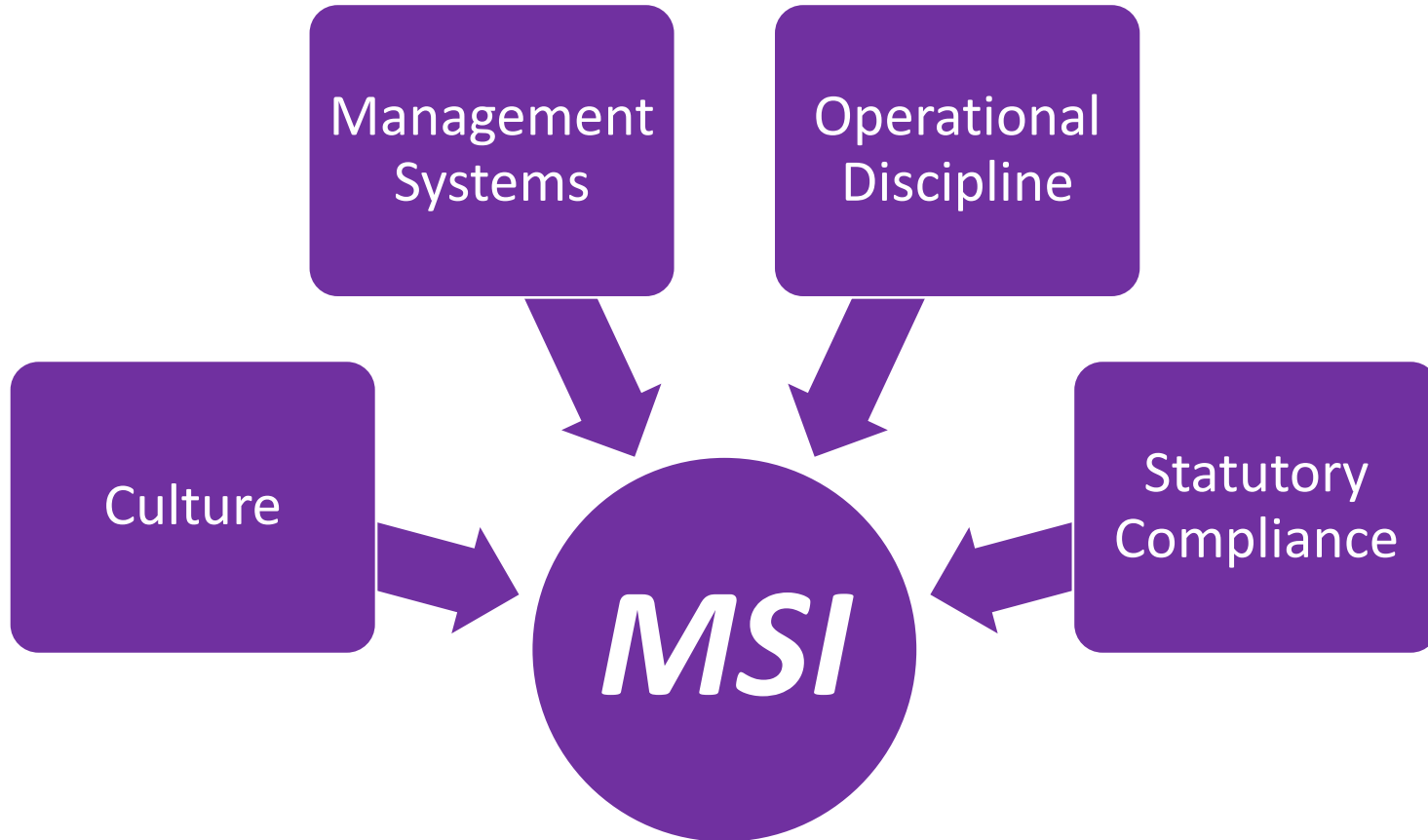
With an objective of developing in-house capabilities in a rigorous and systematic approach to identifying, evaluating, and controlling the process hazards, a team of more than 80 members were identified from all the Business Units and made them PSM ambassadors.

## 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



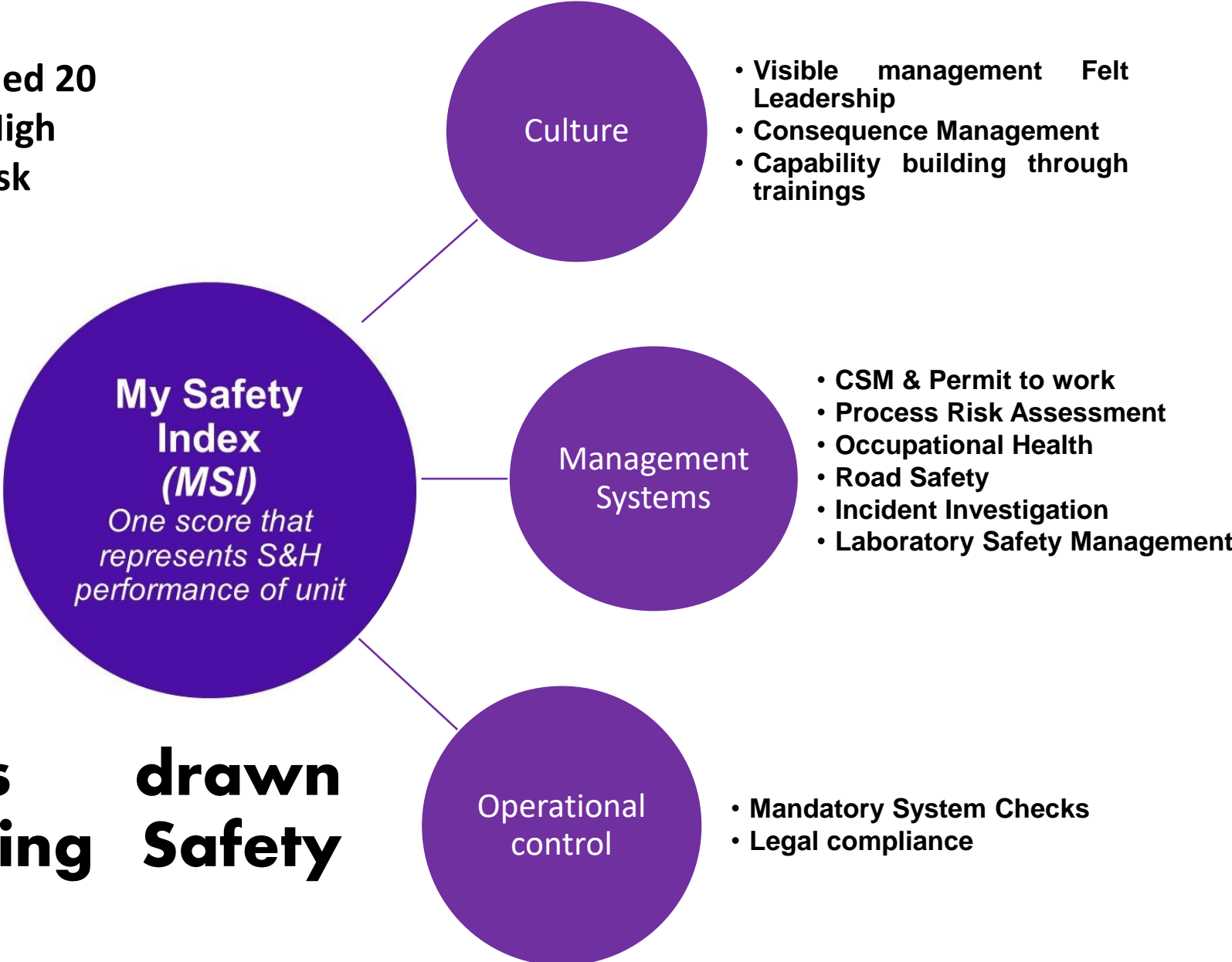
# Risk Assessment Governance



- ✓ 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



**Parameters drawn from existing Safety Standards**



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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.

