PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Process Risk assessment at Dr.Reddy's

SPEAKER NAME : Ravi J.R

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 :

Ravi.J.R
Lead Program Manager Audit and Compliance , Operational Excellence Group
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.

Dr. Reddy’s

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

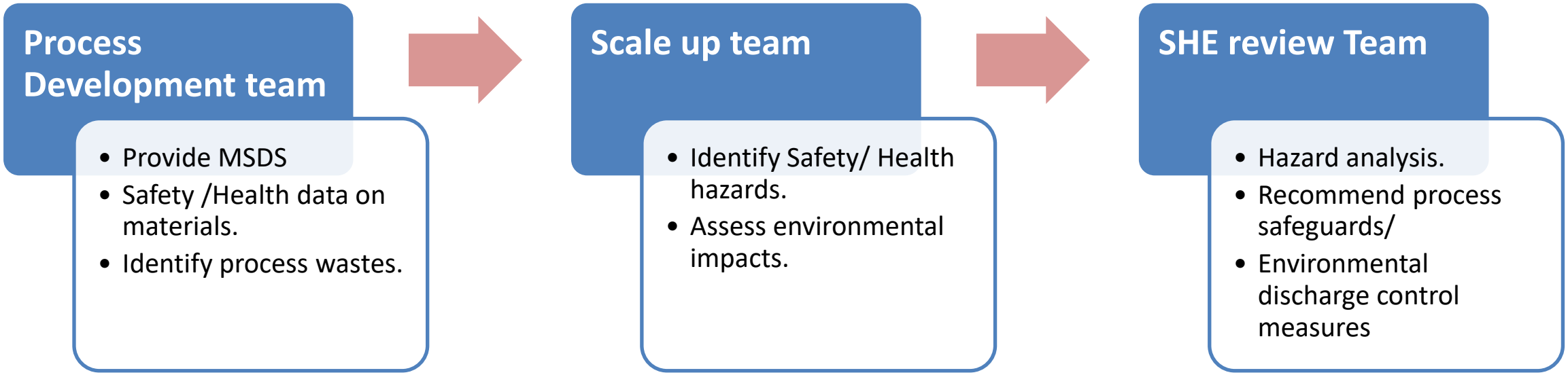
- All work place hazards requires to be identified, assessed for significant risk related to Safety, Health & Environment.

- Site should monitor the implementation of defined control measure's to mitigate the impact of "Identified significant risk".

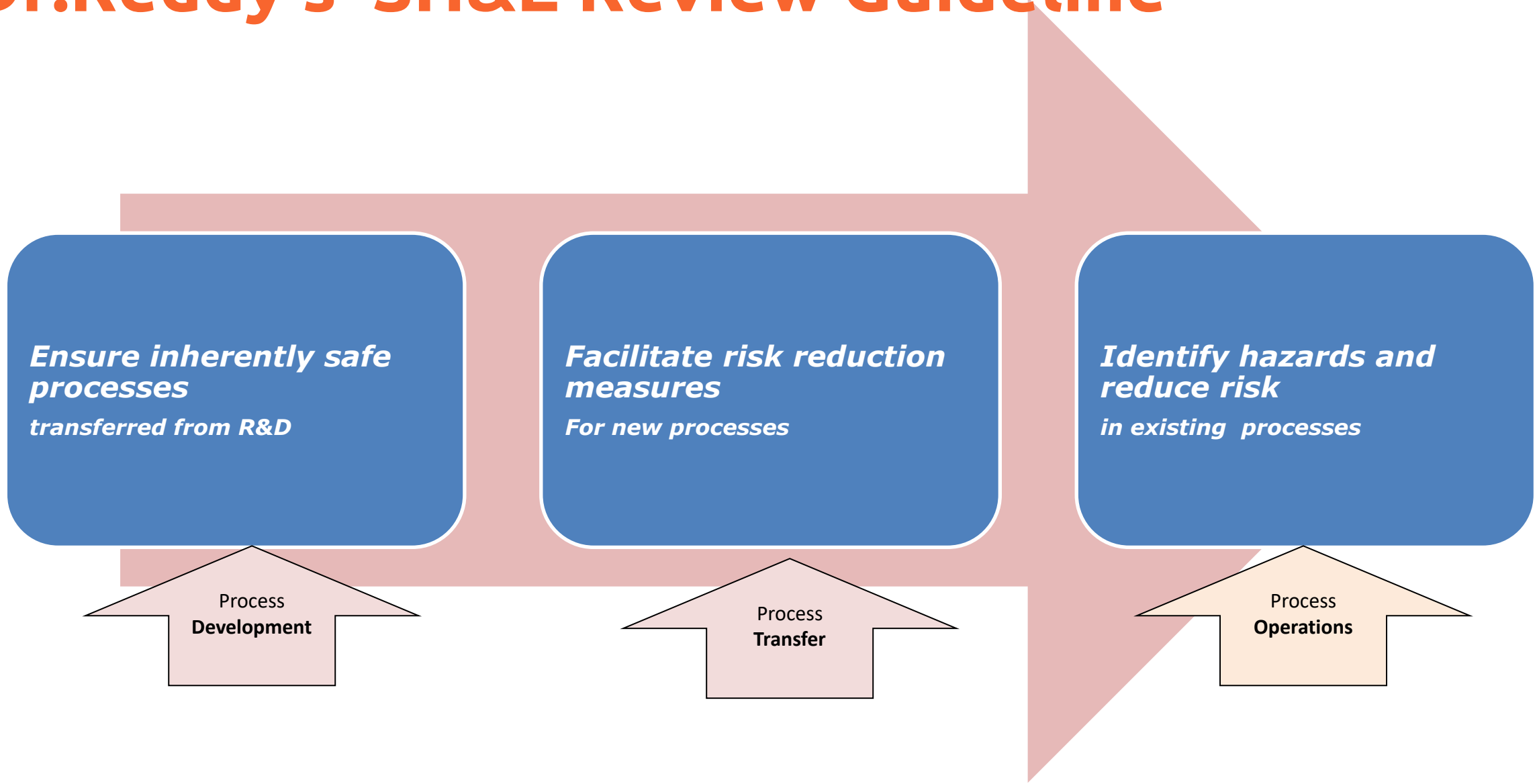
SH&E risk assessment

- 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



SH&E risk assessment

To Implement a structured and systematic method to

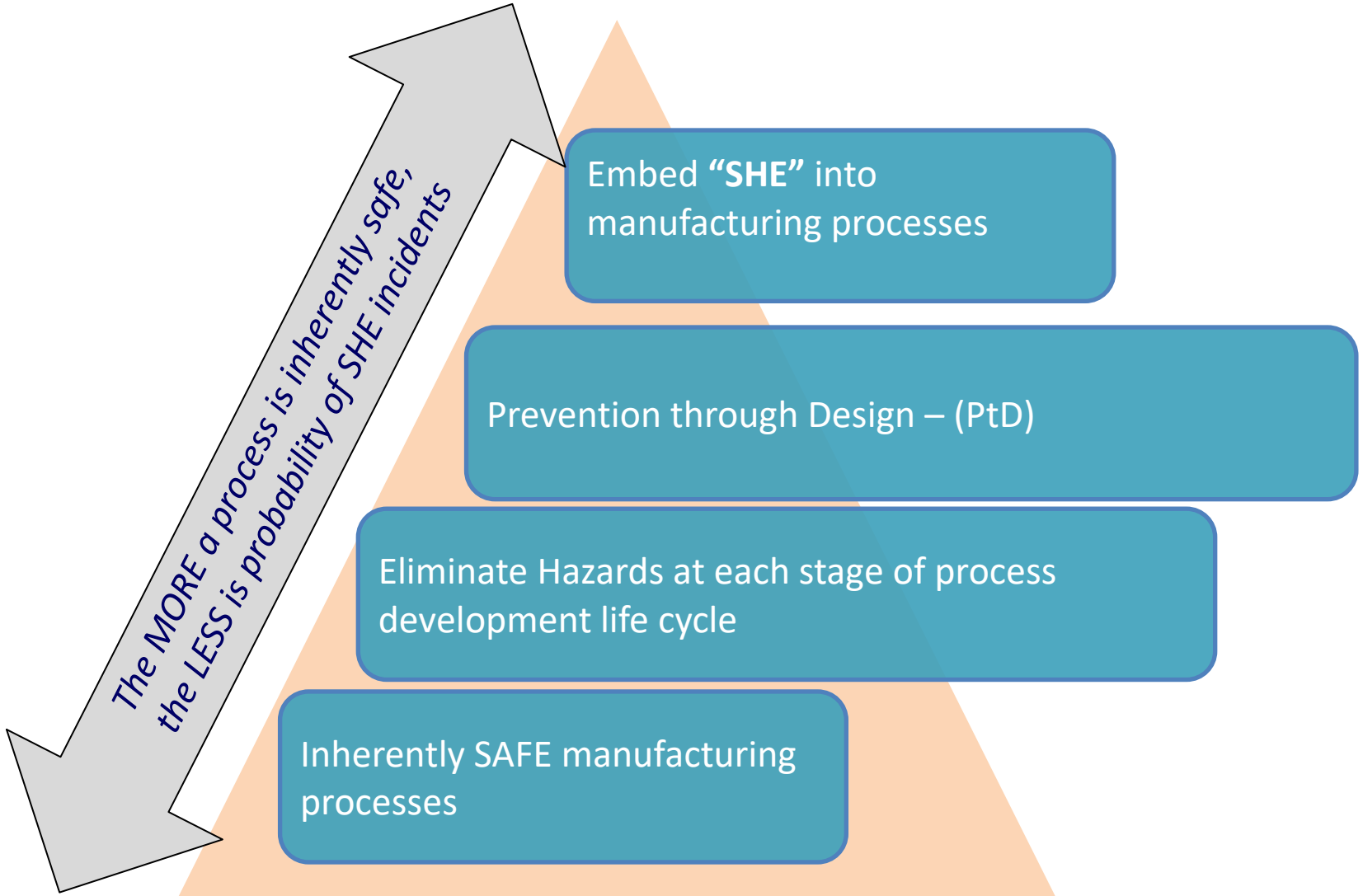
Identify **SHE impacts** arising out of manufacturing

- 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
  - 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

Differential scanning Calorimeter

Accelerating Rate Calorimeter

Thermal screening Unit

Reaction calorimeter

Data Obtained:

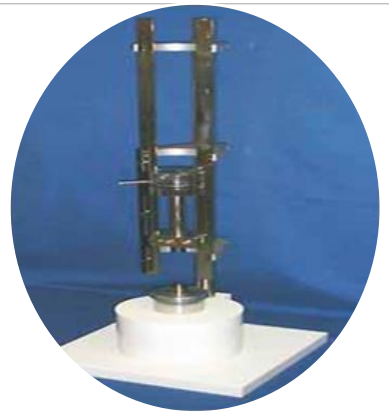
- Thermal Stability
- Amount and rate of Pressure rise
- Amount of gas evolved
- Characteristics of desired reaction
- Characteristics of decomposition reaction

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

Powder explosion testing tools

Minimum Ignition Energy & DES

Minimum Ignition Temperature

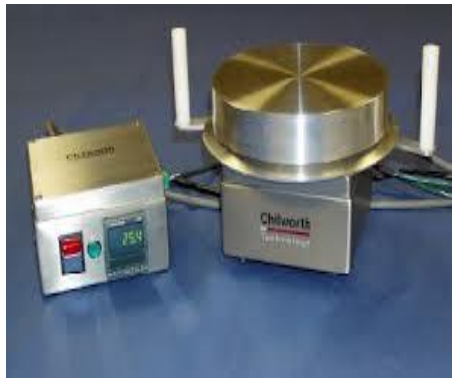


Fall Hammer

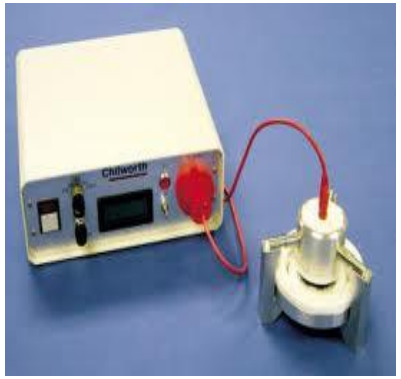
Data obtained:
Fire and Explosion characteristics of powders

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

Burning Behavior



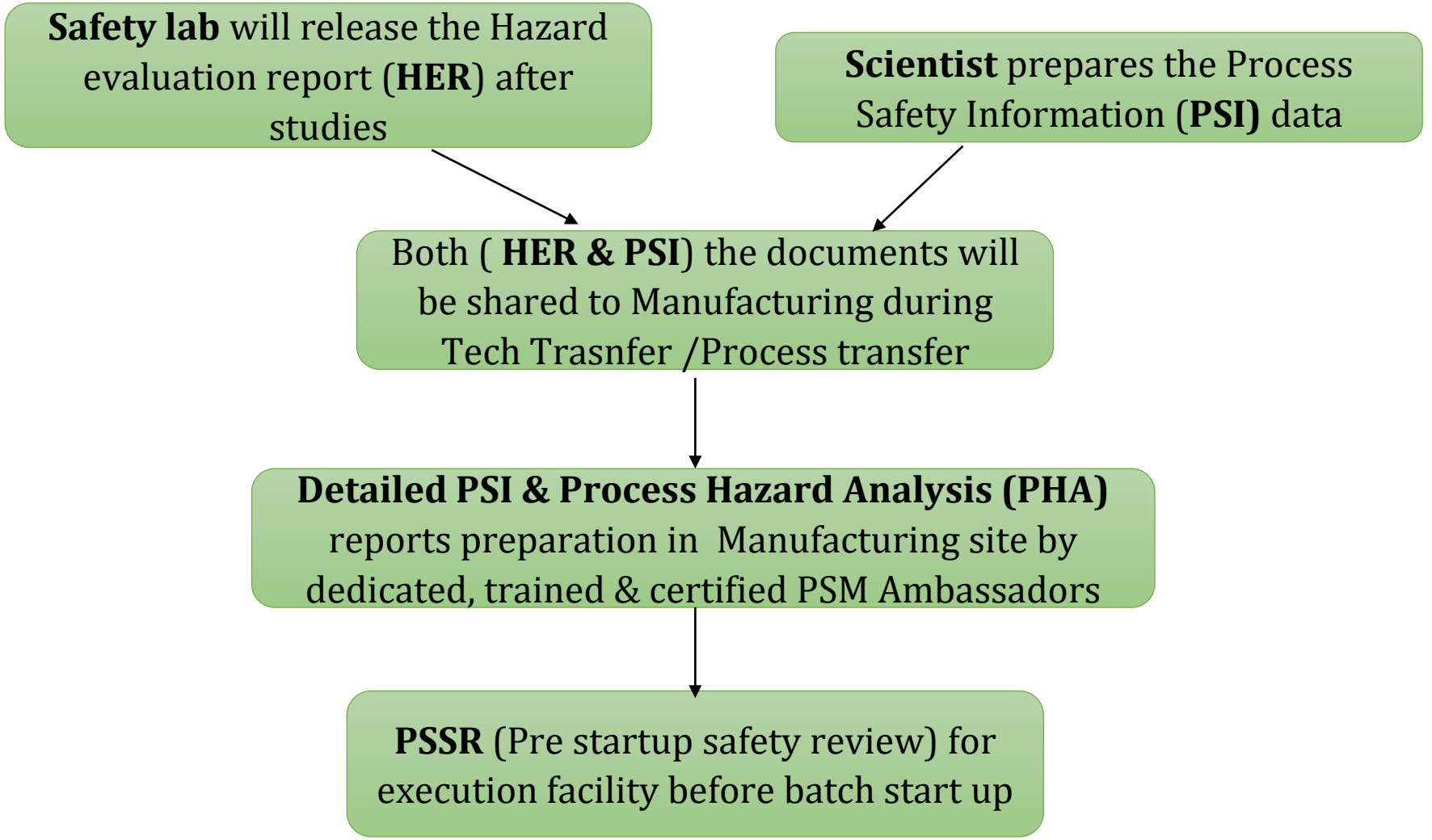
Layer Ignition temperature



Bulk Powder Resistivity

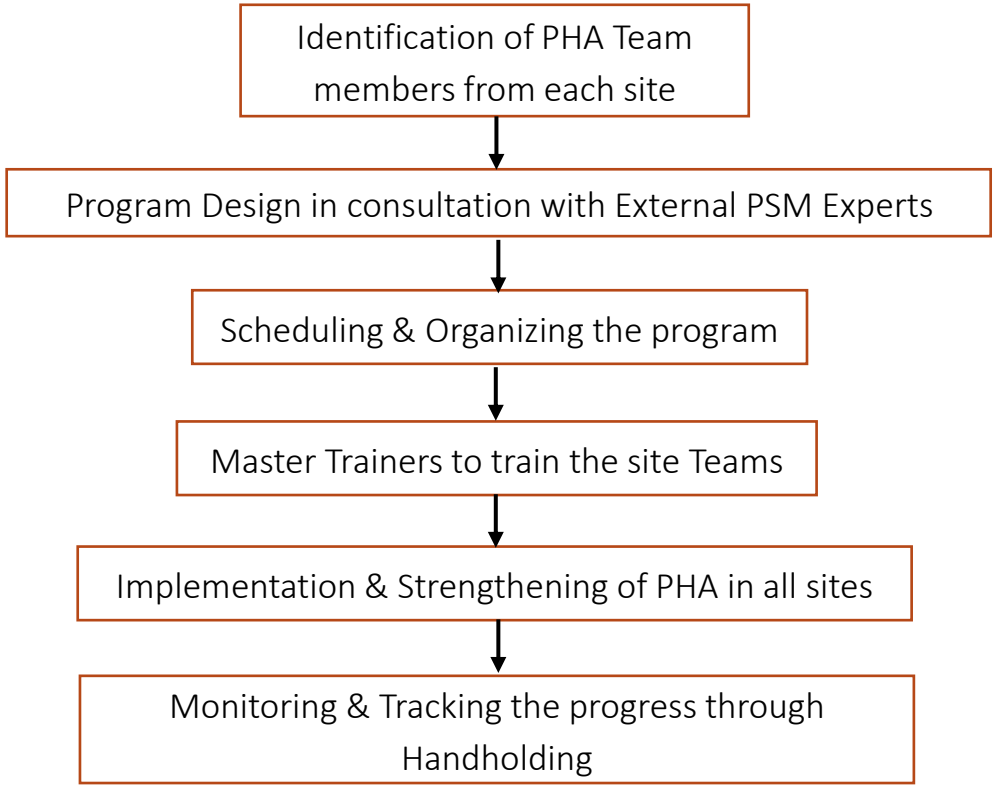
Charge decay time analyzer

Safety data flow from R&D to Manufacturing



PHA Ambassador program

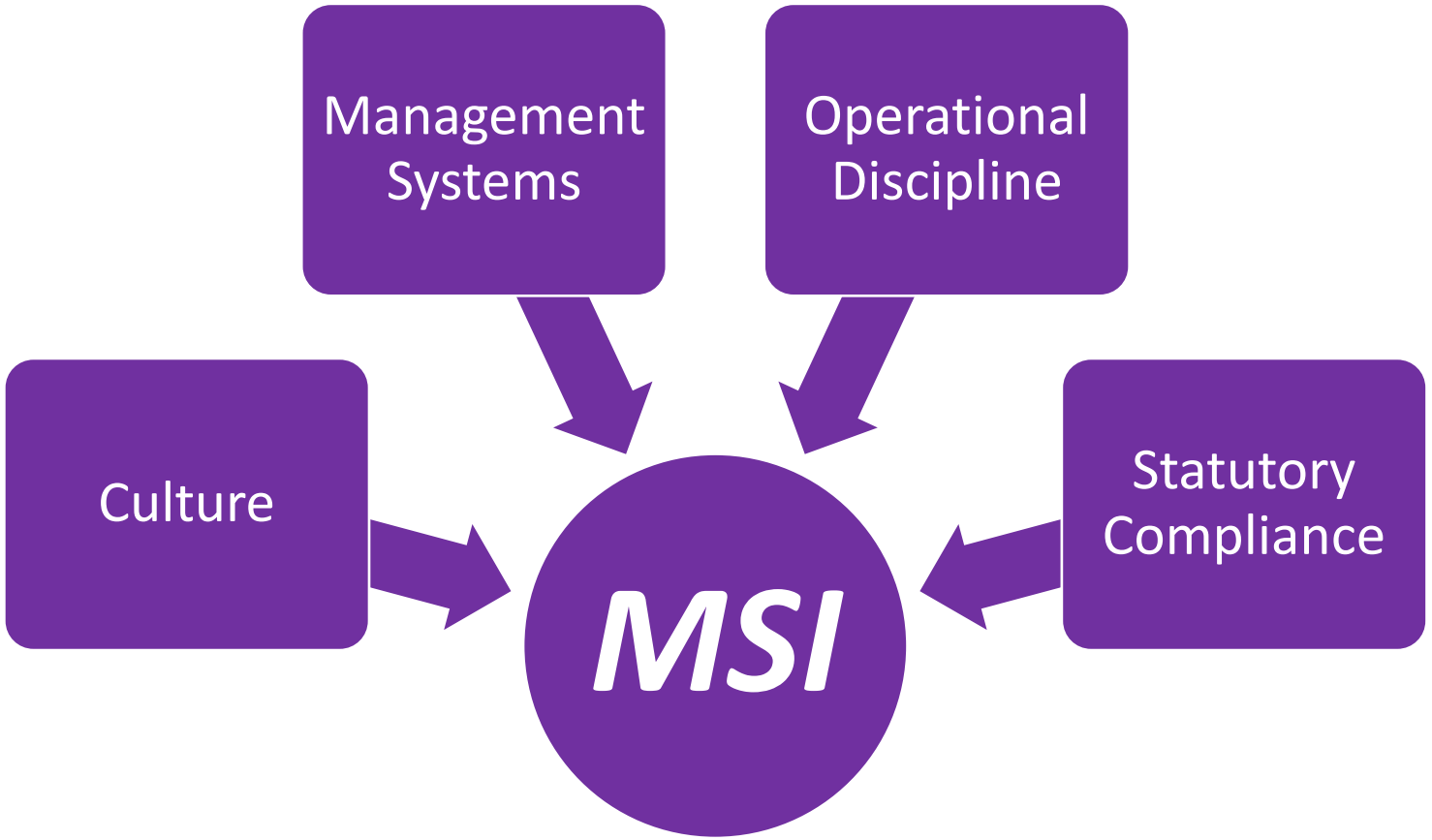
With an objective of developing in-house capabilities in a rigorous and systematic approach to identifying, evaluating, and controlling the process hazards, a team of more than 80 members were identified from all the Business Units and made them PSM ambassadors.



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

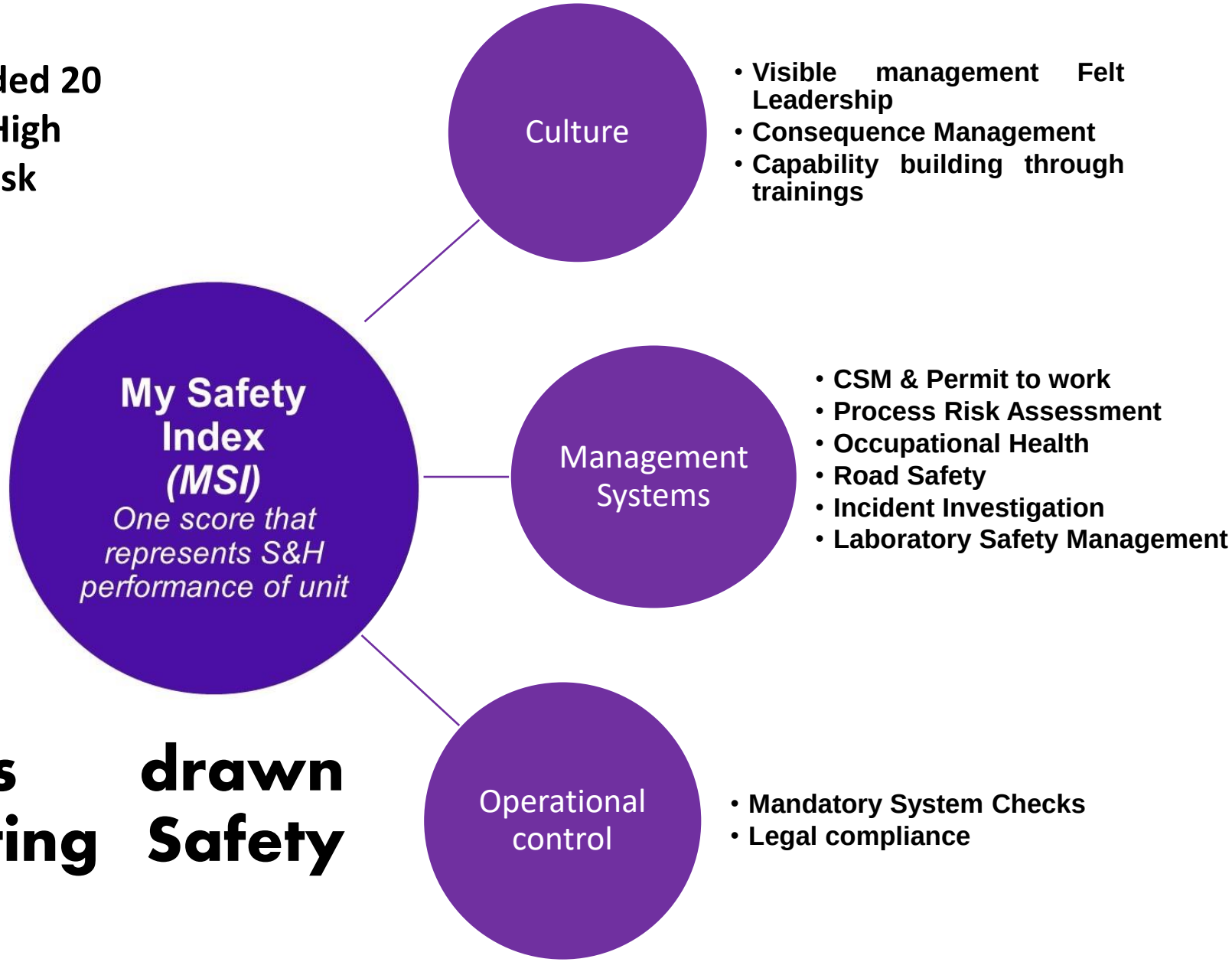
Risk Assessment Governance



- ✓ 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

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+55 (11) 94486 6315

PSCI

@PSCInitiative

WeChat

制药供应链组织PSCI

For more information about the PSCI please contact:

PSCI Secretariat
Carnstone Partners Ltd
Durham House
Durham House Street
London
WC2N 6HG

info@pscinitiative.org

+55 (11) 94486 6315

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

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