Dr. Milind Joshi
President – Global Regulatory Management I 06-04-2018

INTERNATIONAL INSPECTIONS: CONCEPTS & STRATEGIES

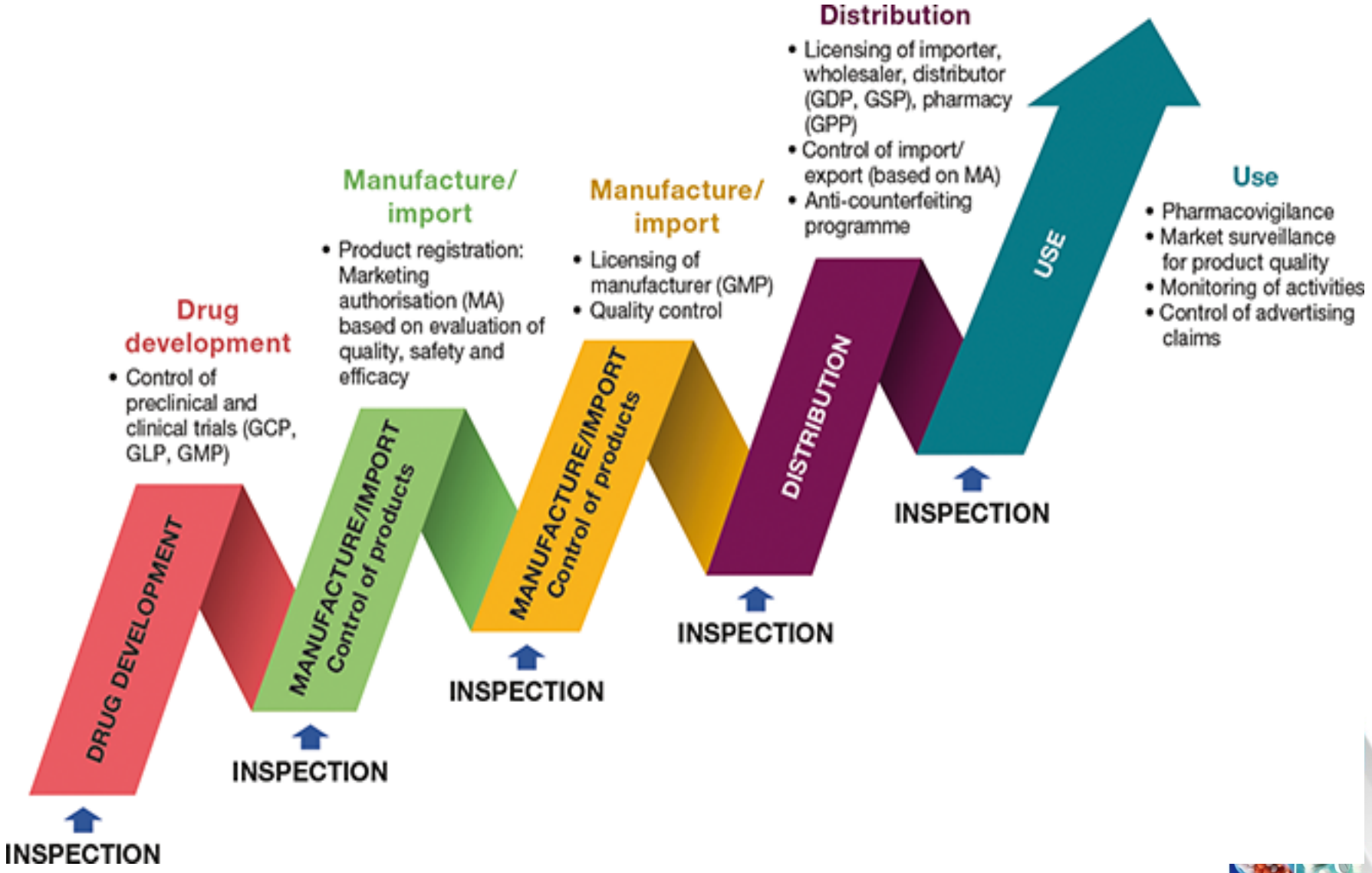
J. B. CHEMICALS & PHARMACEUTICALS LIMITED

INTERNATIONAL INSPECTIONS: CONCEPTS & STRATEGIES

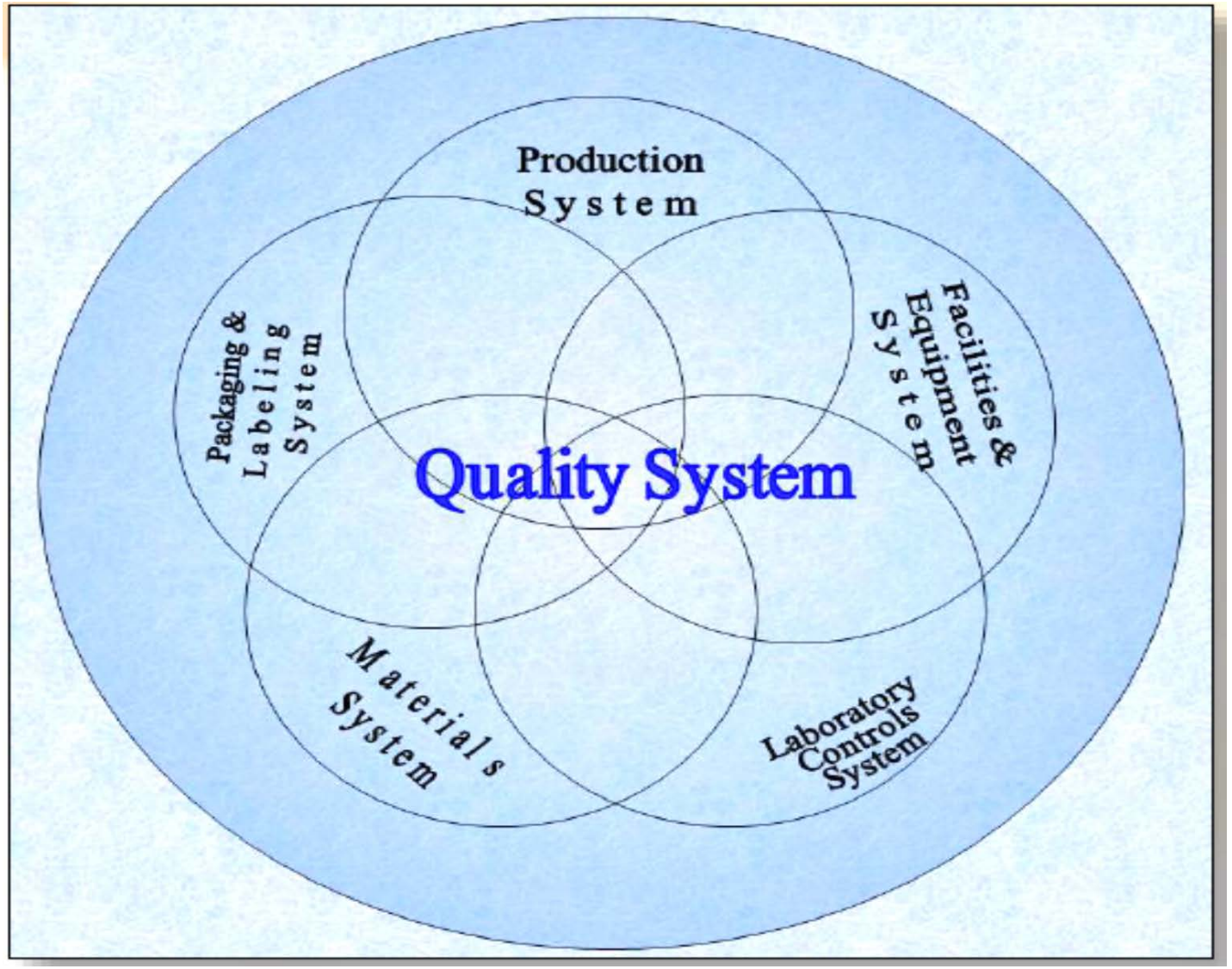
Quality is never an accident. It is always the result of intelligent effort.

John Ruskin

LEVELS OF INSPECTION IN PRODUCT LIFECYCLE



COMPONENTS OF QUALITY



INSPECTION

ENSURES:

1. Product realization achievement
2. State of control establishment and manitanence
3. Continual improvement

PROMOTES:

1. Process & product quality monitoring system
2. Change management system

EXPEDITES:

1. Other member countries approvals
2. Product filling and approval

PERSPECTIVE OF INTERNATIONAL INSPECTIONS

REGULATORY PERSPECTIVE

MANUFACTURER'S PERSPECTIVE

SERIES OF EVENTS

Trigger of Inspection

- New / First Time
- Recall
- Withdrawal
- complaint

Scheduling Visit of Inspection

- Product documentation (Batch Records, Stability)
- Other Audit / Inspection Reports
- Laboratory Documents

Observation & CAPA (Critical, Major & Minor)

- Compliance
- SOP
- Training

GMP Issuance

- Expedites Product Approval
- 3 years validity
- Submission to others member country for Approval

ROLE OF REGULATORY BODY

- To regulate drug development process and harmonization of legal procedures related to drug development.
- Licensing.
- Registration.
- Manufacturing.
- Marketing and labeling of pharmaceutical products.
- Distribution.
- Price control.
- Intellectual property protection.
- To ensure the safety, quality and efficacy of medicines and medical devices.
- Monitoring and ensuring compliance with statutory obligations.

TASK OF AN INSPECTOR

- Identify problem
- Evidence (document, observation)
- Determine scope and impact
- Investigate data, process, operations and other sources of information
- Documentation
- Grading, classification
- Correct phrasing and reference to audit criteria

AROUND THE GLOBE

REPUBLIC OF KENYA
MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA
FDA

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

Australian Government
Department of Health
Therapeutic Goods Administration

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

SAHPRA
South African Health Products Regulatory Authority

TFDA
Tanzania Food & Drugs Authority

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION & CONTROL
NAFDAC

and many more .....

ASSOCIATION OF REGULATORY BODIES

World Health Organization

asean

efpia

PIC/S

Association of 54 member country

ICH

harmonisation for better health

International Organization for Standardization

ISO

9001

INSPECTION AT UNIQUE

MANUFACTUER'S PERSPECTIVE

QUALITY ASPECTS FROM MANUFACTURER'S PERSPECTIVE

- Integrity
- Self Inspection Reports
- SOPs
- Product Recall
- Change Control
- Deviation
- OOS
- Complaint Handling
- Organization Chart
- Site Master File
- Validation Master Plan
- Job Responsibilities
- Observation and CAPA of previous Audits/Inspections

PROCESS ASPECTS FROM MANUFACTURER'S PERSPECTIVE

- Batch Documents
- Lab Records
- Trained Personnel
- Material Handling and Storage
- Packing and Labelling
- Updation of Documents (Stability, Specifications, Documents as per approved changes/variations)
- Validation Procedures
- Sterility Concerns

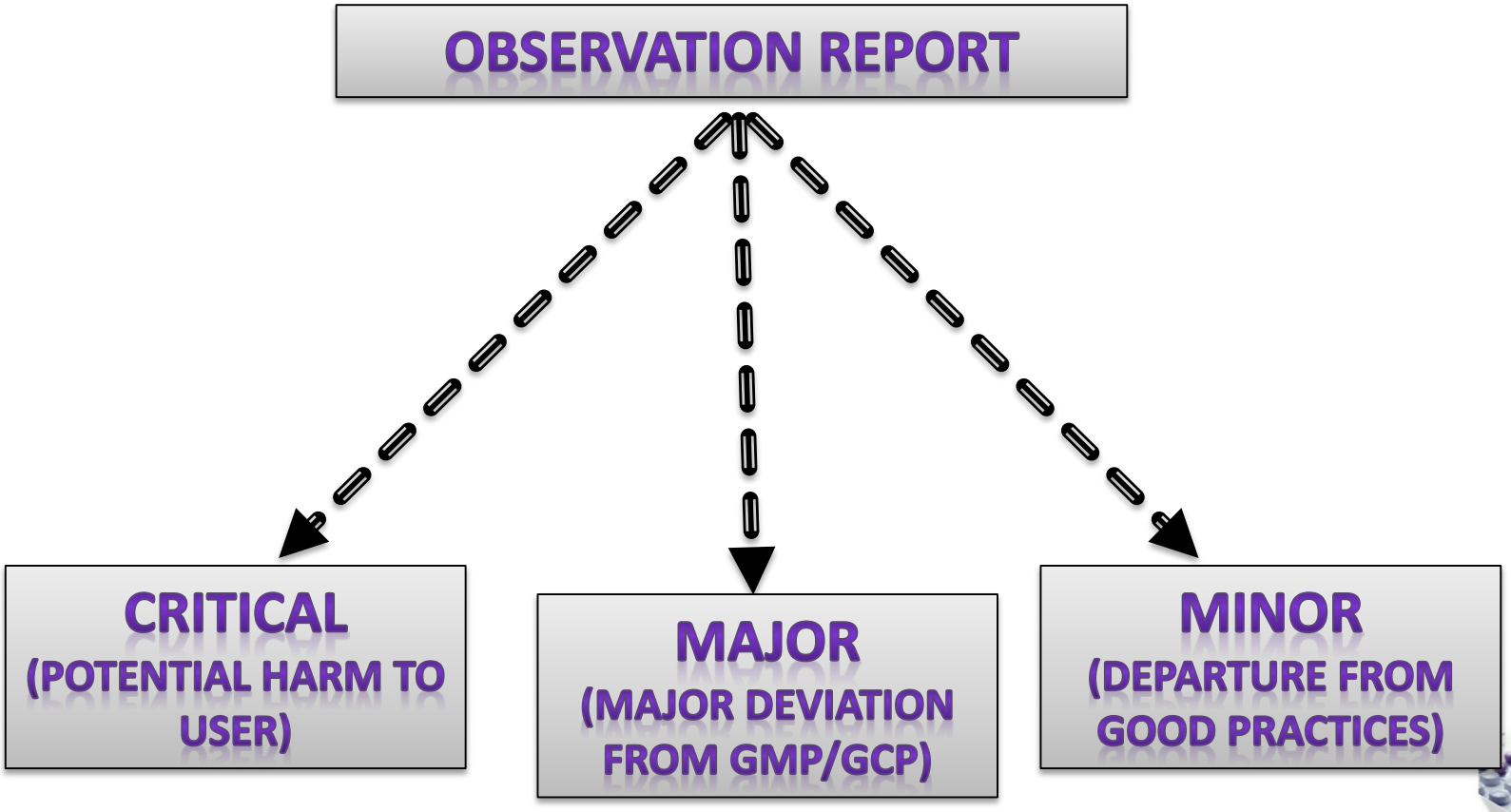
FACILITY ASPECTS FROM MANUFACTURER'S PERSPECTIVE

- R&D
- Cleanliness
- Maintenance
- Equipments (handling, qualification)
- Staff
- Design of facility

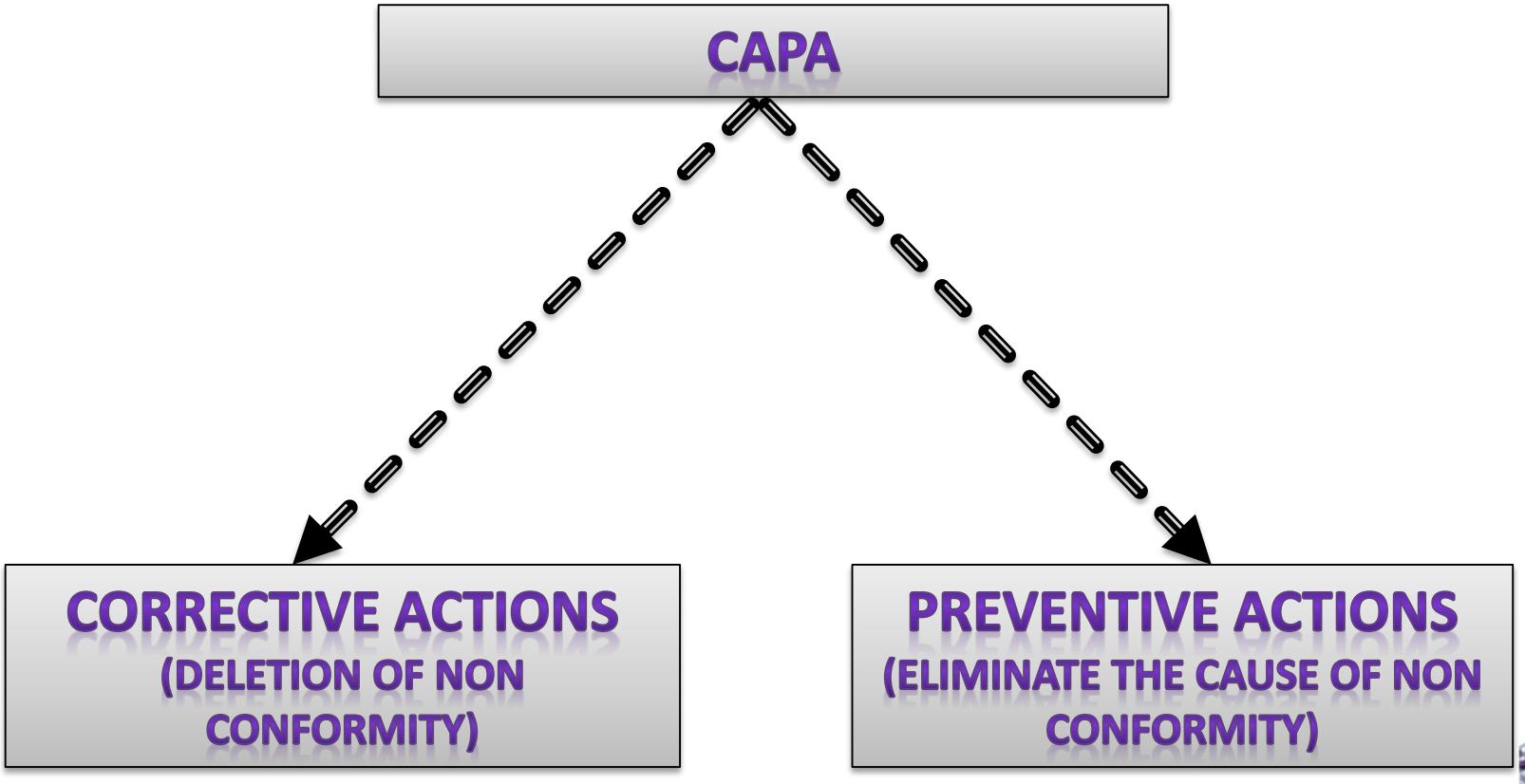
NEWER TRENDS

- CCTV
- Self inspection
- Small is beautiful
- Automation of documentation (eBRM system at Unique)
- Vendor Audits
- Pharmacopoeial vs ICH
- Desktop approvals

POST INSPECTION ACTIVITY (for Inspector)



POST INSPECTION ACTIVITY (for Manufacturer)



ROLE OF MANUFACTURER – POST INSPECTION

- Investigate the root cause
- Analyze data
- Identify the corrective or preventive action requirement
- Validate/Verify the CAPA
- Documentation
- Implementation

NON CONFORMANCES

- **FACILITY:**
  - Sterile grade,
  - Leakage,
  - Rusting,
  - Unclean areas,
  - Contamination

- **PROCESS:**
  - Improper documentation of manufacturing process or changes
  - Deviation from mentioned procedure
  - Improper labeling
  - Improper material storage and handling

- **PERSONNEL:**
  - Unawareness of process/activity
  - Improper way of working
  - Ignorance about activity performance
  - Improper equipment handling

BEING HUMAN

- **CULTURAL DIFFERENCE:**
  - Thoughts
  - Qualities
- **LANGUAGE DIFFERENCE:**
  - Rude / Harsh Replies
  - Misunderstanding
- **BODY LANGUAGE:**
  - Expression
  - Attitude

ACKNOWLEDGEMENT

- Ms. Purvaja Mankar
- Ms. Kani Nadar


Thank you !!!
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