



# **CHALLENGES IN INFLUENCING PROCESS SAFETY CULTURE IN PHARMACEUTICAL INDUSTRIES**

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# Safety Pause

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**Video of Aura Reaction Mix transfer  
Pump Seal Fire (Removed in this  
attachment)**

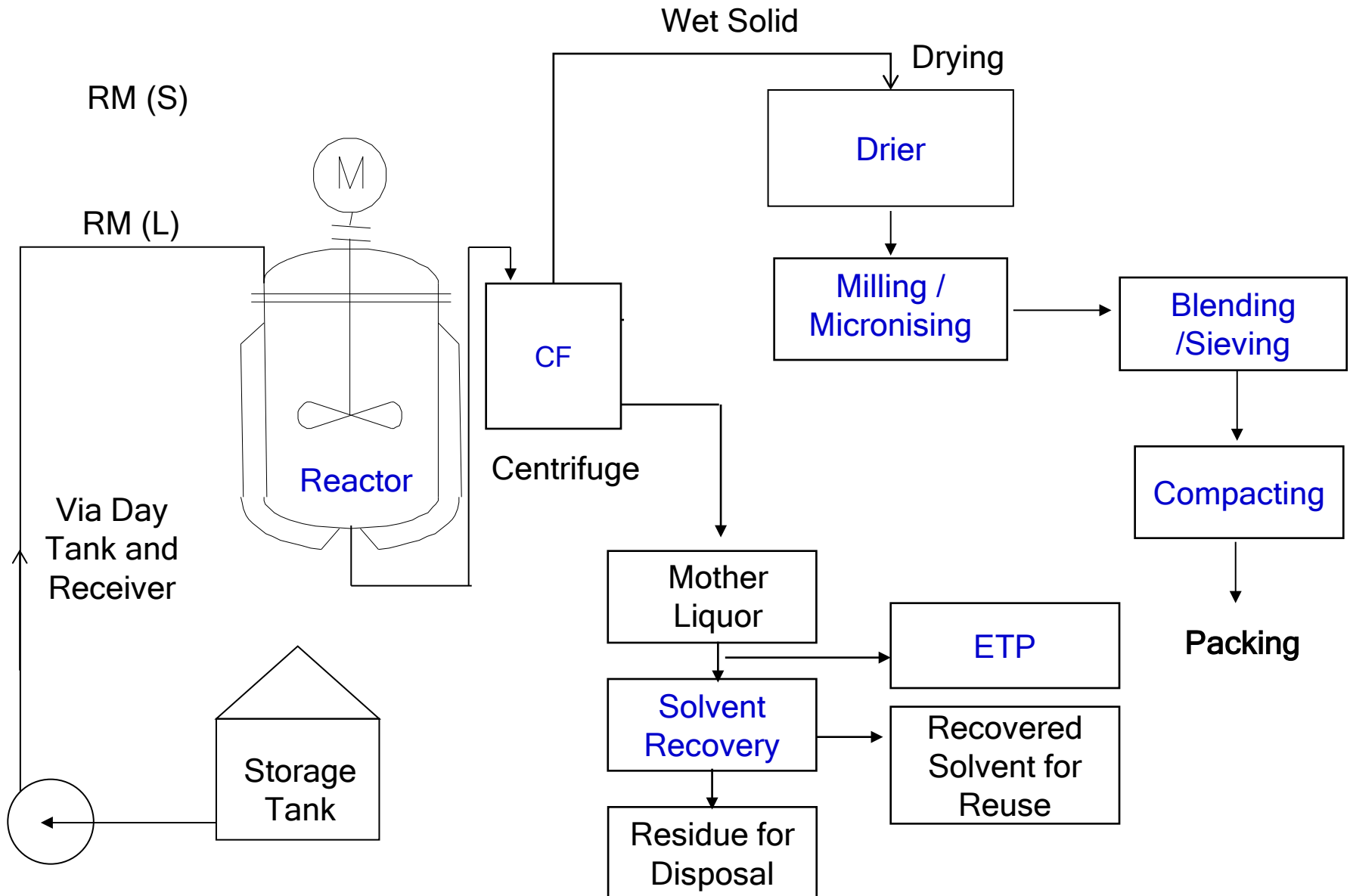
**Mechanical Integrity**

# Introduction

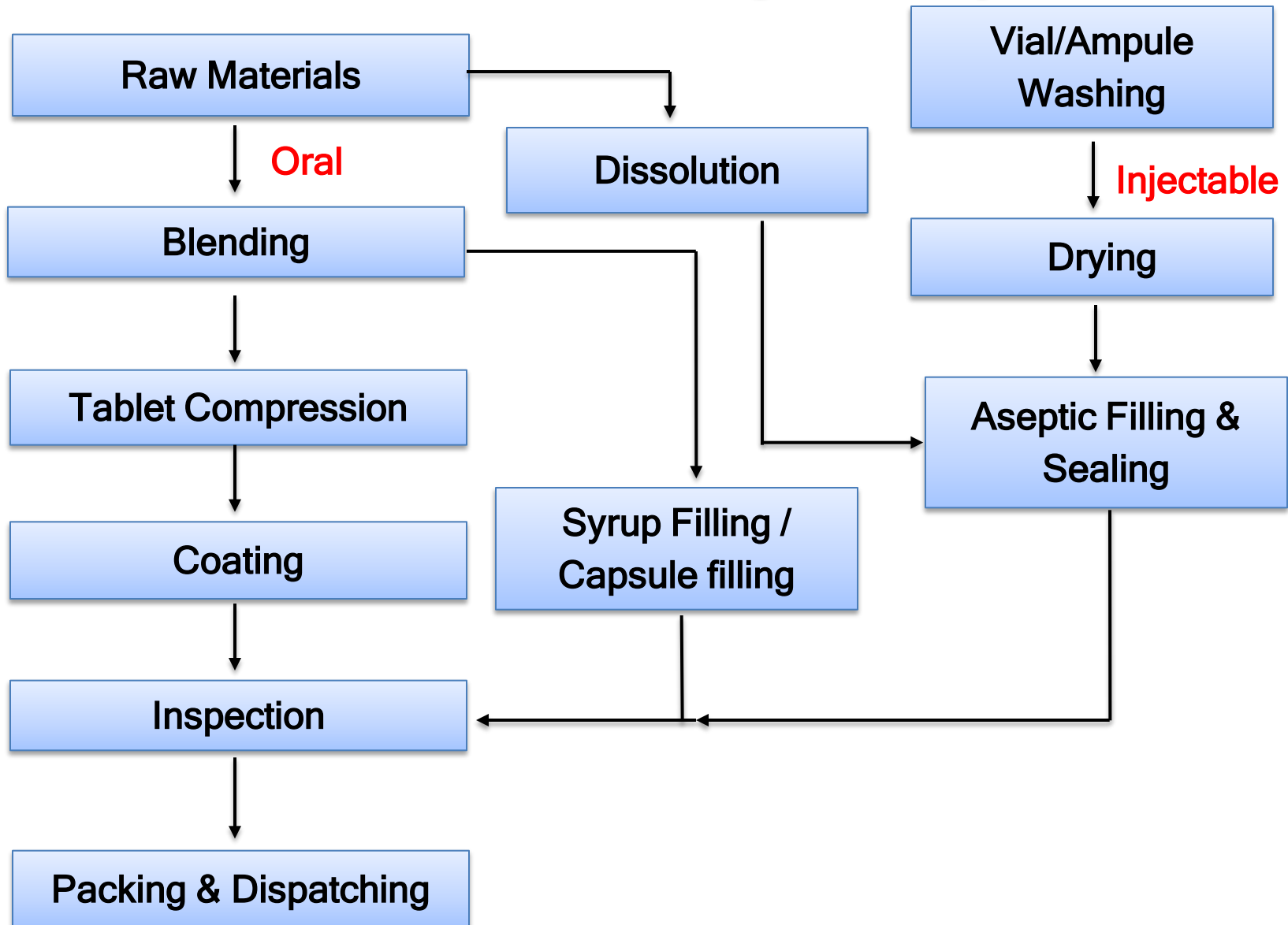
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- Indian Pharmaceutical Industry a low cost producer
- Involves Process Research, Up-scaling to Commercial Production and Formulations
- Products are Oral / Injectable
- Involves very sophisticated equipment and aseptic packaging

# Typical API Plant Configuration



# Process Flow Diagram of Formulation Manufacturing Activity



# Nature of manufacturing

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- Batch processes
- Multi Step, Multi-product
- Low/High temperature technology
- Large quantity of Solvents
- Unit Operations

**“It’s what we do  
when no one is  
watching!”**

# Safety Culture – Driving Factors

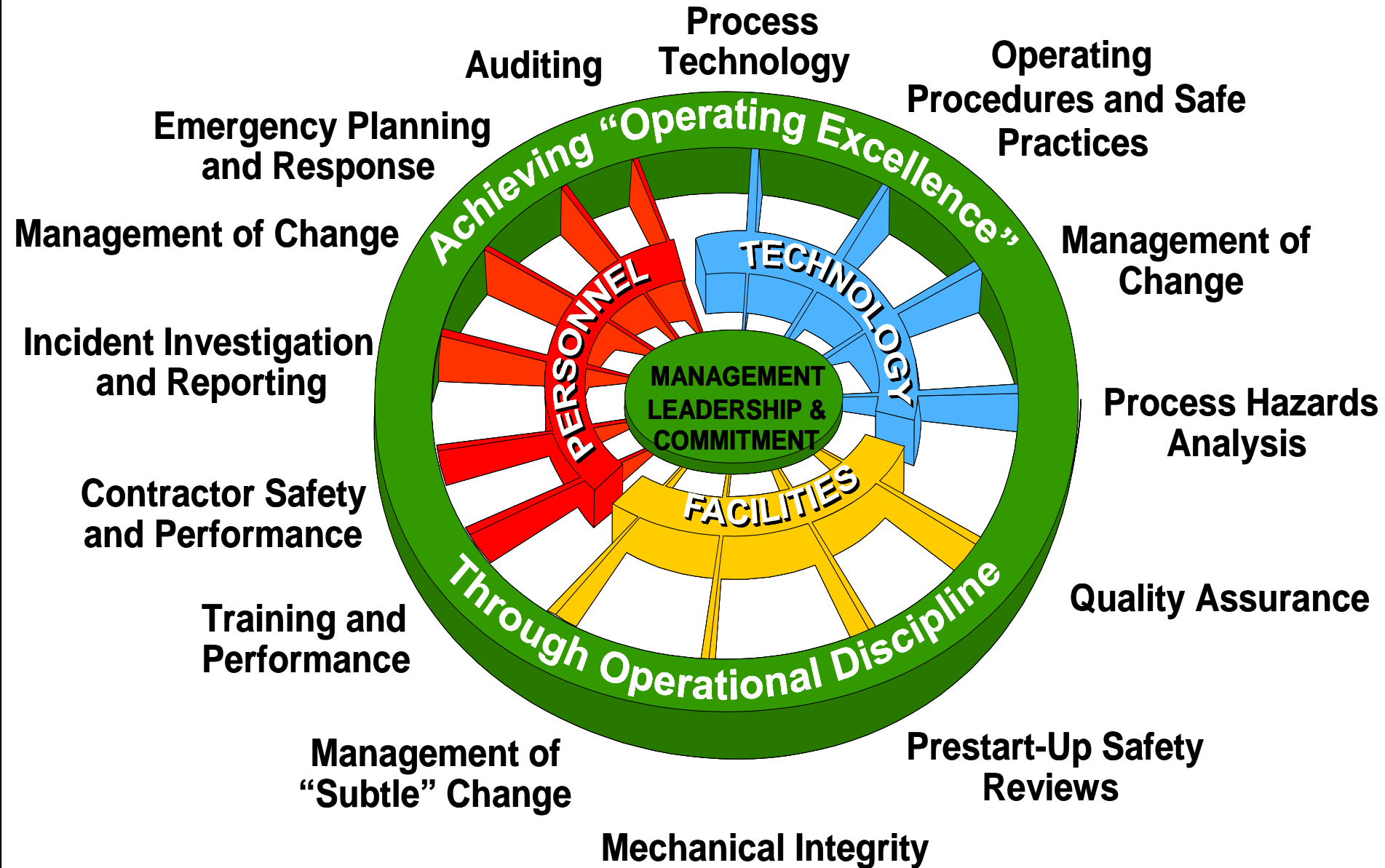
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- Demonstrating visible felt Leadership
- Line Management accountability
- Effective two way Communication
- Willingness to learn & Responsiveness to change
- Manifest attention to work place and process safety
- Intervene “at risk Behaviours” timely
- Strong Observation and Audit Programs
- Foster Mutual trust
- Empower individual to fulfill their responsibility



**PSM**

# Elements of Process Safety Management



# Challenges

# Challenges - PSM – Technology

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- Availability of Process Safety Information
  - ✓ Non availability /Inadequate PSI (PTB+Acetone video to be added)
  - ✓ Confidentiality in “Pharma Process”
  - ✓ Continuous change in Technology
- Gap in Understanding “Why aspects” in Procedures by frontline employees
- Recognition of hazards (reactive) – [deformation of plastic tray in drying oven](#) ; Spark in Steam Hose video (video to be added)
- Inadequate Risk Assessment

# Challenges - PSM – Facility

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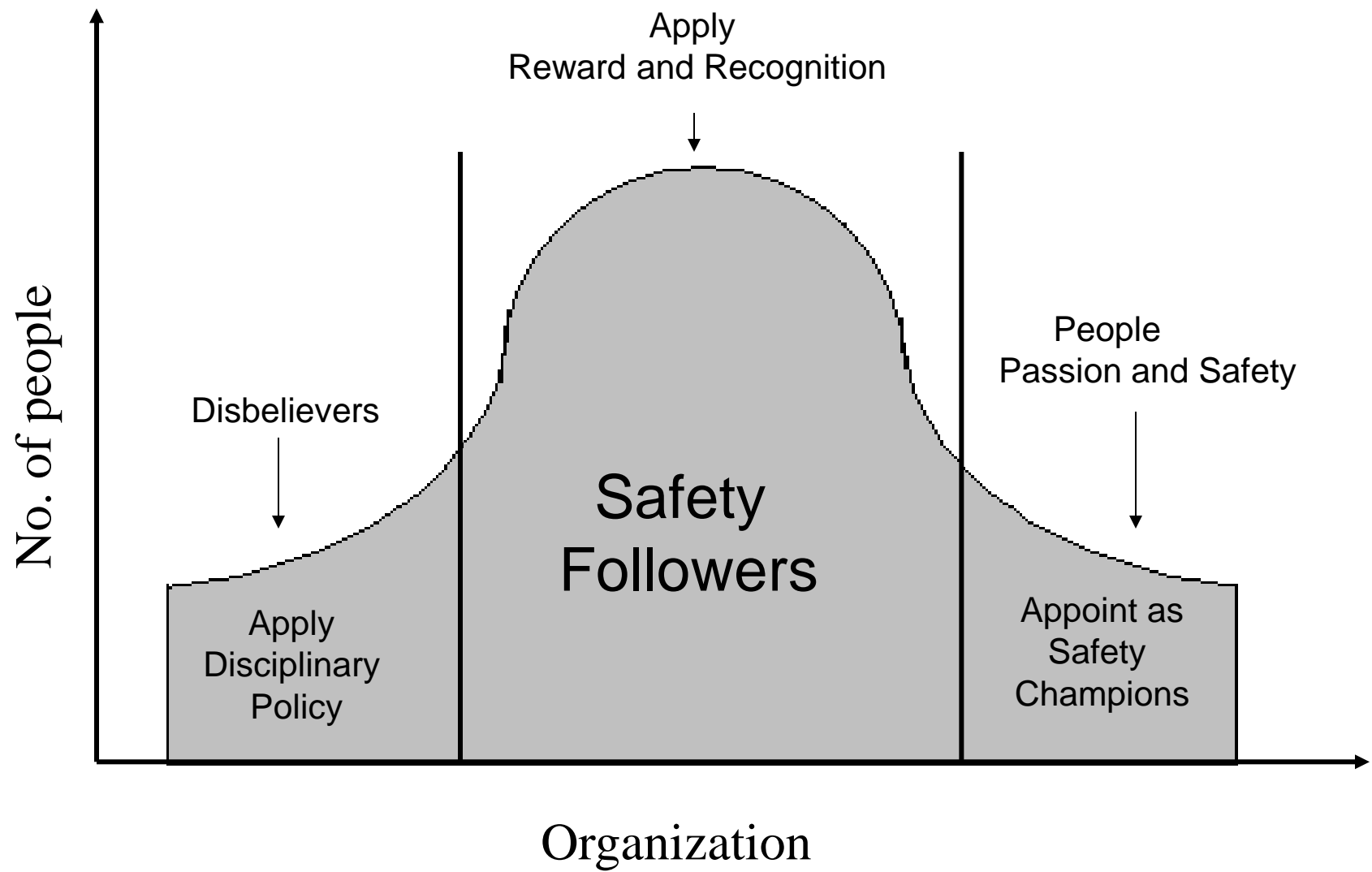
- Quality Assurance
  - ✓ Sound Systems in place
- Frequent changes in facility due to product campaign
- Mechanical Integrity
  - ✓ Compromise on Preventive maintenance
- Shortcoming in risk assessment while carrying out changes in facility / equipment spares

# Challenges - PSM – Personnel

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- Attrition rate
- Identification of training need and methodology
- Training effectiveness
- Recognition and reporting of near miss
- Thorough investigations to find the exact root causes of incident
- Sharing of Lessons learned among pharma industries from Incidents
- Equipping people during promotions / transfers
- Observation by leaders and line managers to demonstrate the care for individual

# Influencing People



Source: DuPont

# Building a Safety Culture

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# Felt Leadership - starts at the top

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Felt leadership is one of the top differentiators between a good and great safety culture.

## 10 Leadership Principles:

1. Be visible to the organization
2. Be relentless about time with people
3. Recognize your role as teacher/trainer
4. Develop your own safety functioning skills and pass them along to the organization
5. Behave and lead as you desire others to do
6. Maintain a self-safety focus
7. Confirm and reconfirm safety as the #1 value
8. Place continuous emphasis and clarity around safety expectations
9. Show a passion for ZERO injuries, illnesses, and incidents
10. Celebrate and recognize ZERO successes

# Felt Leadership

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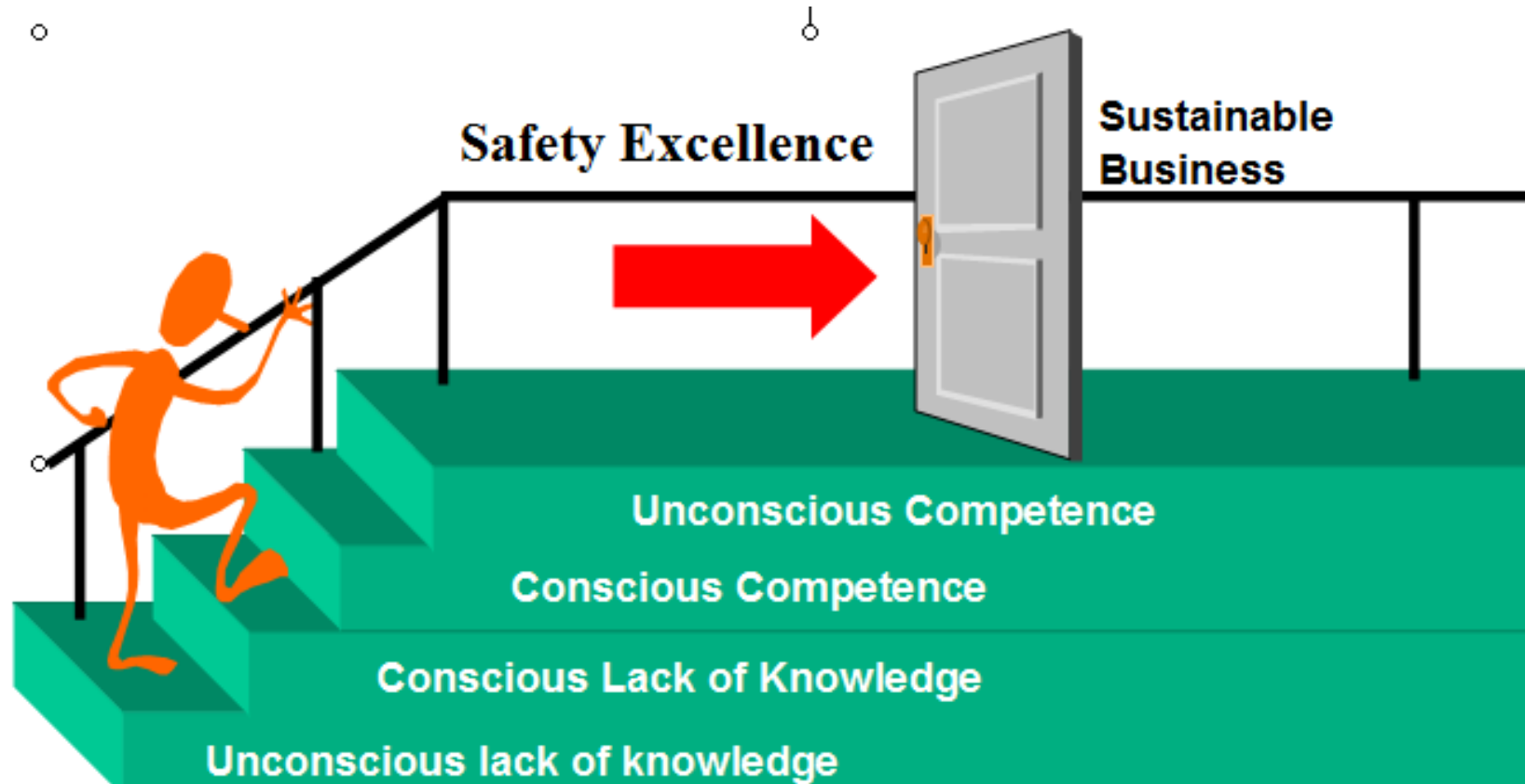
**Safety Excellence is a**

**CULTURAL  
TRANSFORMATION**

**that requires**

***Felt Leadership***

# Safety Excellence --> Cultural Excellence



Thank you



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