



Maintaining Process Safety Culture in Challenging Times



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Introduction...Orchid Pharma

- An integrated Pharma company established in 1992
- Specialized in the area of advanced antibiotics in Oral as well as Sterile form
- Systems and Infrastructure to enable high standards of Quality and Environmental Mgmt.
- International Certifications in Quality, Environment and Safety Mgmt
- Recognized in industry for high standards

Introduction - Safety in Pharma Industry

Pharma Industry

- Active Pharmaceutical Ingredients
- Formulations

Operational Hazards

Active Pharmaceutical Ingredients

- Hazardous Chemicals
- Hazardous Reactions
- Large quantity of Solvents
- Explosible Powders
- Batch Processes – every Batch is a ‘new birth’
- Multi-product Manufacturing Plants with inherent Management of Change challenges

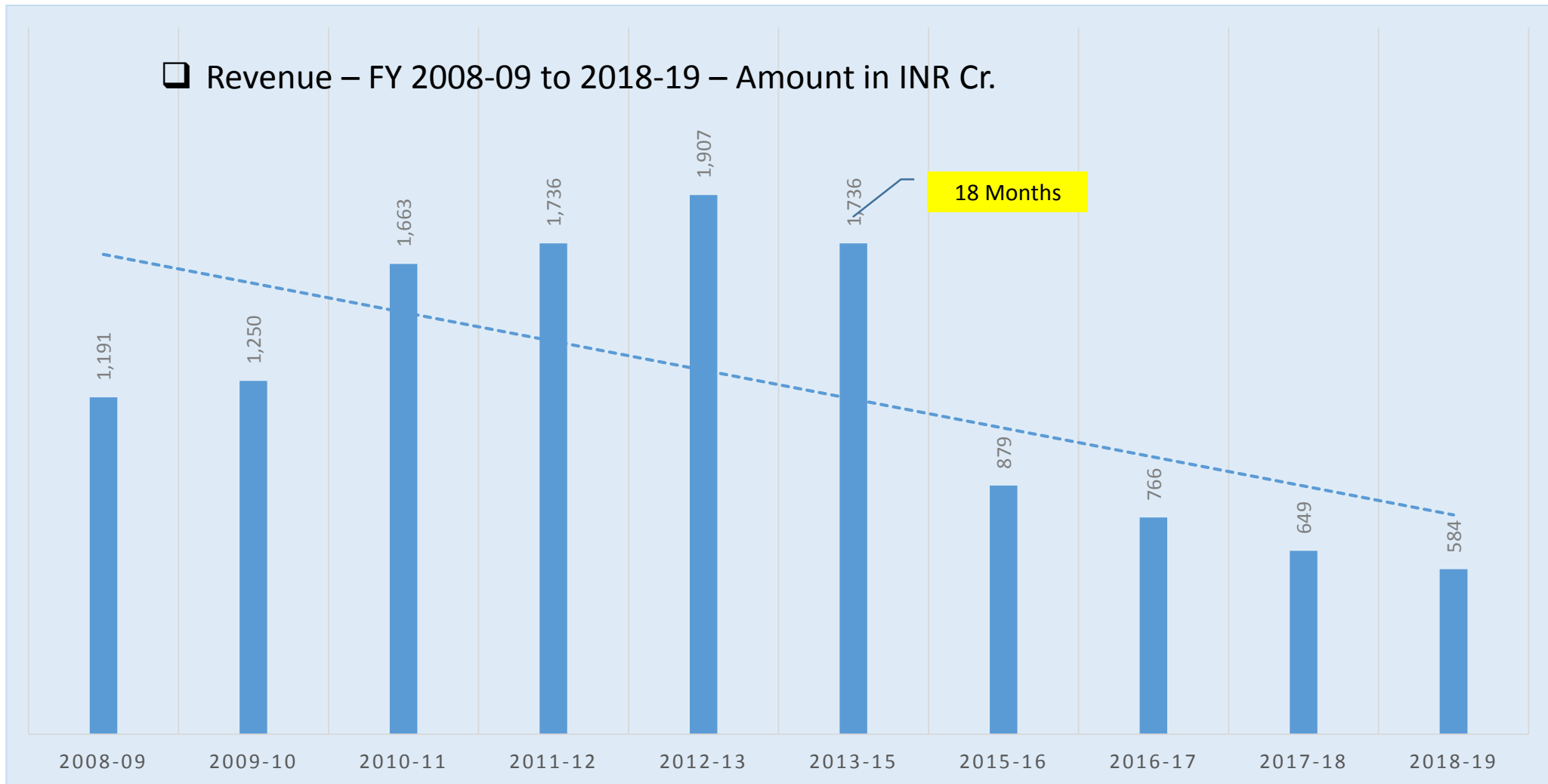
Complexity of API Operations – a representative Snapshot

Apr 2017 – Mar 2019

- No. of Products & Intermediates produced : 170
- No. of Hazardous Processes handled : 382
- No. of Batches produced : 29,003
- No. of Critical Eqpt & Accessories : 4073
- No. of Maintenance Work Orders attended : 71,202

API Business is a complex mix of Hazardous Chemistry and Frequent Change, but delivering World Class Quality

Challenging Times ... Economic slide starting in 2012



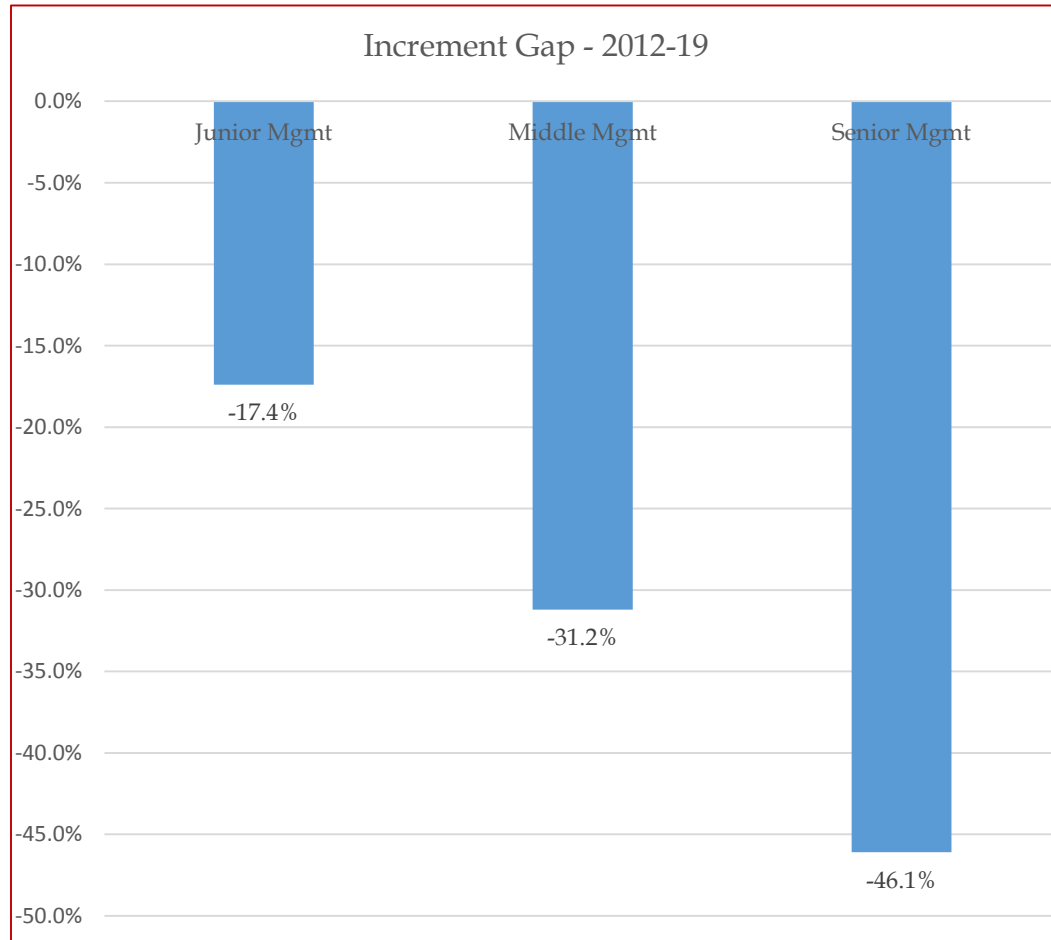
**The next 15 minutes are not about economics
but about how Leadership behaviour helped the Organization
maintain PSM Culture even when faced with adversity**

Effect of Economic downturn on Organization

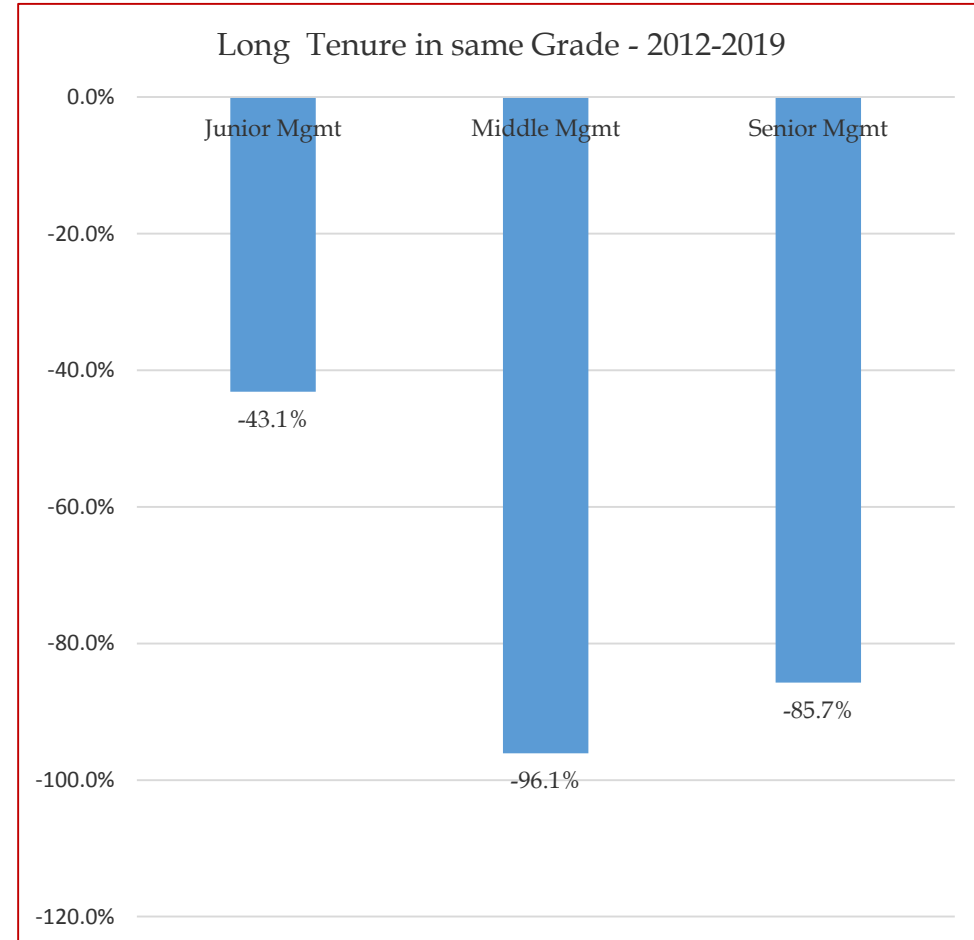
- People – Attrition due to emoluments and growth falling far behind Industry
- Assets – Integrity threatened by ageing, corrosion, fund-constraints
- **Budgets drastically reduced, resource availability unpredictable**

Effect on People

Emoluments falling behind by 17.4% to 46.1%

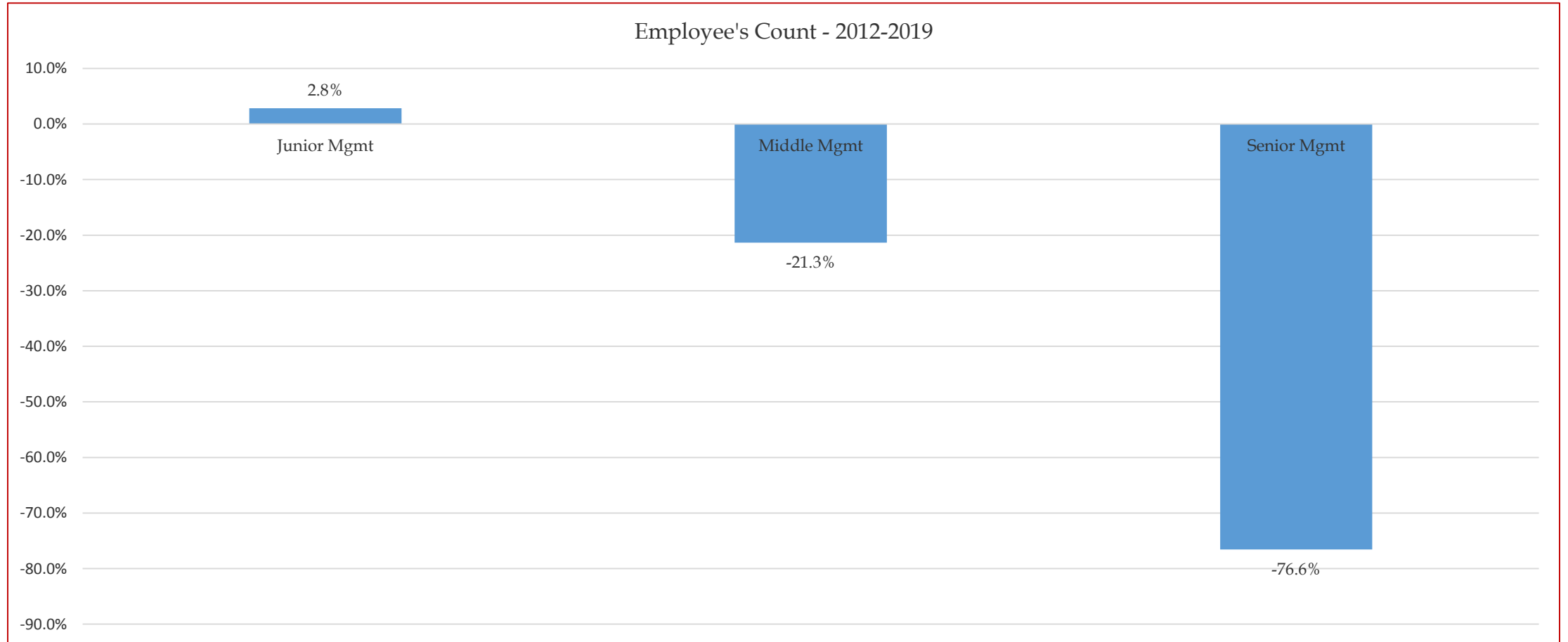


Stagnation in personal growth for 43.1% to 96.1%



Effect on People

Consequent Attrition - 21.3% to 76.6%



Effect on Assets

Structure



Ammonia Receiver



Effect on Assets

Effluent Aeration Tank



Crack in wall



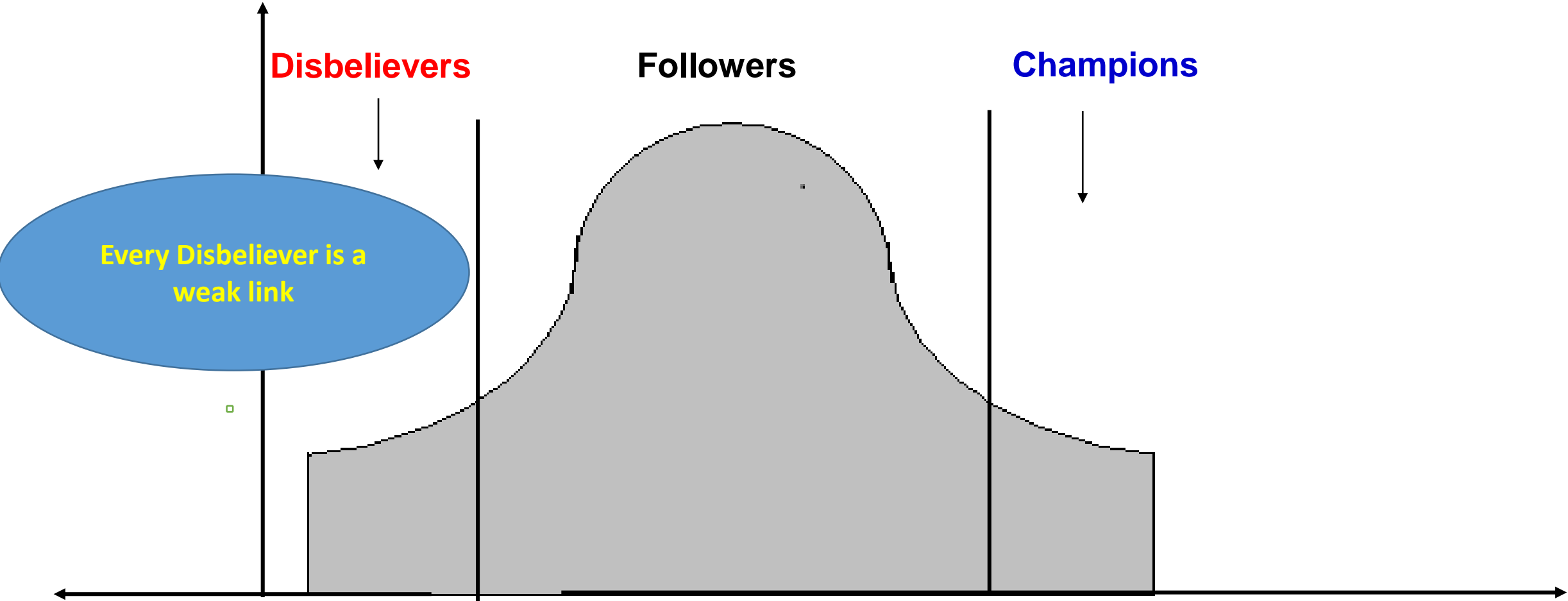
Process Safety Culture started getting eroded...

“I’m not valued here anymore”

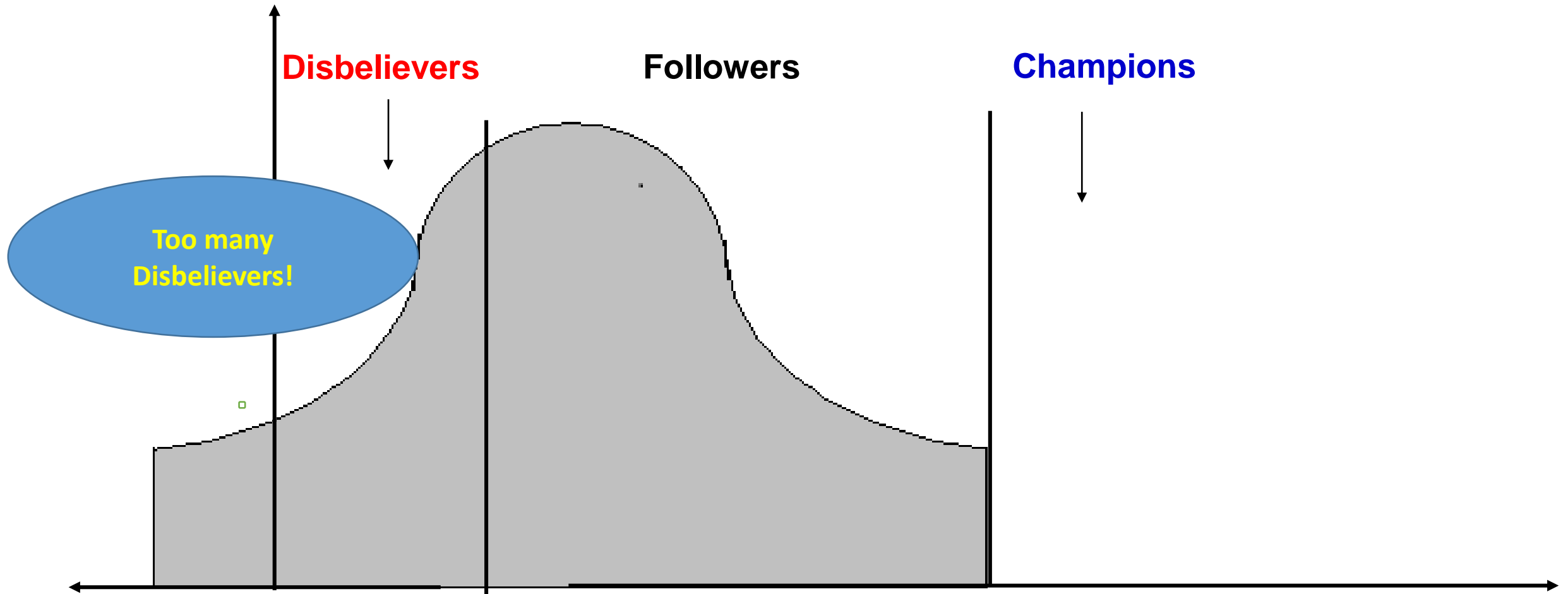
When the People fabric is seen to be developing large attrition holes, and when Plants are seen to be getting weaker by the day, Anxiety creeps in, and Motivation drops.

“What’s the point in doing what I have been quietly and sincerely doing?”

People in the normal Organization



People in the *de-motivated* Organization...Curve moves left



Less Leaders....No Champions...Too many Disbelievers

Complexity remained, Attrition, Mechanical Integrity weakened

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- No. of Maintenance Work Orders attended : 71,202
- No. of Incidents reported : 156

But...Lost Time Injuries : NIL

How did we respond to the Challenging Times?

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Inclusion and Engagement

With this, employees saw **Purpose** and got back **Sense of Value**

How did we respond to the Challenging Times?

Three decisions taken:

1. Sustained Succession of Leadership
2. Risk-based Decision-making
3. Leadership Focus on three aspects :

Culture + **Conduct of Operations** + **Review**

1. Sustained Succession of Leadership

- Transparent process to identify juniors from existing pool
- Communication to all for acceptance
- Mentoring and Coaching of Newcomers
- No Leadership Vacuum at any level

Intentional Competency Development

2. Risk-based Decision-making

- All levels of Line Mgmt encouraged to assess Risk
- Haz Chemicals, Haz Proceses, Critical Eqpt - key aspects
- Collectively agreed A-B-C Priorities based on Risk Assessment
- Empowerment to escalate concerns and seek external expertise

Disciplined Adherence to Standards

Inclusion and Engagement across all levels of employees

Risk-based Decision-making

Highest Risk

Immediate action taken



Risk mitigated temporarily

Phased action taken



Disciplined Adherence to Standards

Risk-based Decision-making

- Appeared to be at highest risk
- Reconstruction would have meant extremely high cost and several months of business stoppage
- **Sought advice from world-class Civil Engg Institute for addressing the situation**



Effluent Aeration Tank



Crack in wall

Risk-based Decision-making

With a combination of Non-Destructive Testing to assess health of concrete, localised repair, and fixing of Glass Strips across cracks for monitoring....the Tank has been in operation for two years

Deferred Action based on Risk Mitigation measures



Disciplined Adherence to Standards

3. Leadership Focus - Three Aspects

1. Culture
2. Conduct of Operations
3. Review

Vibrant Management Systems

3.1 Culture

- Process Safety Culture **not** in-born
- It develops through **Learning**
- Learning comes from **Experience**
- Learning comes from insight triggered by a **Sense of Vulnerability**

Continual Enhanced Application and Sharing of Lessons Learned

**This started years ago in 2005, triggered by a tragic incident ...
This has proved useful in these challenging times several years later**

Triggering Incident

Nov 3, 2005.....2040 Hrs



- This event started the process of **Investigating to Learn**
- It showed the need for **Sense of Vulnerability**
- **Community Inclusion & Engagement** enabled addressal of stakeholder fears

It was considered to be the best-designed Plant at that time.

Why did it happen...?

3.1 Culture

- Visible, Felt Leadership communicated about current realities on Weekly basis – “I am with you”
- Safety Observations & Audits - 22, 811 safety conversations during 2017-19
- Inclusion and Engagement of employees through Safety Action Meetings (SAMs)
- Constant connect and essential support to local community to avoid anxieties

Vibrant Management Systems

Committed Culture

3.2 Conduct of Operations

- Operating personnel empowered to optimally use resources
- Line Mgmt guided when faced with competing priorities
- Criticalities escalated to make resources available for Operations
- Training driven by In-house Middle and Senior Mgmt - 21,000 Man-hours

**Continual Inclusion and Engagement
for
Intentional Competency Development**

3.3 Review

- **Monthly Central Safety Committee Mtg** (Corporate Apex Body) to review progress and setbacks
- **Monthly Site Safety Committee Mtg** (Site Apex Body)
- **Daily Safety Report** tracked for Leading and Lagging Indicators
- **Monthly Operations Review Mtg** to review progress and setbacks.

Vibrant Management Systems

Summary

When resources became scarce and leadership and management competencies got eroded, the Organization's existing Leadership followed the following Principles to maintain Process Safety Culture :

- Vibrant Management Systems
- Committed Culture
- Intentional Competency Development
- Communication
- Inclusion and Engagement across all levels
- Learning from Experience and Sense of Vulnerability

“ We Included, Engaged and Empowered people...and found Champions!”

Evidence, and satisfaction that this approach is working...

September 26, 2019

Mr Narayanan, Frontline employee demonstrating the Model he has made to explain the Swiss Cheese Model



Dr Sarangdhar
Site Head

Mr
Gopinathan -
Narayanan's
Manager

These three, and others, are the Champions who maintain Process Safety Culture

“ We Included, Engaged and Empowered people...and found Champions!”

“Everyone can!”

Thank you