



# Quality First

Building Quality Culture and Capabilities:  
Experience Sharing by Lupin

**Johnny Mikell, President – Global Quality & Compliance**

**5<sup>th</sup> Indian Pharmaceutical Forum  
February, 2020**

# Objective of today's engagement

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**What is a Quality Culture?**

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**Lupin's Road Map & Governance Structure**

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**Quality Culture – How do we measure & sustain it?**

6

**Questions & Answers**

# Lupin at a Glance



## Lupin Today

Leadership in Global Generics with a Diversified Geographical Footprint

### Key Metrics

Market Cap <sup>(3)</sup>	US \$ 4.8 bn
Revenue (FY19)	US \$ 2.3 bn
EBITDA (FY19)	US \$ 468 mn

### Globally

8<sup>th</sup>

Largest Generic Company  
*(by sales<sup>1</sup>)*

3<sup>rd</sup>

Largest Indian Pharma  
*(by global sales<sup>1</sup>)*

### Other Key Markets

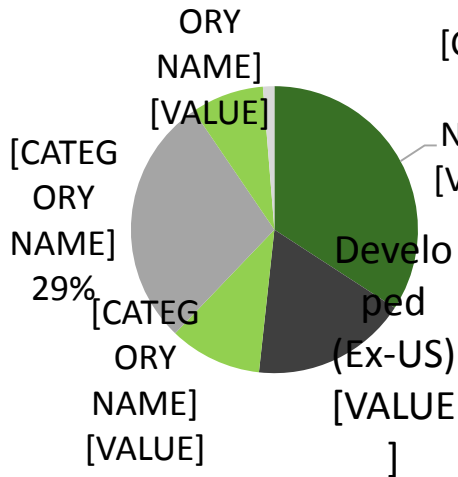
3<sup>rd</sup>

Largest South Africa Generics<sup>4</sup>

5<sup>th</sup>

Largest Philippines Generics<sup>4</sup>

### FY19 Revenues Split



### Major Markets

3<sup>rd</sup>

Largest in the US  
*(by prescriptions<sup>2</sup>)*

6<sup>th</sup>

India Pharma Market Rank<sup>2</sup>

4<sup>th</sup>

Largest Australia Generics<sup>4</sup>

Leading global supplier of treatment for tuberculosis

Major supplier of antibiotics and treatment for HIV

1. LTM sales available as of 30<sup>th</sup> Sep 2019

2. IQVIA MAT Sep-19 for respective markets

3. . IQVIA MAT Aug-19

4. 4. As of 8<sup>th</sup> Jan 2020

- Lupin Today: By the Numbers

20,000

Employees Globally

15%

CAGR\* in  
5 Years till FY18

9%

Spend on R&D  
(as % of Sales)

\$2.5 bn

Global Revenue

15

Manufacturing  
Sites Globally

Market Leader in Cardiovascular, Diabetology, Asthma, CNS and Anti-Infectives in addition to holding leadership position in the Anti-TB and Cephalosporins space

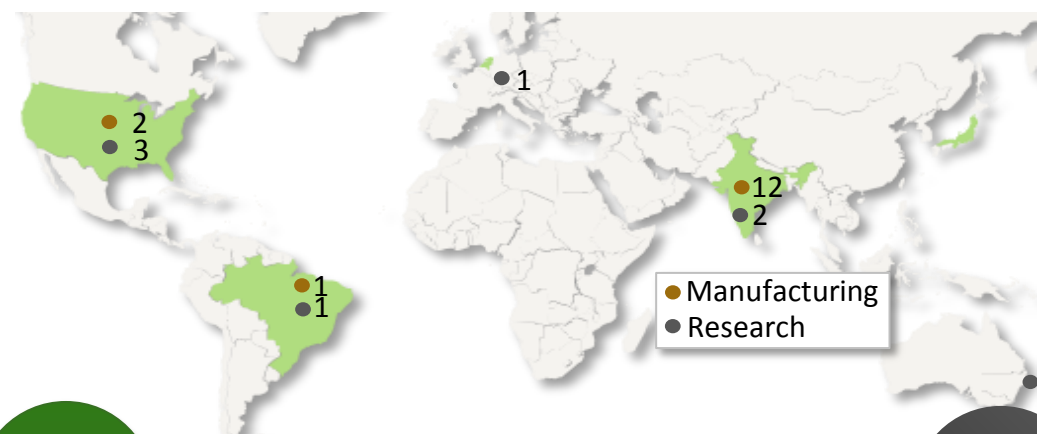
Emerging Specialty play in US, Europe and Japan

# Lupin at a Glance



## Manufacturing and R&D: Diverse Global Network

Global Commercial Presence		
<b>&gt;100</b>	<b>&gt;25</b>	<b>15</b>
Countries where products are sold	Countries with marketing offices	Countries with subsidiaries



● Manufacturing  
● Research

- 12 USFDA inspected sites
- 30 bn+ extended unit capacity

**15**  
Mfg. sites

**7**  
R&D sites

- 424 US ANDAs; 272 approved
- 40 pending US First to Files
- 207 US DMFs Filed

# Lupin's Quality Journey- We get it!!!



## Our Commitment to a Culture of Quality



“We are kicking off this global quality transformation program with the objective of enhancing our quality systems and processes to re-establish ourselves as the torchbearer for quality ... We want quality to be a way of life at Lupin.”

— Vinita Gupta, CEO

“Our credentials, our capabilities and you, our people, give us the confidence that we have the ability to re-establish our record of compliance and emerge as a benchmark for the industry in quality manufacturing.”

— Nilesh D. Gupta, Managing Director



*We will stay the course...*

# Lupin's Quality Journey- We get it!!!



Company values and principles – that which defines us!



## Integrity

- Ethical
- Truthful
- Transparent
- Confidentiality
- Honest
- Trustworthy



## Passion for Excellence

- Innovation
- Improvement
- Quality
- Perseverance
- Benchmarks
- Stretch

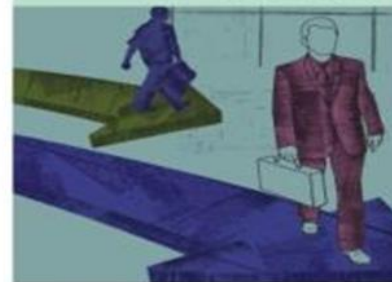
## Teamwork

- Consensus
- Coordination
- Support
- Collaboration
- Recognition
- Encouragement



## Entrepreneurial Spirit

- Ownership
- Risk-taking
- Conviction
- Empowerment
- Analysis
- Innovation



## Respect and Care


- Compassion
- Sensitivity
- Fairness
- Equality
- Dignity
- Harmony



## Customer Focus


- Delivery
- Responsiveness
- Investment
- Professionalism
- Commitment
- Delight

# What is a quality culture? We hear you...




Awareness,  
Ownership,  
Engagement,  
Empowerment


Communication-  
Our patients,  
Employees & key  
stake-holders




Right people,  
Right position,  
Right time




## How do you define Quality Culture?



Quality embedded in  
the operating model  
and a priority in  
decision making



Unvarnished  
discussion on  
quality issues  
Speak-up culture



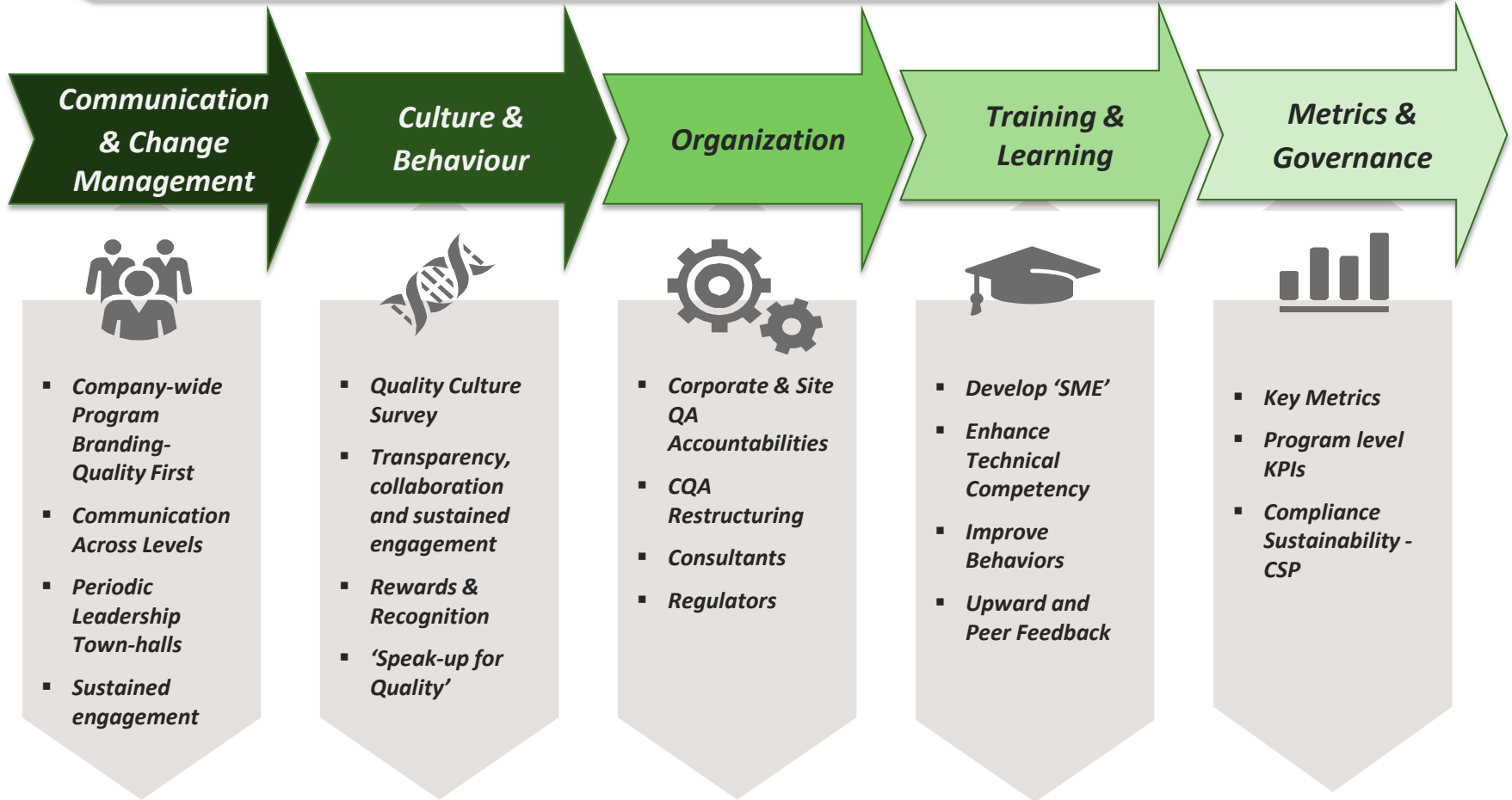
Sustainable root  
cause problem  
resolution –  
Stay Fixed!

**“There is nothing worse than a sharp image of a fuzzy concept”**



# Lupin's Road Map

## Lupin's Global Quality Action Plan



## Lupin's Core Values and Guiding Principles

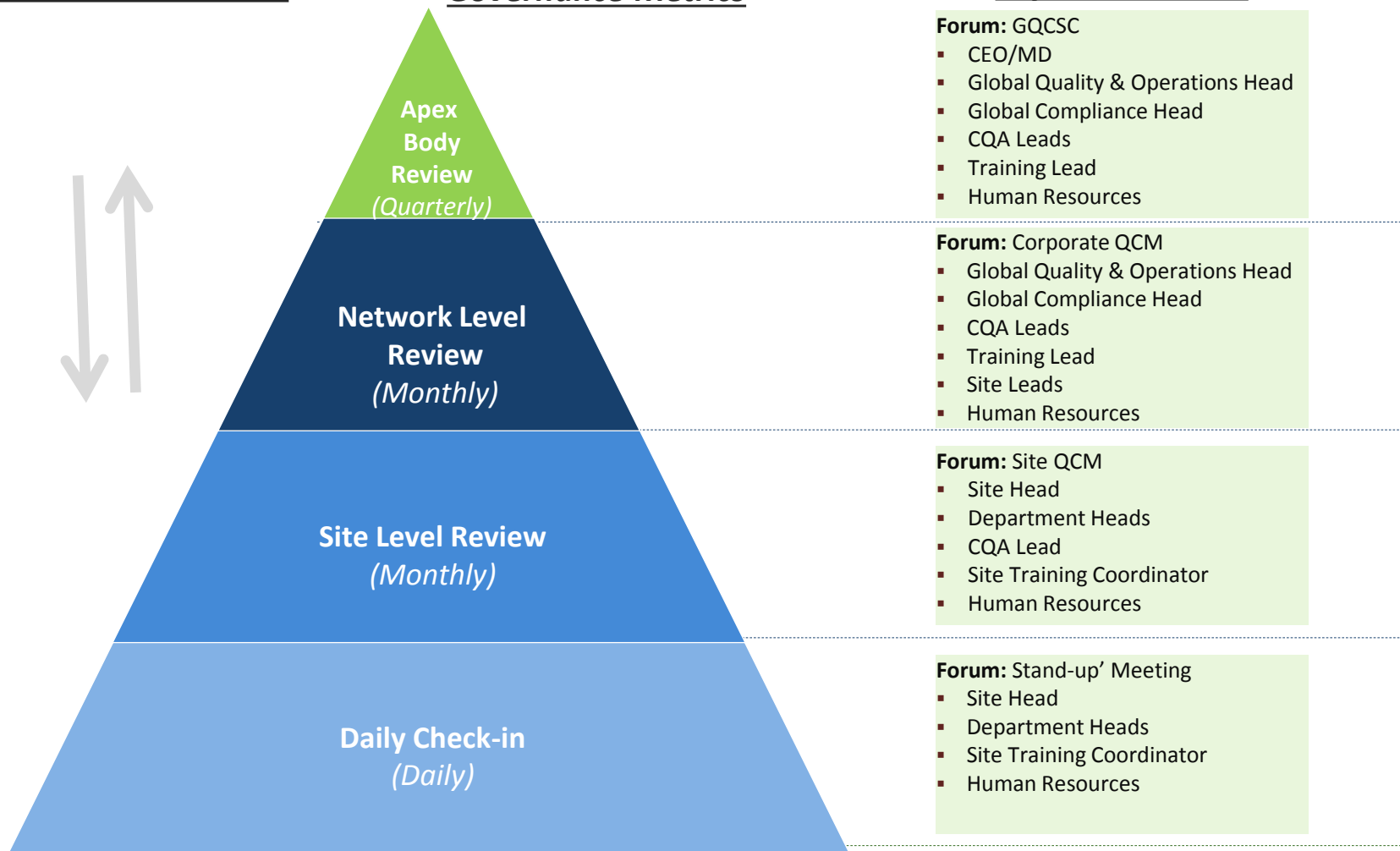
# Lupin's Road Map – Governance Structure



## Communication Channel

## Governance Metrics

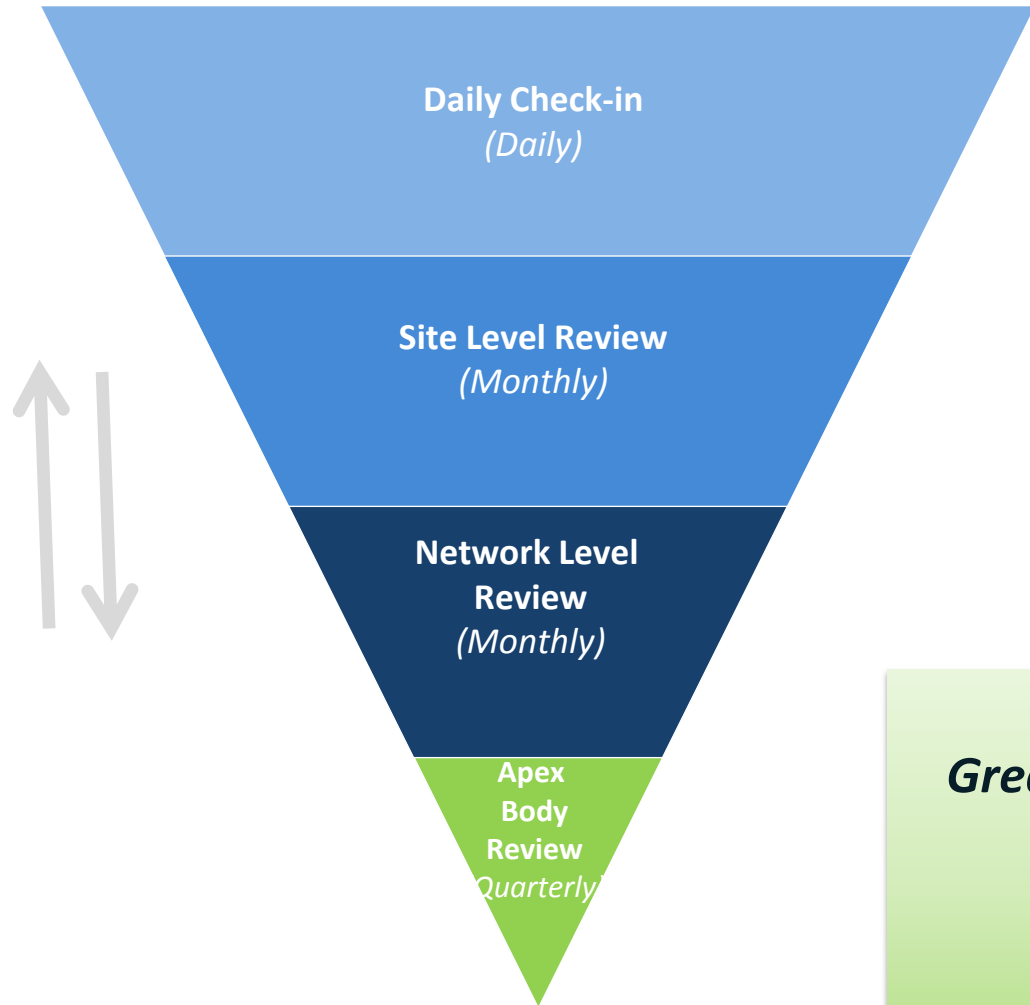
## Key Stakeholders



# Lupin's Road Map – Governance Structure



## Governance Metrics



***Greatest value can often be found  
in turning the pyramid  
upside down***

# Lupin's Road Map

## 'Critical Few Behaviours'

### Smarter Ways

*Constructive Restlessness*

### High impact

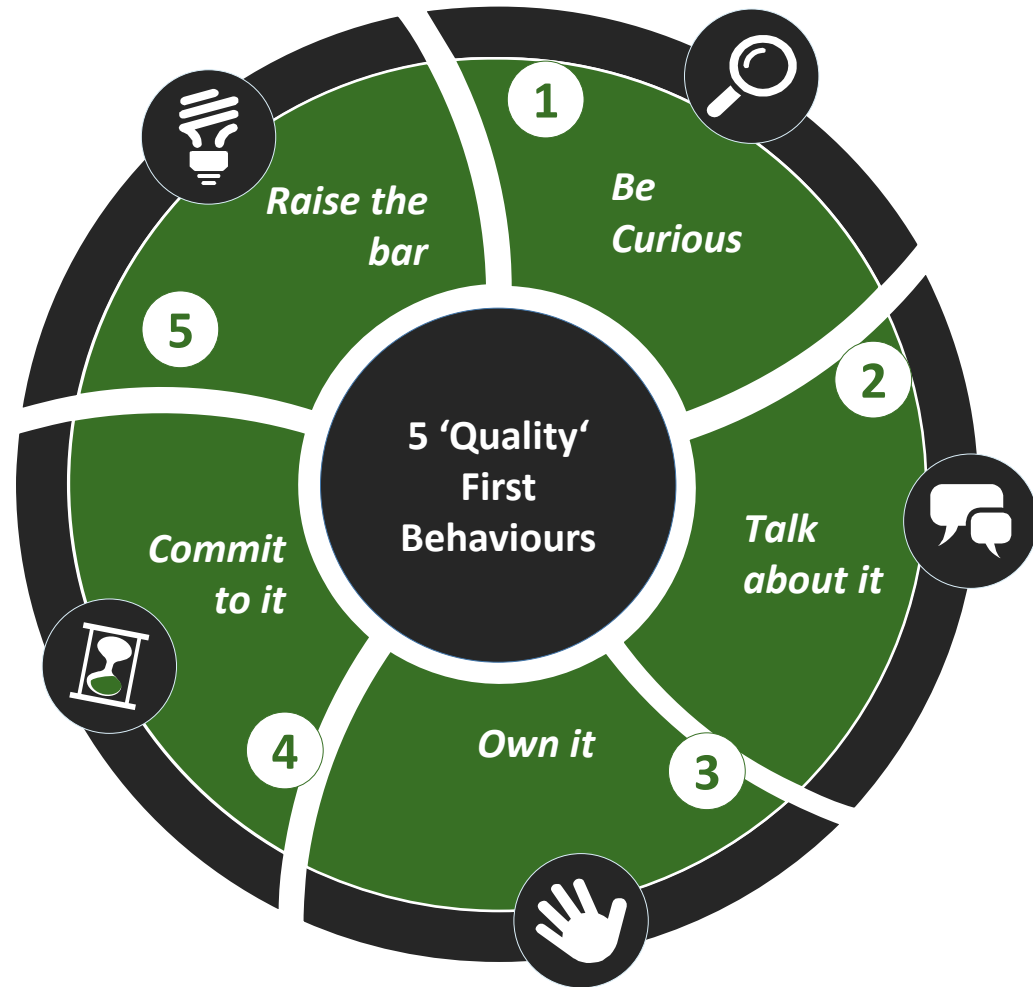
*Move the Needle*

### Becoming practitioners

*Doing it*

### Celebrating Success

*It's a Journey not a Destination*



# Global Quality Action Plan-Here's what is being done!!



## Commitment

- Leadership Commitment
- Townhall
- Leadership Changes
- Quality Restructuring
- Compliance Sustainability Program
- Quality First Program
- Increased Resources QA/Opex/Training
- Capex spending (Lab)
- Increased communication
- Reward Recognition
- Employee Survey



## Execution

- Gemba Walk
- SOP Simplification
- Process/Procedures review by industry consultants
- Gap Analysis
- Risk Assessment
- Corporate Audit Program improved
- Comprehensive Metrics
- Implementation of - Trackwise



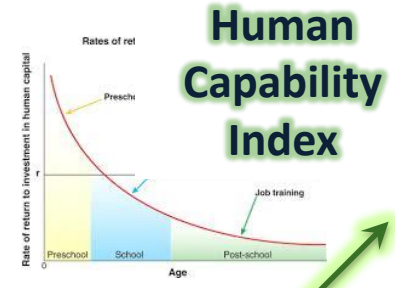
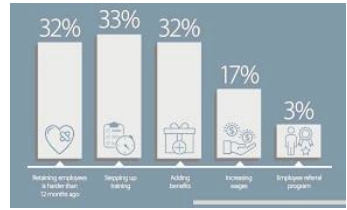
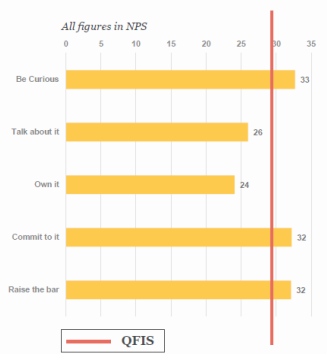
## Capability

- Competency based training
- SME development
- OEM Onsite Training
- Investigation Training by industry recognised experts
- Employee behaviour assessment

# How do we measure Quality Culture?



## Multiple Quality Culture Metrics



Employee Survey

Employee Retention

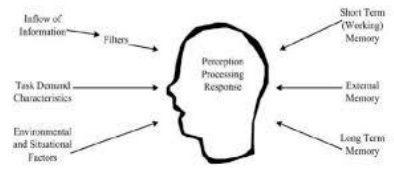
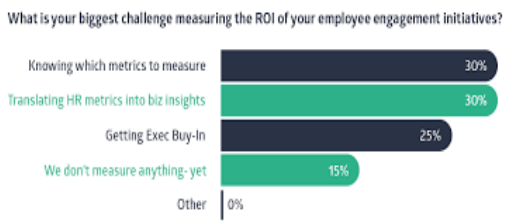
Operational Metrics

Regulatory Inspection Outcome

Employee Engagement

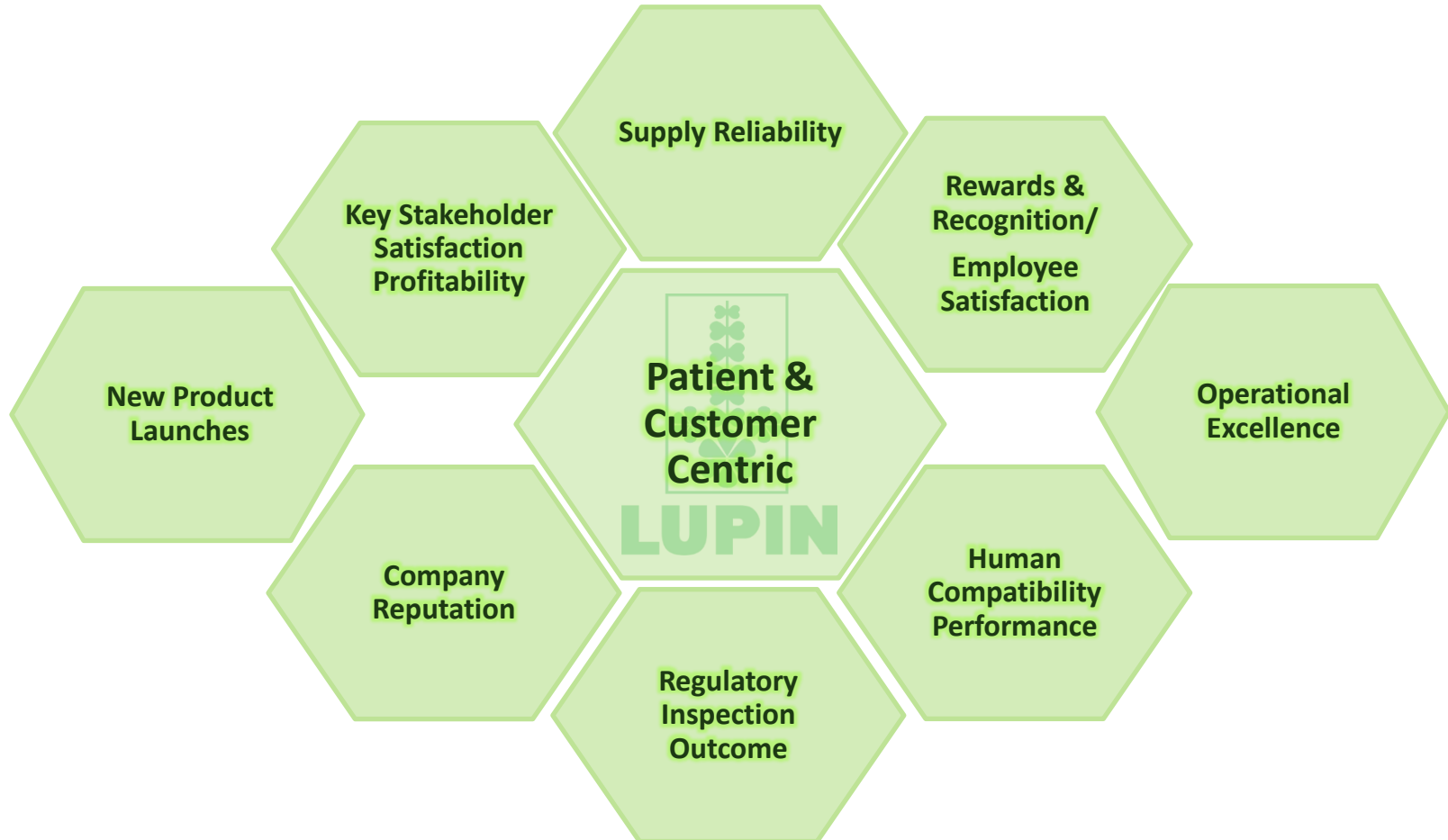
Reward Recognition

Human Reliability



# How do we sustain Quality Culture ?

**DATA DRIVEN**  
**Relentless Human Commitment**



# Summary thoughts

**Building Sustainable Global Quality Culture and Capabilities means:  
Being *'fit for purpose'* in all that we do. Our Patients deserve no less...**

✓ Patient centric

Not a tick the box exercise

Has a beginning  
but no end

Not a destination but an enduring  
journey

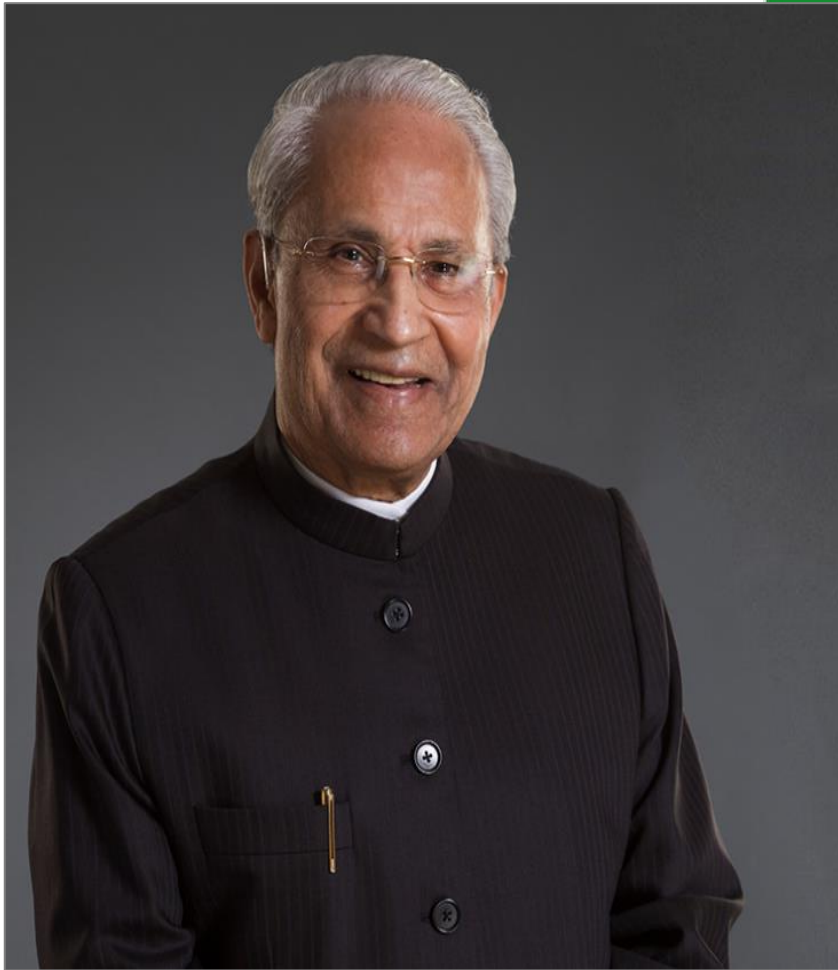
Drives innovation

Not an effort to appease regulators

**It's the right thing to do !!!**

*We believe, that an organization deeply rooted in its core values, quality culture and capabilities will always provide a competitive advantage*





*Dr. Deshbandhu Gupta (1938-2017)*

## *Important lessons for us*

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*What we do is more than just a job,  
We hold lives in our hands!*

*There is no place to be like at the  
shop floor.  
Where all the magic happens*

*Never trade quality for a lesser  
objective.  
Time and money are feeble and  
short-lived competitors.*

# Final thought



It is all about change...

*If the rate of change on the outside exceeds the rate of change on the inside, the end is near*

.....Jack Welch



**Thank You!**

# Questions?

