Quality First

Building Quality Culture and Capabilities: Experience Sharing by Lupin

Johnny Mikell, President – Global Quality & Compliance

5th Indian Pharmaceutical Forum
February, 2020
Lupin Today

Leadership in Global Generics with a Diversified Geographical Footprint

Key Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
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<tr>
<td>Market Cap (3)</td>
<td>US $ 4.8 bn</td>
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<tr>
<td>Revenue (FY19)</td>
<td>US $ 2.3 bn</td>
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<td>EBITDA (FY19)</td>
<td>US $ 468 mn</td>
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Globally

8th Largest Generic Company (by sales)

3rd Largest Indian Pharma (by global sales)

Other Key Markets

3rd Largest South Africa Generics

5th Largest Philippines Generics

Major Markets

3rd Largest in the US (by prescriptions)

6th India Pharma Market Rank

FY19 Revenues Split

- Developed (Ex-US) 29%
- Category Name [VALUE]
- Category Name [VALUE]
- Category Name [VALUE]

Leading global supplier of treatment for tuberculosis

Major supplier of antibiotics and treatment for HIV

Footnotes:
1. LTM sales available as of 30th Sep 2019
2. IQVIA MAT Sep-19 for respective markets
3. IQVIA MAT Aug-19
4. As of 8th Jan 2020
Lupin at a Glance

• Lupin Today: By the Numbers

20,000
Employees Globally

$2.5 bn
Global Revenue

15
Manufacturing Sites Globally

15%
CAGR* in 5 Years till FY18

9%
Spend on R&D (as % of Sales)

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

*Compound Annual Growth Rate (CAGR)
Lupin at a Glance

Manufacturing and R&D: Diverse Global Network

Global Commercial Presence

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<th>&gt;100</th>
<th>&gt;25</th>
<th>15</th>
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<tr>
<td>Countries where products are sold</td>
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<td>Countries with marketing offices</td>
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<td>Countries with subsidiaries</td>
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- **OPERATIONS**
  - 12 USFDA inspected sites
  - 30 bn+ extended unit capacity
  - 15 Mfg. sites

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

- **15 Mfg. sites**
  - 2
  - 3
  - 1

- **7 R&D sites**
  - 12
  - 2
Lupin’s Quality Journey- We get it!!!

Our Commitment to a Culture of Quality

“"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 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

We will stay the course...
Company values and principles – that which defines us!

Lupin’s Quality Journey- We get it!!!
What is a quality culture? We hear you...

- Awareness, Ownership, Engagement, Empowerment
- Communication - Our patients, Employees & key stakeholders
- 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**

**Communication & Change Management**
- Company-wide Program Branding - Quality First
- Communication Across Levels
- Periodic Leadership Town-halls
- Sustained engagement

**Culture & Behaviour**
- Quality Culture Survey
- Transparency, collaboration and sustained engagement
- Rewards & Recognition
- ‘Speak-up for Quality’

**Organization**
- Corporate & Site QA Accountabilities
- CQA Restructuring
- Consultants
- Regulators

**Training & Learning**
- Develop ‘SME’
- Enhance Technical Competency
- Improve Behaviors
- Upward and Peer Feedback

**Metrics & Governance**
- Key Metrics
- Program level KPIs
- Compliance Sustainability - CSP

**Lupin’s Core Values and Guiding Principles**
Lupin’s Road Map – Governance Structure

**Communication Channel**

**Governance Metrics**

- Apex Body Review (Quarterly)
- Network Level Review (Monthly)
- Site Level Review (Monthly)
- Daily Check-in (Daily)

**Key Stakeholders**

**Forum: GQCSC**
- CEO/MD
- Global Quality & Operations Head
- Global Compliance Head
- CQA Leads
- Training Lead
- Human Resources

**Forum: Corporate QCM**
- Global Quality & Operations Head
- Global Compliance Head
- CQA Leads
- Training Lead
- Site Leads
- Human Resources

**Forum: Site QCM**
- Site Head
- Department Heads
- CQA Lead
- Site Training Coordinator
- Human Resources

**Forum: Stand-up’ Meeting**
- Site Head
- Department Heads
- Site Training Coordinator
- Human Resources
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

1. Be Curious
2. Talk about it
3. Own it
4. Commit to it
5. Raise the bar

5 ‘Quality’ First Behaviours

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 Engagement

Employee Survey

What is your biggest challenge measuring the ROI of your employee engagement initiatives?

- Insufficient metrics to measure: 30%
- Translating HR metrics into biz insights: 30%
- Getting exec buy-in: 25%
- We don't measure anything yet: 20%
- Other: 5%

Employee Retention

Reward Recognition

Human Reliability

Operational Metrics

Regulatory Inspection Outcome

Human Capability Index

Regulatory Compliance
How do we sustain Quality Culture?

DATA DRIVEN
Relentless Human Commitment

- Supply Reliability
- Rewards & Recognition/Employee Satisfaction
- Operational Excellence
- Human Compatibility Performance
- Regulatory Inspection Outcome
- Company Reputation
- Key Stakeholder Satisfaction/Profitability
- New Product Launches

Patient & Customer Centric
We believe, that an organization deeply rooted in its core values, quality culture and capabilities will always provide a competitive advantage.

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
- Has a beginning but no end
- Drives innovation

- Not a tick the box exercise
- Not a destination but an enduring journey
- Not an effort to appease regulators

It’s the right thing to do !!!
Few Time-Tested Thoughts

Important lessons for us

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.

Dr. Deshbandhu Gupta (1938-2017)
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?