Leadership’s role enabling Quality Culture

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**DEFINITIONS**

**Culture:** The beliefs and behaviors characteristic of a particular group (social, ethic, age, etc.)

**Quality:** A distinctive characteristic or attribute, grade of excellence

**Quality Culture**
The beliefs and behaviors characteristic of a particular company that define and enable excellence of their operations and of the products they produce.
**Leader:** A person who guides a group

Leadership’s role in enabling a Quality Culture ....

...provide guidance within the company to define and enable beliefs and behaviors that promote operational excellence and product quality.
QUALITY CULTURE

What does it mean to have a Culture of Quality?

- Quality is not only the responsibility of the Quality Unit
  - Product quality and operational excellence are owned by every employee
  - ALL functions – are accountable for identifying, correcting and preventing issues
  - Management is responsible for creating an environment that promotes beliefs and behaviors that enable product quality and operational excellence

- Quality is a business imperative
  - Poor product quality can result in operational disruptions, recalls and regulatory enforcement
  - Disruptions, recalls and regulatory enforcement are expensive and tarnish company reputation, customer trust and consumer/patient loyalty
What Does it Mean to Have a Culture of Quality?

- Integrating quality into company culture is to **think beyond compliance**

- It is about **behaviors and decision-making** at all levels in the organization
Why have a culture of Quality?

- Leaders emphasize the right behaviors and decision-making at all levels in the organization.
- You have internal standards to reliably produce high quality product, beyond merely meeting the “regulator’s minimum standards”.

Culture of Quality
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- Consistent product quality minimizes supply interruptions.
- Employees do right, the right thing, consistently.
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- You have internal standards to reliably produce high quality product, beyond merely meeting the “regulator’s minimum standards”.
- Consistent product quality minimizes supply interruptions.
- Deduction of waste, operational cost, increase yield.
- Employees do right, the right thing, consistently.
- Enables company reputation, good regulatory standing, customer trust, consumer safety.
- Good Business Practice.
How Can Leaders enable a Culture of Quality?
LEADERSHIP’s ROLE

Integrating quality into the organizational culture

<table>
<thead>
<tr>
<th>Governance</th>
<th>Systems</th>
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<tbody>
<tr>
<td>•Mechanisms to escalate and resolve issues</td>
<td>•Well-defined quality systems framework</td>
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<tr>
<td>•Metrics to monitor and address operational,</td>
<td>•IT systems that enable real time data</td>
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<td>product and people performance</td>
<td>collection, evaluation and reporting</td>
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<tr>
<th>Process</th>
<th>People</th>
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<td>•Adequate facilities and manufacturing processes</td>
<td>•Employees are knowledgeable, experienced and</td>
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<td>trained for the task they perform</td>
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Above all, management involvement is key!
Leaders play a key role?

- Cross-functional leaders must have a close and active partnership and share common goals.
- Create an environment where every employee owns product quality and excellence in their workspace.
- Enforce the focus on quality through consistent and active communication.
  - Is quality everyone’s responsibility when things go wrong?
  - Do you talk of “risk management” or of “taking risk”? 
Product Quality Metrics

- # or rate of confirmed product quality complaints
- # of product lots rejected
- # of confirmed OOS and OOT
- Product Stability failure incidents
- # of recalls, Field Alerts
Operational Excellence Metrics

• Extent of product and process knowledge

• Multi-year trending of: repeat deviations, investigations with impact to product quality, investigations without root cause

• Change Control process- Primarily addresses externally identified issues or internally identified issues? Are changes proactive to improve robustness and reliability?

• 10 year review of investments in facilities, equipment, technology
**Governance Metrics**

- Employee engagement surveys, turn-around and absenteeism rates
- What actions are rewarded - firefighting/crisis management or preventing issues and continuous improvement
- Are there employee communication and recognition forums?
- Date of occurrence vs. date of detection of GMP events
- Multi-year trending of adherence to Quality System requirements

Ex: Adherence to on-time closure of CAPA, Investigations, Change Controls, periodic review of SOPs, Training
Summary

• Embracing a culture of quality is simply a **Good Business Practice**

• Leaders must provide **guidance** within the company to **define and enable** beliefs and behaviors that promote **operational excellence** and **product quality**.

• Leadership’s effectiveness in fulfilling their responsibility **can be measured and monitored**
QUESTIONS?

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