Leadership's role enabling Quality Culture

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Culture: The <u>beliefs and behaviors</u> characteristic of a particular group (social, ethic, age, etc.)

Quality: A distinctive characteristic or attribute, grade of excellence

Quality Culture

The <u>beliefs and behaviors</u> characteristic of a particular company that <u>define and enable excellence</u> of their operations and of the products they produce.

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Leader: A person who <u>guides</u> a group

Leadership's role in enabling a Quality Culture ….

…provide <u>guidance</u> within the company to define and enable <u>beliefs and behaviors</u> that promote operational excellence and product quality.

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

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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

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Why have a culture of Quality?

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".

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Product Quality

- Consistent product quality minimizes supply interruptions
- Employees do right, the right thing, consistently

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Product Quality

- Consistent product quality minimizes supply interruptions
- Deduction of waste, operational cost, increase yield
- Employees do right, the right thing, consistently

Sustainable Compliance

- Enables company reputation, good regulatory standing, customer trust, consumer safety
- Good Business Practice

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How Can Leaders enable a Culture of Quality?

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Integrating quality into the organizational culture

Governance	Systems
• Mechanisms to escalate and resolve issues • Metrics to monitor and address operational, product and people performance	• Well-defined quality systems framework • IT systems that enable real time data collection, evaluation and reporting
Process	**People**
• Adequate facilities and manufacturing processes	• Employees are knowledgeable, experienced and trained for the task they perform

Above all, management involvement is key!

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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"?

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Quality Culture Metrics

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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

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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

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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

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Summary

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

- Leaders must provide <u>guidance</u> within the company to <u>define and enable</u> beliefs and behaviors that promote <u>operational excellence </u>and <u>product quality.</u>

- Leadership's effectiveness in fulfilling their responsibility <u>can be measured and monitored</u>

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QUESTIONS?

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