



Building Quality Culture and Capabilities

IPA Advanced GMP Workshop | November 2018

The typical questions we face on “quality culture”:

“

1 How much does it matter?

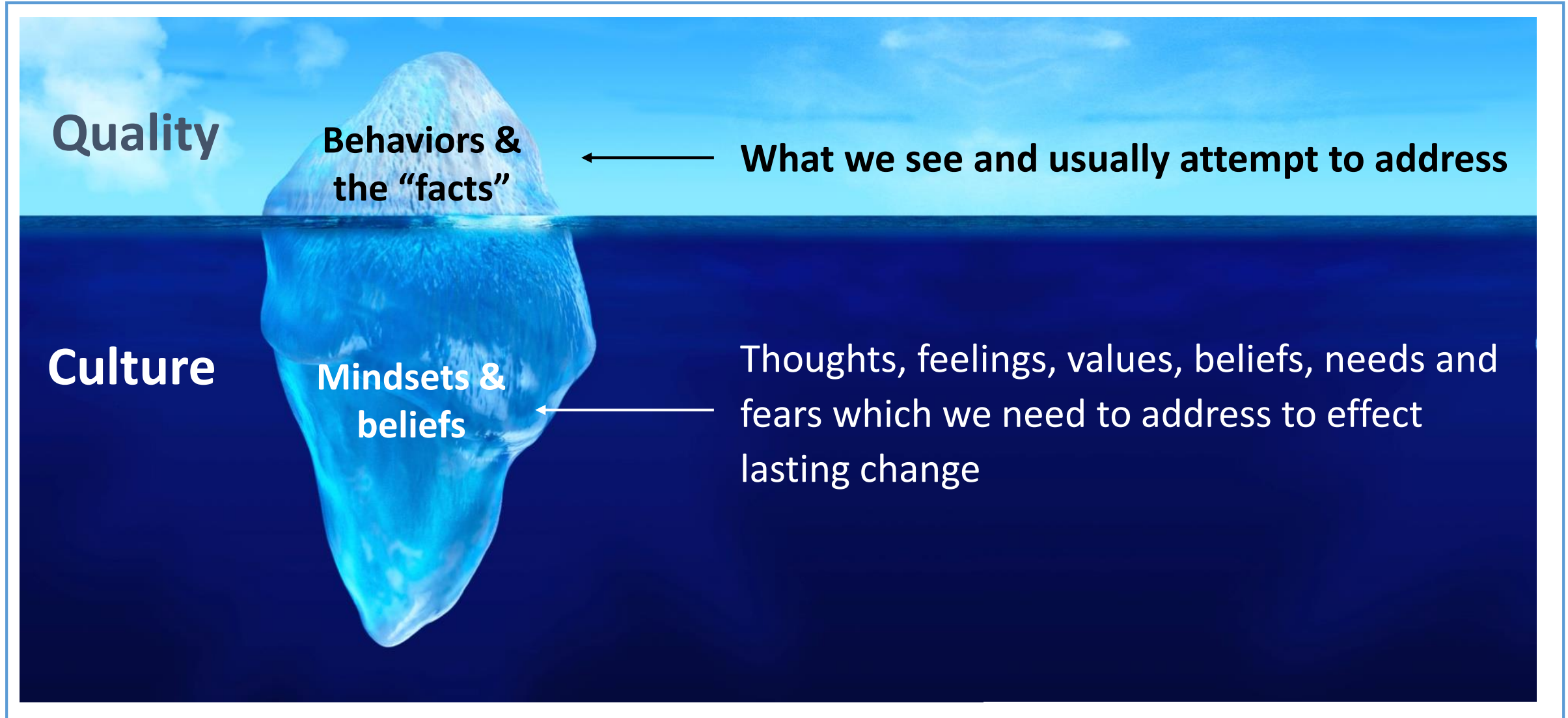
2 Can you measure it?

3 How do you build it?

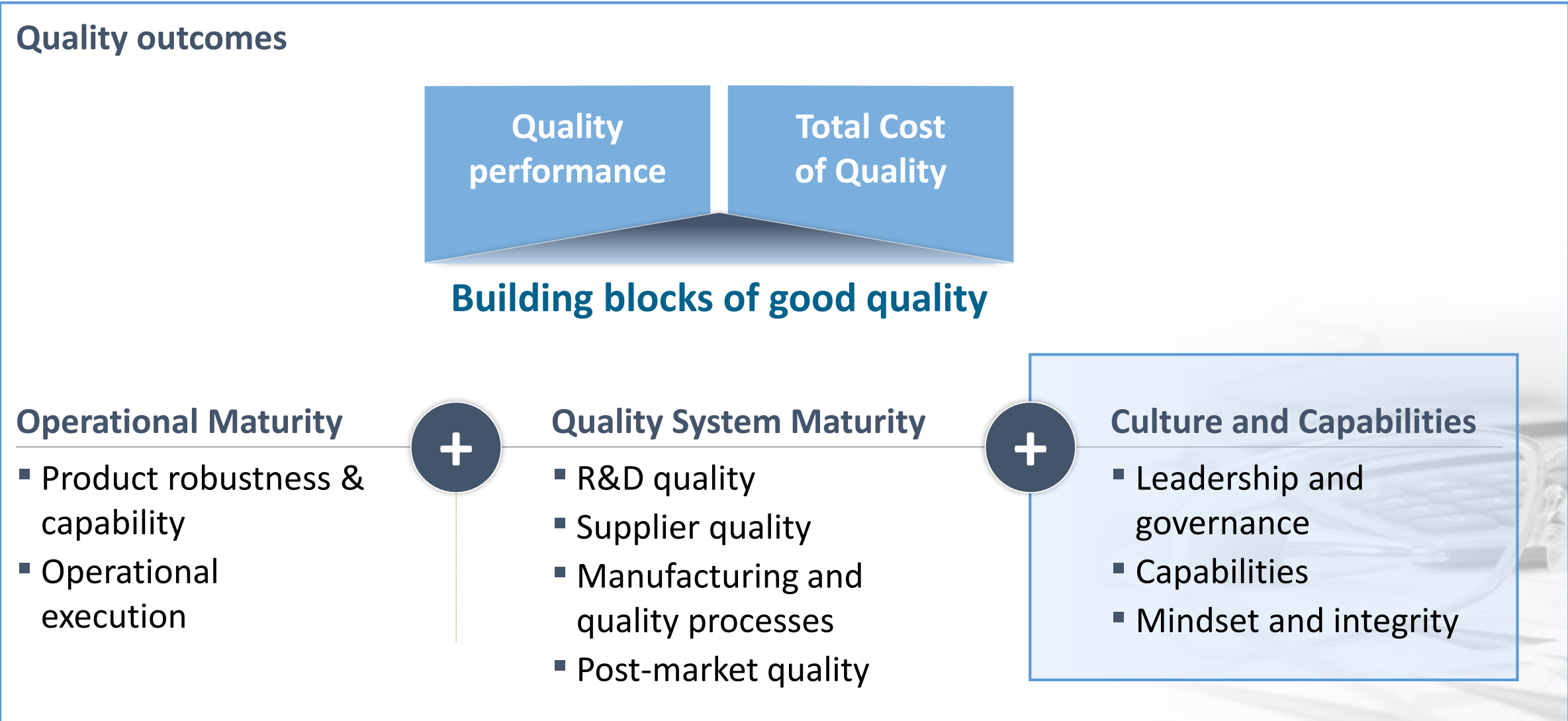
”



1 Culture matters- Culture forms the foundation of good quality



1 Culture plays a critical role in delivering good quality outcomes

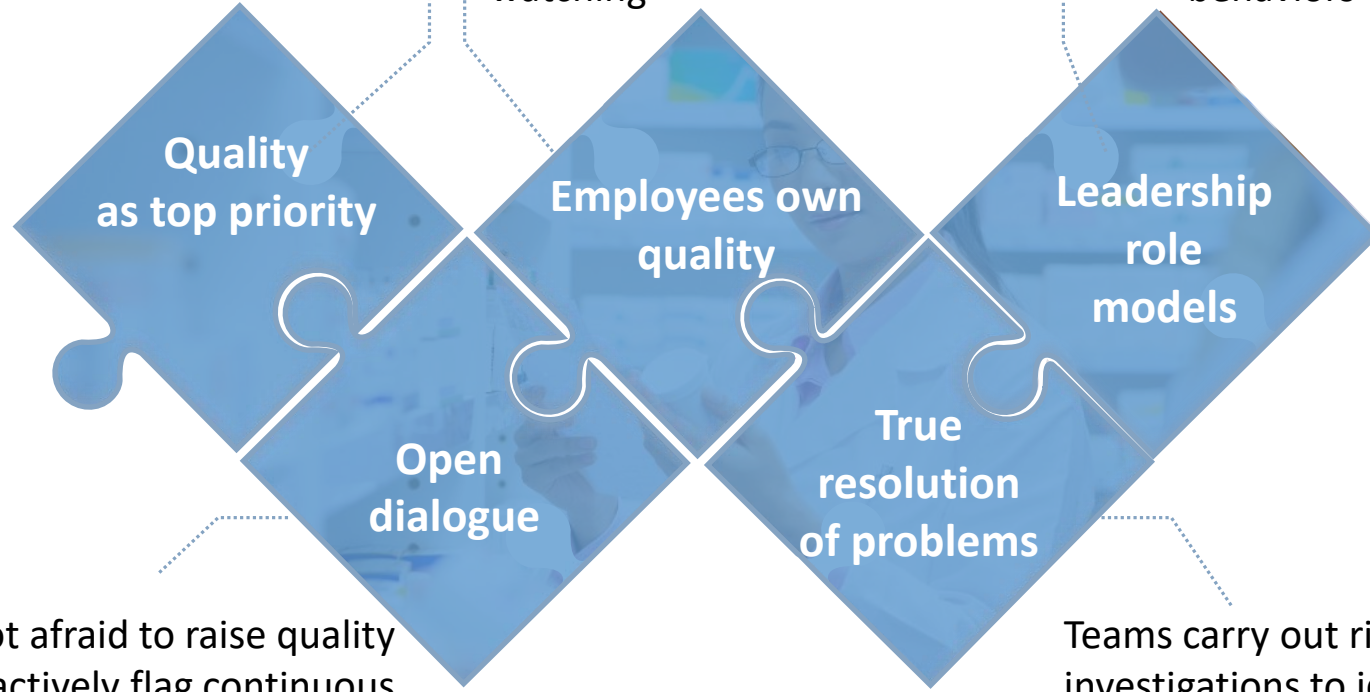


2 We believe there are 5 key pillars for strong quality culture

Quality performance is communicated clearly, regularly monitored and reinforced through robust metrics, governance and incentives. The impact on quality is a critical part of any decision

All employees especially “shop floor” ones understand and are capable in the relevant SOPs and guidelines, and follow them even when “no one is watching”

Managers spend time on the shop floor to observe operations (“gemba”), effectively identify quality improvements and coach employees. Managers reinforce the importance of quality in their day-to-day behaviors



Employees are not afraid to raise quality issues and proactively flag continuous improvement opportunities, whereupon leaders listen and act appropriately

Teams carry out rigorous, high-quality investigations to identify the right root causes and preventive actions and drive solutions to avoid recurrence of issues

2 Holistic approach is required to identify culture gaps across the 5 pillars

Assessment methodology

Quality as top priority	Employees own quality	Leadership role models	Open dialogue	True resolution of problems
<p>Review of sample decisions and trade-offs made for quality</p> <hr/> <p>Compare metrics, incentives and governance vs. actual behaviors, including unintended consequences</p>	<p>Assess shop floor practices and adherence to SOPs (“practice vs. procedure”), and root causes of adherence failures</p>	<p>Observe and review management “gemba” walks and resulting actions</p> <hr/> <p>Observe manager and employee interactions</p> <hr/> <p>Compare employee feedback on management with industry peers</p>	<p>Assess frequency, source and quality of improvement ideas relative to industry peers</p> <hr/> <p>Review select examples of issue escalation and resolution</p> <hr/> <p>Observe shop floor performance dialogue</p>	<p>Review of select investigations for quality of root cause analysis and CAPA effectiveness</p>



3 We use a 4-part culture transformation approach to build Quality culture (1/2) – Guiding philosophy

4-part culture-transformation framework

“I will change my behavior if...”

Fostering understanding and conviction

“I know what is expected of me – I agree with it, and it is meaningful”

Reinforcing with formal mechanisms

“The structures, processes and systems reinforce the change in behavior I am being asked to make”

Culture transformation

Role-modeling

“I see superiors, peers and subordinates behaving in the new way”

Developing talent and skills

“I have the skills and competencies to behave in the new way”

3 We use a 4-part culture transformation approach to build Quality culture (2/2) – Sample interventions

4-part culture-transformation framework

“I will change my behavior if...”



Fostering understanding and conviction

- On-going, two-way communication on importance of quality
- Formal platforms for employee to raise issues
- Language and rituals

Reinforcing with formal mechanisms

- Setting the right metrics along with robust governance processes to drive quality
- Structure Rewards & Recognition to encourage employees contributing to good quality outcomes

Role-modeling

- Senior leader/senior team role modeling quality in day-to-day behaviors
- Symbolic acts by leadership team that further establish importance of quality

Developing talent and skills

- Building technical, managerial & behavior skills across levels
- Adult-learning approach based on Field and forum