PDA's Journey in Understanding Quality Culture

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Only 12% of companies believe they understand their culture

Companies that proactively manage culture demonstrate revenue growth over a 10-year period that is, on average,

516% higher

than those who do not.[3]

Deloitte Culture Perspectives, Aug 2016

"Mission-driven" companies are poised for success.

They tend to have

30% higher levels of innovation.[4]

And **40%** higher levels of retention.[4]

Additionally, companies with highly engaged workforces outperform their peers by **147%** in earnings per share.[5]

Executives think culture and engagement are important, yet few are actively addressing it.

Nearly

9 out of 10 executives surveyed cited culture and engagement as important or very important.[1]

Yet only **12%** of companies believe they understand their culture.[1]

While less than half (46%) reported that they are prepared to tackle the engagement challenge.[2]

> **Where quality has a strong presence in the culture, employees make fewer significant mistakes, saving as much as $350 million annually.**

- Employees in top-quintile culture of quality environments have to address 46% fewer mistakes and 75% fewer significant mistakes.

- Employees in top-quintile culture of quality environments also experience 75% fewer customer-facing product mistakes.

- For every 5,000 employees in a company, moving from bottom quintile to top quintile in Culture of Quality Index performance can result in savings of $67 million.

A strong culture of quality pays

Culture's Impact on Mistakes Addressed by Employees
Weekly Average per Employee

Overall Number of Mistakes Addressed

7.2 — Bottom Quintile
3.9 — Top Quintile
Δ = 46%

Number of Customer-Facing Product Mistakes Addressed

1.57 — Bottom Quintile
0.40 — Top Quintile
Δ = 75%

Number of Significant Mistakes Addressed

1.04 — Bottom Quintile
0.26 — Top Quintile
Δ = 75%
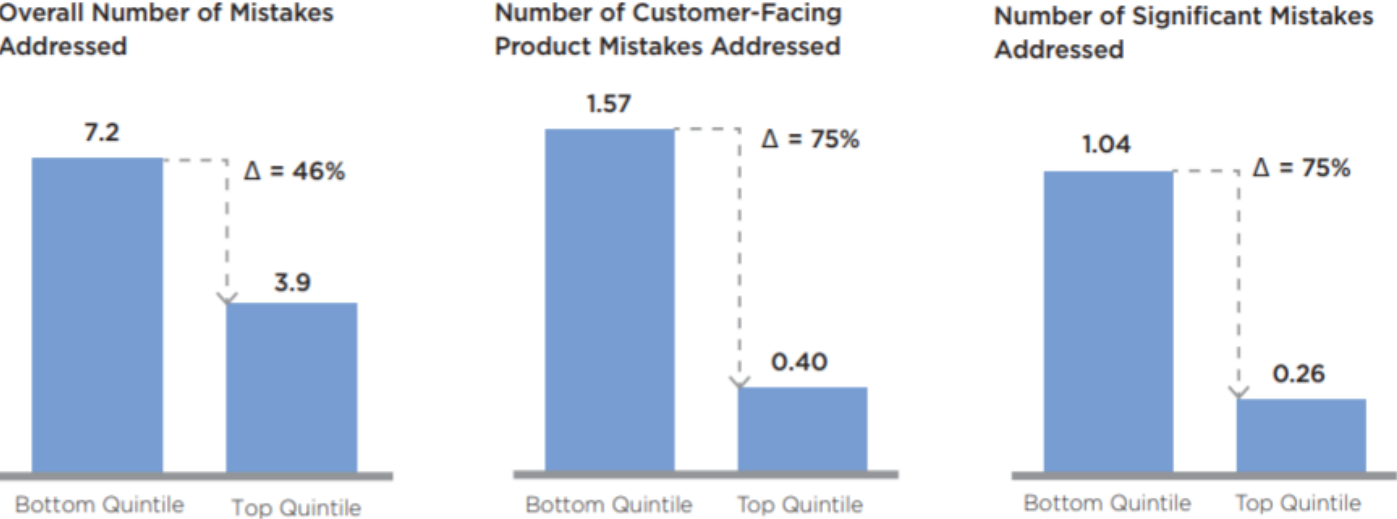
A $350 Million Opportunity

Moving from the bottom 20% to the top 20% in Culture of Quality Index performance can lead to more than **$350 million in added employee productivity.**[1]
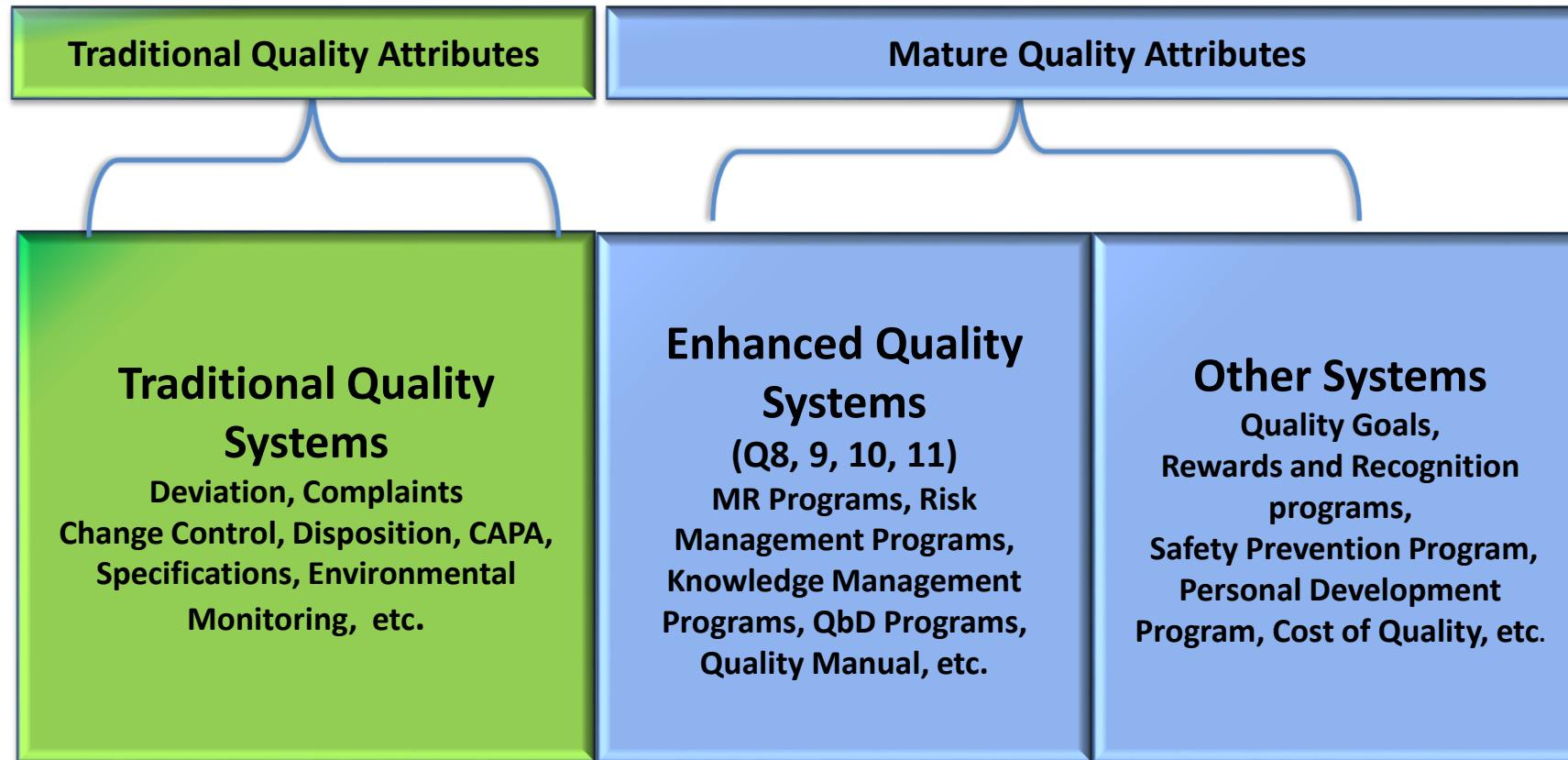
Why focus on culture of quality now in the pharma industry?

- Pharma focus on manufacturing cost and productivity
- Rising regulator scrutiny on quality & their focus on metrics
- Regulators are beginning to assess quality culture
- Rising consumer scrutiny (i.e. social media)
- Research has shown a positive ROI for strong quality culture

Three components for Culturing Quality

1. Giving employees the quality knowledge for Critical Thinking

2. Creating an environment for "psychological safety or safe teaming"*

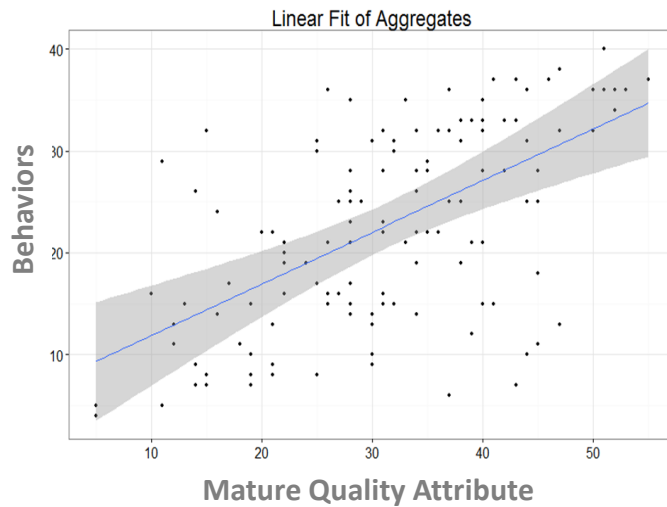3. Establishing a framework to facilitate discussion / decisions on quality issues and risks.

* Dr. Amy Edmonson, Harvard Business School

PDA's approach - Mature Quality Attributes

Traditional Quality Attributes	Mature Quality Attributes

Traditional Quality Systems
Deviation, Complaints
Change Control, Disposition, CAPA, Specifications, Environmental Monitoring, etc.

Enhanced Quality Systems
(Q8, 9, 10, 11)
MR Programs, Risk Management Programs, Knowledge Management Programs, QbD Programs, Quality Manual, etc.

Other Systems
Quality Goals, Rewards and Recognition programs, Safety Prevention Program, Personal Development Program, Cost of Quality, etc.

St. Gallen confirms PDA's Quality Culture Survey outcome

PDA Survey Analysis 2014

St.Gallen Analysis 2017
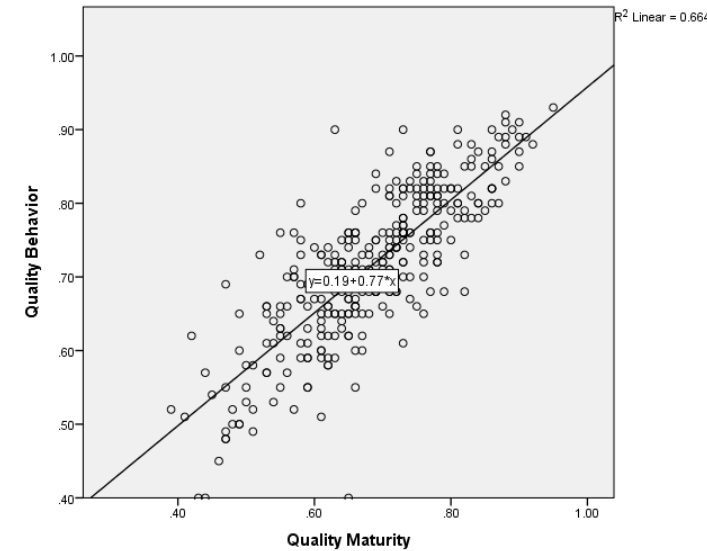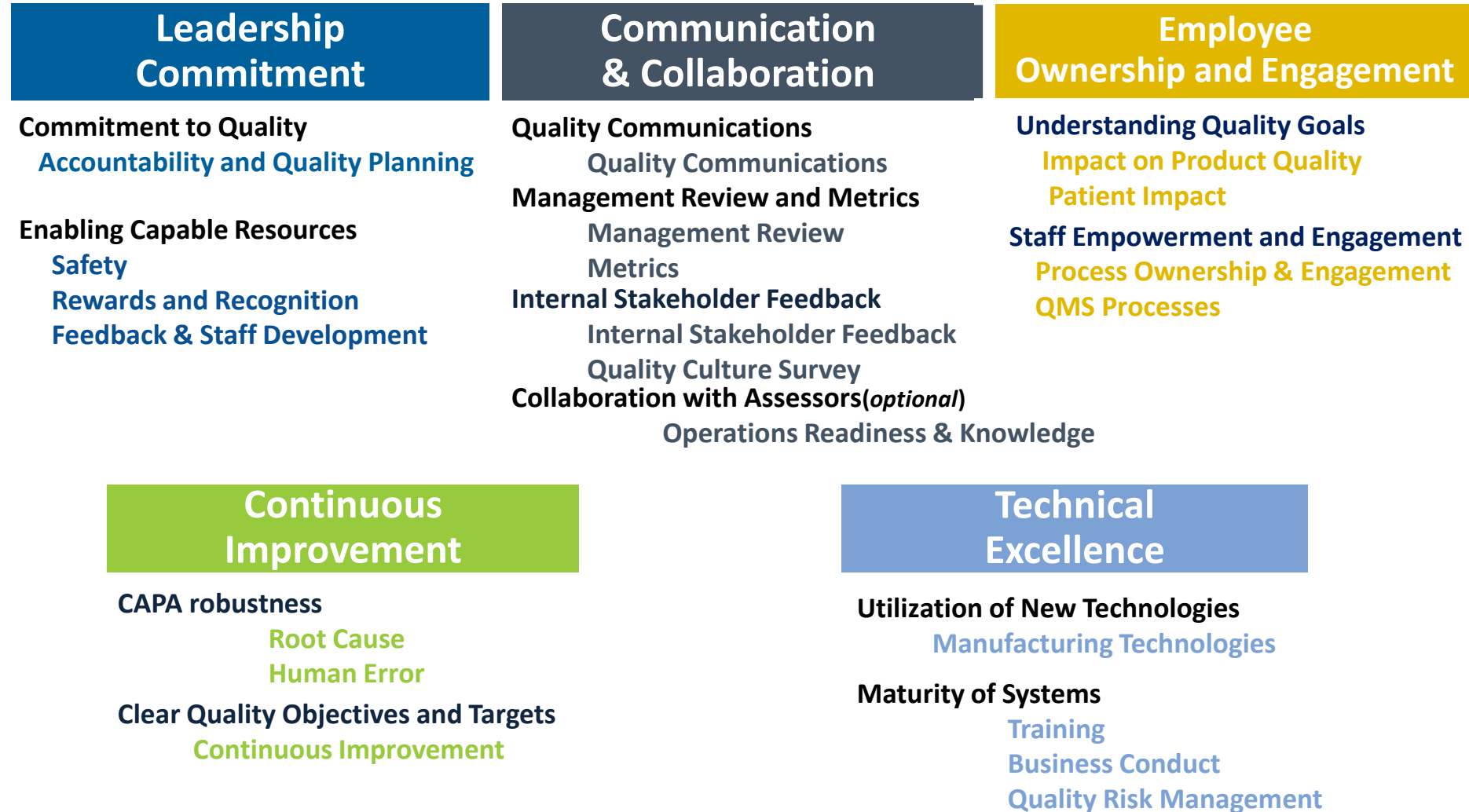

$R^2 = 0.34$ ⟶ $R^2 = 0.66$

- 326 pharmaceutical sites of different size and focus within St.Gallen database confirm PDA

Top Mature Quality Attributes based on PDA's research

1. Collecting Error Prevention Metrics
2. Management Communication that Quality is Everyone's Responsibility
3. Utilization of new proven technologies
4. Clear performance criteria for feedback and coaching
5. EH&S Environmental Program with trained staff
6. Site has formal quality improvement objectives and targets
7. Quality topics included in at least half of "all hands" meetings
8. Collecting Management Review Metrics
9. Program to show how employee's specific goals contribute to overall quality goals
10. Program to measure, share and discuss product quality performance and improvement from shop floor to executive management.
11. Continuous Improvement Program / Plans with active support of CEO and Corp Management of QMS
12. Program that establishes quality system maturity model and action plan and tracking to measure progress
13. Internal survey measuring a company/ site quality culture

Quality Culture Attributes in a Maturity Model

Leadership Commitment

Commitment to Quality
  Accountability and Quality Planning

Enabling Capable Resources
  Safety
  Rewards and Recognition
  Feedback & Staff Development

Communication & Collaboration

Quality Communications
  Quality Communications
Management Review and Metrics
  Management Review
  Metrics
Internal Stakeholder Feedback
  Internal Stakeholder Feedback
  Quality Culture Survey
Collaboration with Assessors(*optional*)
  Operations Readiness & Knowledge

Employee Ownership and Engagement

Understanding Quality Goals
  Impact on Product Quality
  Patient Impact
Staff Empowerment and Engagement
  Process Ownership & Engagement
  QMS Processes

Continuous Improvement

CAPA robustness
  Root Cause
  Human Error
Clear Quality Objectives and Targets
  Continuous Improvement

Technical Excellence

Utilization of New Technologies
  Manufacturing Technologies
Maturity of Systems
  Training
  Business Conduct
  Quality Risk Management

Pre-view of a section of the tool

5. Understanding Quality Goals
Impact on Product Quality
Patient Impact

Employee Ownership: **Understanding Quality Goals**				
1	**2**	**3**	**4**	**5**
Impact on Product Quality • Associates <u>can't</u> clearly explain their role and impact on quality goal	• Associates <u>can</u> clearly explain what they have to get done, not necessarily what's <u>important to general quality</u>	• Associates can clearly explain what they have to get done and what the <u>critical process parameters</u> are	• Associates can clearly explain the specific <u>critical quality attributes</u>, their importance and <u>linkages</u> to the operations / processes they oversee	• Associates at all levels can explain <u>process capabilities</u> and their <u>impact</u> on specific product critical quality attributes
Patient Impact • Associates <u>don't understand</u> how the product impacts the patients. (e.g. product indication, population) • Management <u>doesn't communicate</u> how the product impacts patients	• Associates <u>understand how</u> the product is used in patients but <u>don't</u> understand how Quality impacts <u>clinical outcomes</u> • Only <u>occasional communication</u> from Management on the importance of Quality and how that can affect patients	• Associates understand how the product is used in patients and how Quality impacts <u>clinical outcomes</u> • Management communicates <u>frequently</u> in meetings and other forms of communication the importance of Quality and how that can affect patients	• Associates understand how the product is used in patients and <u>specific CQA</u> impact on clinical outcomes • Management <u>regularly communicates stories</u> of how their work benefits patients in staff meeting and other means of communications such as email, videos, etc.	• Associates understand the <u>patient expectations</u> and how product is used in patients and specific CQA impact on clinical outcomes • Associates <u>share with each other</u> the importance of Quality on clinical outcomes

Interested in participating in the PDA Program?

- **Interactive 1.5 day training utilizing a "live case study" approach to help understand the application of the tool**
- **Ability to benchmark within pharma industry**
- **Driving continuous improvement of culture within the company**
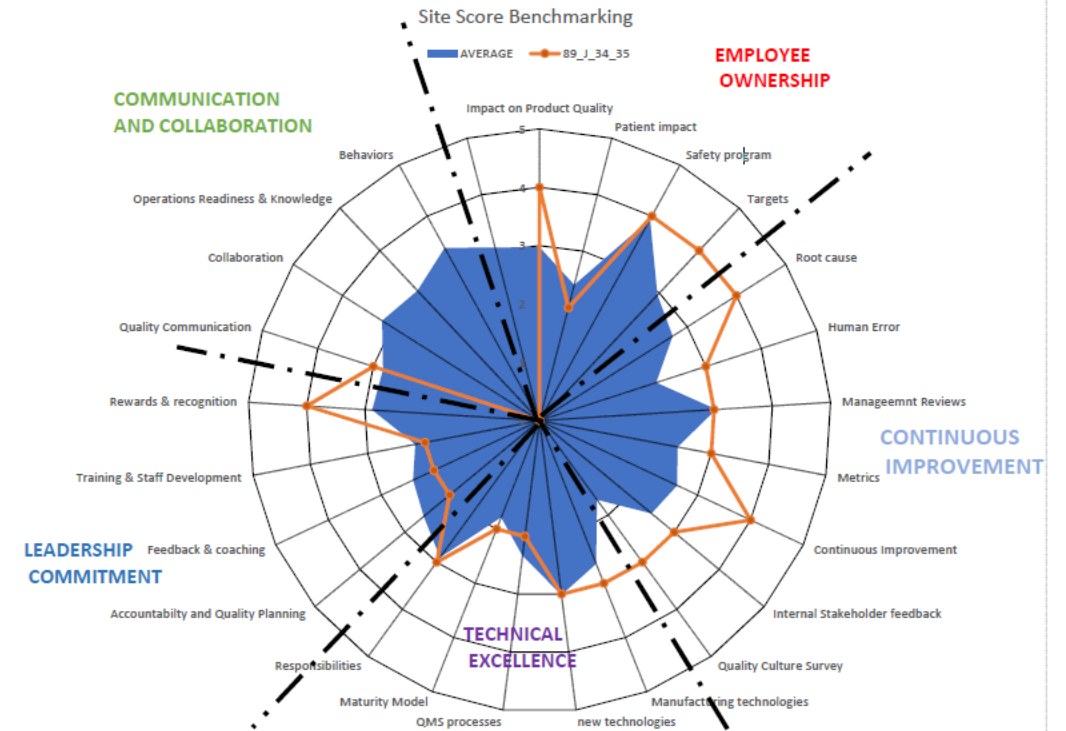
Visit PDA's website (www.pda.org) for upcoming training dates

"If you can't measure it, you can't improve it." Peter Drucker

"Many of the things you can count don't count. Many of the things you can't count really count" Albert Einstein

Acknowledgements

PDA Quality Metric/ Quality Culture Task Force Team

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