

PDA's Journey- Aspiring to Measure Quality Culture

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PDA Annual Singapore Conference 2018

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Agenda

- The value of quality culture
- PDA's approach in assessing quality culture
- Pilot summary
- Next steps

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Companies that proactively manage their culture demonstrate revenue growth that is 516% higher over 10 year period.... However, only 12% of companies believe they understand their culture

"Mission-driven" companies are poised for success.

They tend to have **30%** higher levels of innovation.* And **40%** higher levels of retention.* Additionally, **147%** in earnings per share.*

companies with highly engaged workforces outperform their peers by

Deloitte Culture Perspectives, Aug 2016

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.*

only **12%** of companies believe they understand their culture.*

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


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WHAT IS A QUALITY CULTURE & WHY DOES IT MATTER?

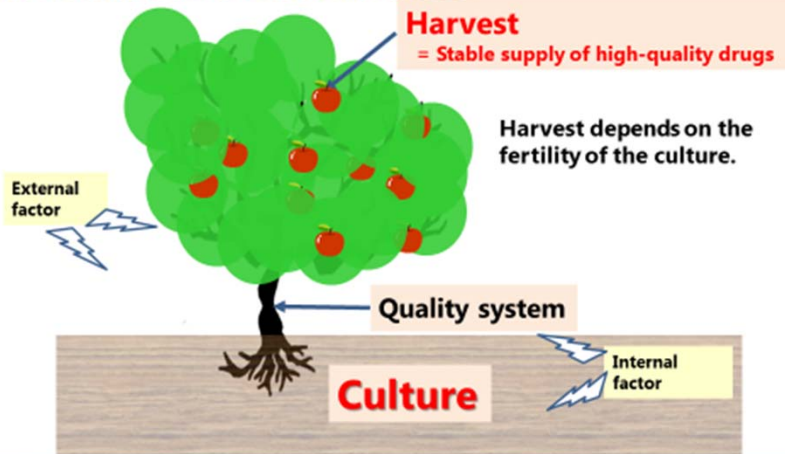
A true culture of quality is an environment in which employees not only follow quality guidelines but also consistently **see** others taking quality-focused actions, **hear** others talking about quality and **feel** quality all around them.

April 2014 Harvard Business Review.
"Creating a Culture of Quality" by Ashwin Srinivasan & Bryan Kurey.

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The Pharmaceutical Firm is like a tree.



Harvest
= Stable supply of high-quality drugs

Harvest depends on the fertility of the culture.

External factor

Quality system


Culture

Internal factor

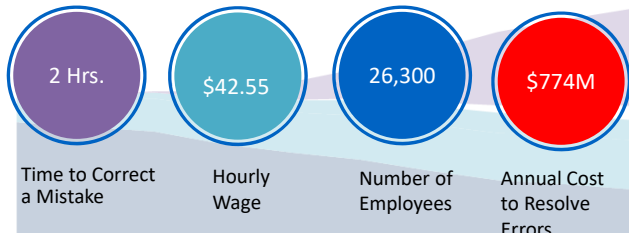
Dec 1-2, 2015 PDA Japan Annual Meeting 2015 14

Courtesy of QAQC Committee, Quality Culture Study Group, PDA Japan

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The Business Benefits




2 Hrs.	\$42.55	26,300	\$774M
Time to Correct a Mistake	Hourly Wage	Number of Employees	Annual Cost to Resolve Errors

For every 5,000 employees, moving from the bottom to the top quintile would save a company \$67 million annually

Harvard Business Review April 2014 "Creating a Culture of Quality"
CEB (Corporate Executive Board) Results of Two Years of Research


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PIC/S guidance on data integrity highlights importance of quality culture


- Management should aim to create a work environment (i.e. quality culture) that is transparent and open, one in which personnel are encouraged to freely communicate failures and mistakes. Organisational reporting structure should permit the information flow between personnel at all levels.
 - Ensure awareness and understanding of expectations
 - Lead by example, management should demonstrate the behaviors they expect to see ;
 - Ensure accountability for actions and decisions;
 - Stay continuously and actively involved;
 - Set realistic expectations, consider the limitations that place pressures on employees;
 - Implement fair and just consequences and rewards;

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FDA's Quality Metrics Program

- Prevention of drug shortages
- Risk-based inspection scheduling
 - Focus on the sites that requires oversight
 - Provide relief for sites with good track records
 - Relief in post approval change management oversight
 - Frequency of inspection



A maximally efficient, agile, flexible, pharmaceutical manufacturing sector that reliably produces high quality drug products without extensive regulatory oversight. Janet Woodcock, October 5, 2005

Change the current oversight paradigm to include positive reinforcement

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Why the focus on Quality Culture?

- Realization about root cause of human errors
- Quality Metric programs must be balanced with strong Quality Culture to be valuable



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Our Vision and Mission...

Promote Quality Culture, its **understanding, assessment and improvement** within the Pharmaceutical / Biopharmaceutical Industry by providing tools and knowledge to enable continuous improvement. **The ideal state is to ensure a quality mindset and behaviors are imbedded into the daily work of all functions resulting in positive patient outcomes.**




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Can Quality Culture be measured?

Is there a set of Mature Quality Attributes that are a surrogate for Quality Culture Behaviors?



1. Is there a relationship between Quality Culture Behavior scores and Mature Quality Attribute scores?
2. Which Mature Quality Attributes relates to Quality Culture behavior?




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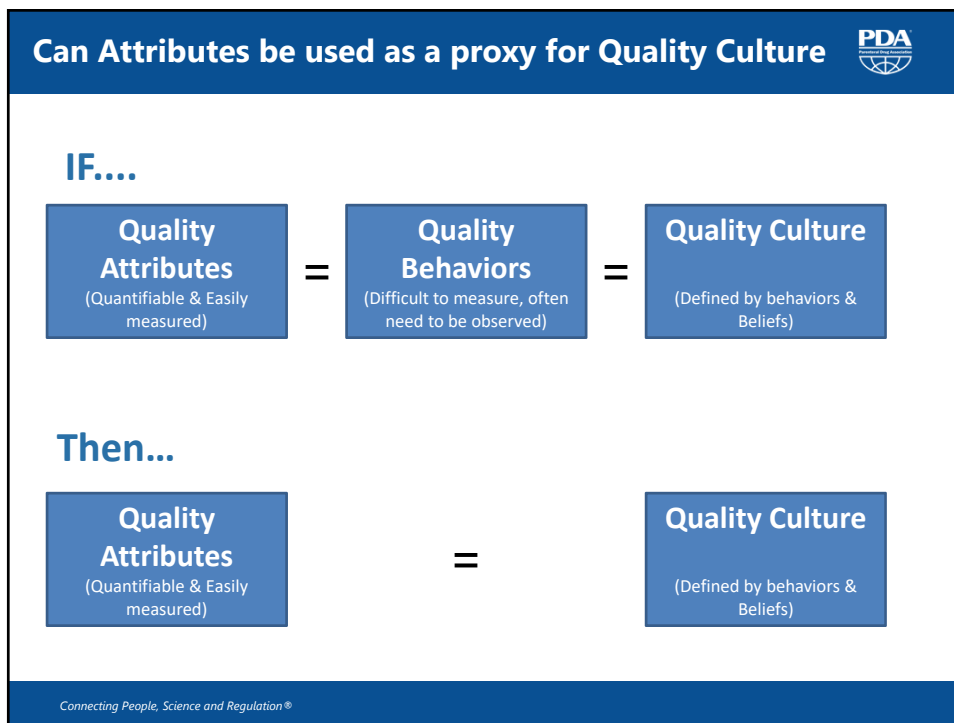
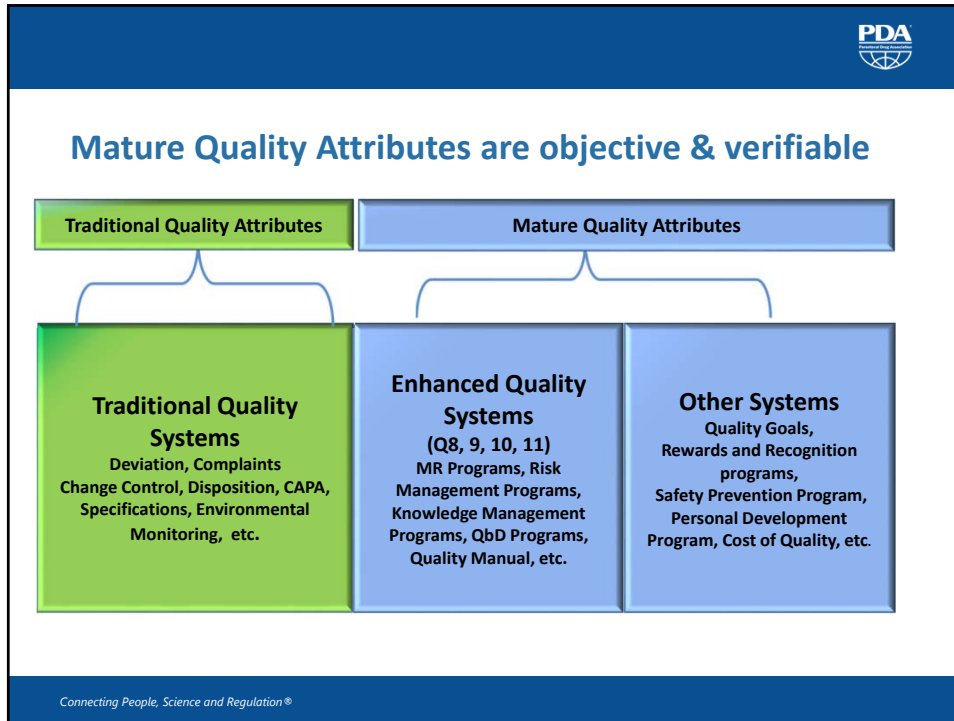
PDA's Quality Culture Survey Conducted


- Draft Survey June / July 2014
- Launched Sept 4th – Oct 20th 2014
- Two surveys (Executive & Open to All Survey)
- Three Sections
 - A. Demographic (product, site, size)
 - B. Quality Culture Behavior
 - C. Mature Quality Attributes



137 Global Responses Received from the Survey

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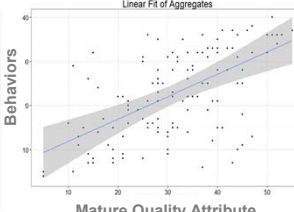
42 Behaviors

Relationship established!

55 Mature quality attributes

Seven Areas of Behavior Questions

1. Communication & Transparency
2. Commitment & Engagement
3. Technical Excellence
4. Standardization of Criteria or Requirement
5. Cross Functional Vision
6. Rewards and Recognition
7. Speak Up for Quality Culture



Behaviors

Mature Quality Attribute

Enhanced Quality Systems (Q8, 9, 10, 11)


Risk management, QbD, MR, Quality Manual, CI, etc.

Other Systems

Quality goals & plans, rewards & recognition, staff development / training, safety, business conduct, etc.

Key Mature Quality Attributes were identified

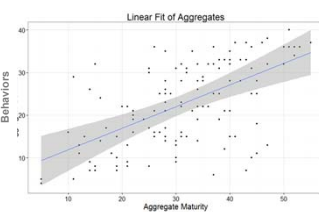
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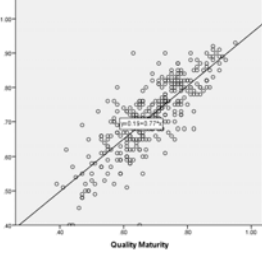
Higher Quality Maturity is accompanied with Higher Quality Behavior

St. Gallen confirms PDA's Quality Culture Survey outcome

PDA Survey Analysis 2014

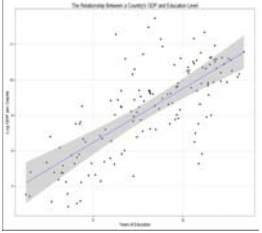


St. Gallen Analysis 2017



Social Science Analysis

Education vs. Income



$R^2 = 0.34$ ➔ $R^2 = 0.66$

- 326 pharmaceutical sites within St. Gallen database confirms PDA's hypothesis

Dr. Thomas Friedli, Measuring Quality Systems & Quality Culture February 2017



Top 10 Quality Attributes significant impact

1. Participation at conferences to stay current
2. Collecting Error Prevention Metrics
3. Management Communication that Quality is Everyone's Responsibility
4. Utilization of new proven technologies
5. Clear performance criteria for feedback and coaching
6. EH&S Environmental Program with trained staff (risk assessments, emission controls, spill prevention and response)
7. Site has formal quality improvement objectives and targets
8. Quality topics included in at least half of "all hands" meetings
9. Collecting Management Review Metrics
10. Collecting Employee Turn Over Rate Metrics



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Five Additional Mature Quality Attributes were identified


11. Program to show how employee's specific goals contribute to overall quality goals
12. Program to measure, share and discuss product quality performance and improvement from shop floor to executive management.
13. Continuous Improvement Program / Plans with active support of CEO and Corp Management of QMS
14. Program that establishes quality system maturity model and action plan and tracking to measure progress
15. Internal survey measuring a company/ site quality culture



Voted by ~225 Conference Participants, Dec 2014

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There are several existing quality maturity models



NACCHO

DuPont

ISO

ISPE


CEB

PwC

Crosby

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Quality Culture Attributes and Metrics in PDA Tool



Leadership Commitment

Communication & Collaboration

Employee Ownership and Engagement

Commitment to Quality
Accountability and Quality Planning

Enabling Capable Resources
Safety
Rewards and Recognition
Feedback & Staff Development

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

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

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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
<p>Impact on Product Quality</p> <ul style="list-style-type: none"> Associates <u>can't</u> clearly explain their role and impact on quality goal 	<ul style="list-style-type: none"> Associates <u>can</u> clearly explain what they have to get done, not necessarily what's <u>important to general quality</u> 	<ul style="list-style-type: none"> Associates can clearly explain what they have to get done and what the <u>critical process parameters</u> are 	<ul style="list-style-type: none"> Associates can clearly explain the specific <u>critical quality attributes</u>, their importance and <u>linkages</u> to the operations / processes they oversee 	<ul style="list-style-type: none"> Associates at all levels can explain <u>process capabilities</u> and their <u>impact</u> on specific product critical quality attributes
<p>Patient Impact</p> <ul style="list-style-type: none"> Associates <u>don't</u> understand how the product impacts the patients. (e.g. product indication, population) Management <u>doesn't</u> communicate how the product impacts patients 	<ul style="list-style-type: none"> Associates <u>understand</u> <u>how</u> the product is used in patients but <u>don't</u> understand how Quality impacts <u>clinical outcomes</u> Only <u>occasional</u> communication from Management on the importance of Quality and how that can affect patients 	<ul style="list-style-type: none"> Associates understand how the product is used in patients and how Quality impacts <u>clinical outcomes</u> Management <u>frequently</u> communicates in meetings and other forms of communication the importance of Quality and how that can affect patients 	<ul style="list-style-type: none"> Associates understand how the product is used in patients and <u>specific CQA</u> impact on clinical outcomes Management <u>regularly</u> communicates stories of how their work benefits patients in staff meeting and other means of communications such as email, videos, etc. 	<ul style="list-style-type: none"> 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

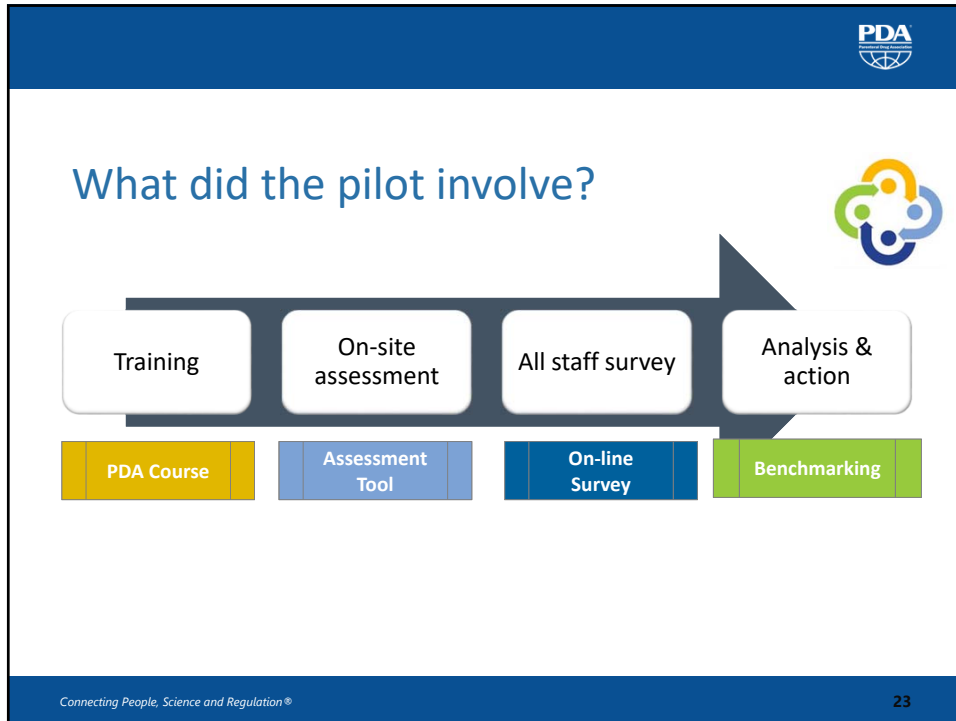
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Who participated in the pilot?

Pilot included 43 sites from 24 companies.

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- Goals defined for pilot were met!**
- Training readiness
 - Differentiability
 - Assessment tool & survey results alignment
 - Tool user-friendliness
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Feedback on the Assessment Tool

- The tool allows sites to assess quality culture in an organized way
- In-person discussions provides more value in understanding the culture at the site (vs. only a survey)
- Culture assessment without audit mindset encouraged openness
- Reliable way to help select partners and CMOs
- The tool is a roadmap for identifying ways to make continuous improvements

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PDA Quality Culture Assessment Tool has driven continuous improvement and proven valuable




Scientific

- Developed based on data
- Objective & verifiable
- Specific to pharma industry



ICH

- Based on ICH Q10 principals
- Other ICH guidance (Q8, 9, 11)
- Factors beyond GMP (rewards/recognition, safety culture)



Training

- Trained > 100 industry reps from >50 industry mfg sites
- Trained over 100 FDA and MHRA regulators

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Quality Culture Assessment Program

Course: Hands On Active Learning for 2 Assessors

Tool: Quantitative Assessment for 2 sites

Survey: Blinded, direct employee feedback, 2 sites

Benchmark: Compare against sites in Europe, North America, Asia



Sign Up Now at pda.org or contact David Talmage at Talmage@pda.org

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PDA Quality Culture Team

<p>Cylia Chen (Amgen) – team lead</p> <p>Steve Mendivil (Amgen)</p> <p>Machelle Eppler (Patheon)</p> <p>Pritesh Patel (Novartis)</p> <p>Sue Schniepp (Regulatory Compliance Associates)</p> <p>Chuck Bornhoeft (Upsher-Smith)</p> <p>Joerg Gampfer (Hovione)</p> <p>Dixie Webster (Allergan)</p>	<p>Matija Gabrovsek (Novartis)</p> <p>Brianna Peterson (BI)</p> <p>Jan Paul Zonnenberg (PwC)</p> <p>Sandra Lueken (MedImmune/AZ)</p> <p>Anne Eickhoff (GSK)</p> <p>Rick Burdick (consultant)</p> <p>Bob Kieffer (consultant)</p> <p>David Leuck (Patheon)</p>
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