



# Aspiring to Measure Quality Culture

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PDA Director of Science and Regulatory Affairs

**Pharmaceutical Quality Congress**  
**The Unintended Consequences of Quality**  
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# Parenteral Drug Association



- **Founded in 1946**
- **Mission:** To advance pharmaceutical and biopharmaceutical manufacturing science and regulation so members can better serve patients.
- **Science Based:** Science is the foundation of our organization. We utilize a scientific approach to meet challenges and continuously improve. It is not subjective or emotional, but rather a logical, open, rational and transparent process.

# Why Should I Focus on Quality Culture?



- *A company with a highly developed culture of quality spends, on average, **\$350 million** less annually fixing mistakes than a company with a poorly developed one.*

Harvard Business Review April 2014

- **Regulators are increasingly focused on quality culture** as they recognize its impact on the production of quality products.
- We have the privilege of **servicing patients**.

## Can you objectively measure Quality Culture?

- Quality Culture is a set of behaviors, beliefs, values, attitudes and governance (subjective)
- Mature Quality Attributes goes beyond Traditional Quality Systems to create a framework for a strong Quality Culture (objective)
- Hypothesis – Mature Quality Attributes have a strong relationship to positive Quality Culture behavior

Identify a set of Mature Quality Attributes that are a surrogate for Quality Culture Behaviors

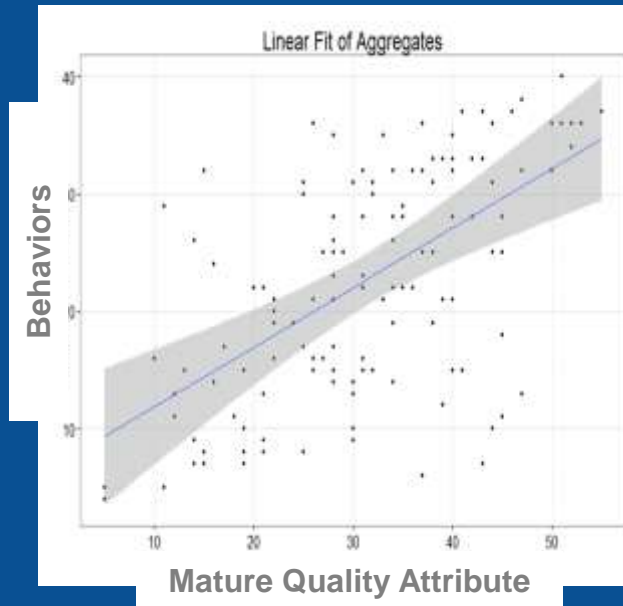
# Relationship established with Survey Results



## Behaviors

### 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



## Mature Quality Attributes

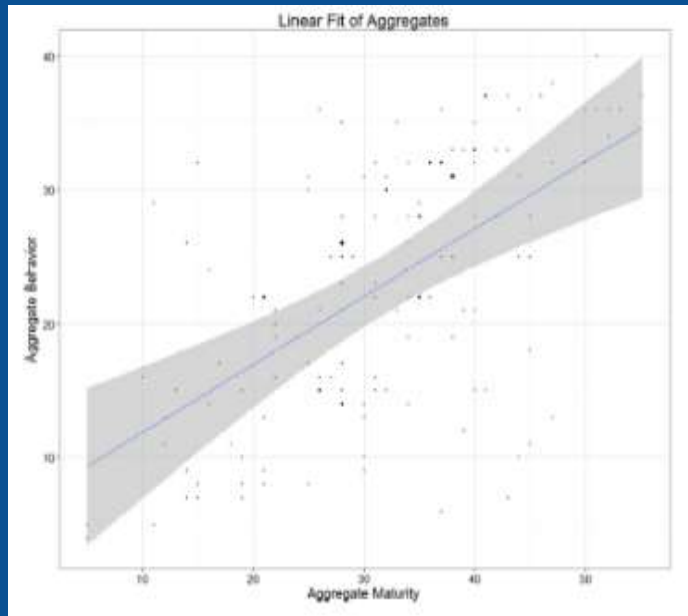
**Enhanced Quality Systems (Q8, 9, 10, 11)**  
Risk management, MR, QbD, etc.

**Other Systems**  
Quality goals, rewards & recognition, personnel development, etc.

Higher Quality Maturity is accompanied with Higher Quality Behavior.

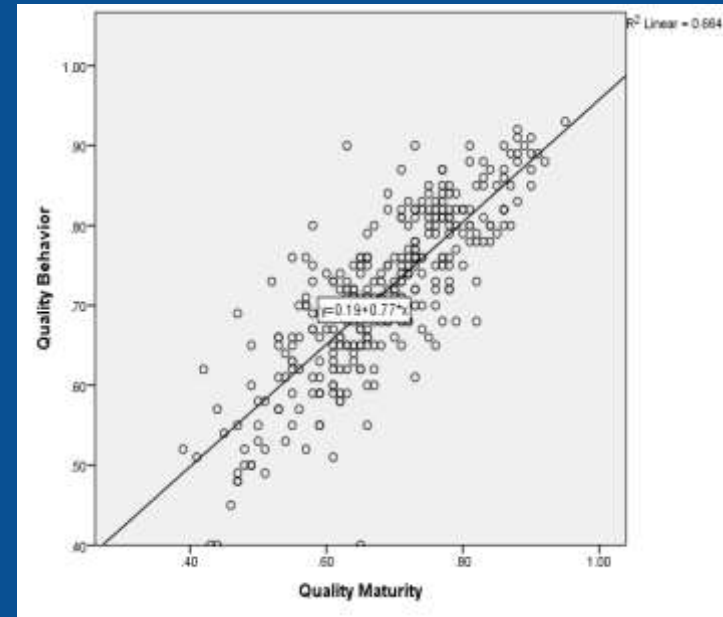
# St. Gallen confirms PDA's Survey Outcome

## PDA Survey Analysis 2014



$$R^2 = 0.34$$

## St. Gallen Analysis 2017



$$R^2 = 0.66$$

- 326 pharmaceutical sites of different size and focus within St. Gallen database confirm PDA
- 96% of variability of Quality Behavior can be explained by the Quality Maturity Attributes

# Quality Culture Model and Tool

- Objective June 2015
  - Develop a quality culture maturity model as an assessment tool to be used during audits
    - Simple
    - Objective and verifiable
- Pilot Launch May 2016
  - On-Site Self-Assessment Tool and Training
    - Internal Sites, Suppliers, CMOs
  - All Employee Survey
  - Pilot Data, Benchmarking, Feedback

# On-site assessment tool – 5 Categories



**Leadership  
Commitment**

**Communication  
& Collaboration**

**Employee  
Ownership**

**Continuous  
Improvement**

**Technical  
Excellence**



# On-site assessment tool – 12 Attributes



## Leadership Commitment

- 1. Leadership Commitment to Quality
- 2. Enabling Capable Resources

## Communication & Collaboration

- 3. Quality Communications
- 4. Collaboration with Auditors

## Employee Ownership

- 5. Understanding Quality Goals
- 6. Safety Culture

## Continuous Improvement

- 7. CAPA robustness
- 8. Management Review and Metrics
- 9. Clear Quality Objectives
- 10. Internal Stakeholder Feedback

## Technical Excellence

- 11. Utilization of new proven technologies
- 12. Maturity of Systems

# On-site assessment tool – 24 Sub Attributes



## Leadership Commitment

1. Leadership Commitment to Quality  
Accountability and Quality Planning
2. Enabling Capable Resources  
Feedback and Coaching  
Training & staff development  
Rewards and Recognition

## Communication & Collaboration

3. Quality Communications  
Quality Communications
4. Collaboration with Auditors  
Collaboration  
Operations Readiness &  
Knowledge Behaviors

## Employee Ownership

5. Understanding Quality Goals  
Impact on Product Quality  
Patient Impact
6. Safety Culture  
EHS Program  
Targets

## Continuous Improvement

7. CAPA robustness  
Root Cause  
Human Error
8. Management Review and Metrics  
Management Reviews  
Metrics
9. Clear Quality Objectives  
Continuous Improvement
10. Internal Stakeholder Feedback  
Internal Stakeholder Feedback  
Quality Culture Survey

## Technical Excellence

11. Utilization of new proven technologies  
Manufacturing Technologies  
New Technology
12. Maturity of Systems  
QMS Processes  
Maturity Model  
Responsibilities

# Sample of the PDA Quality Culture Tool

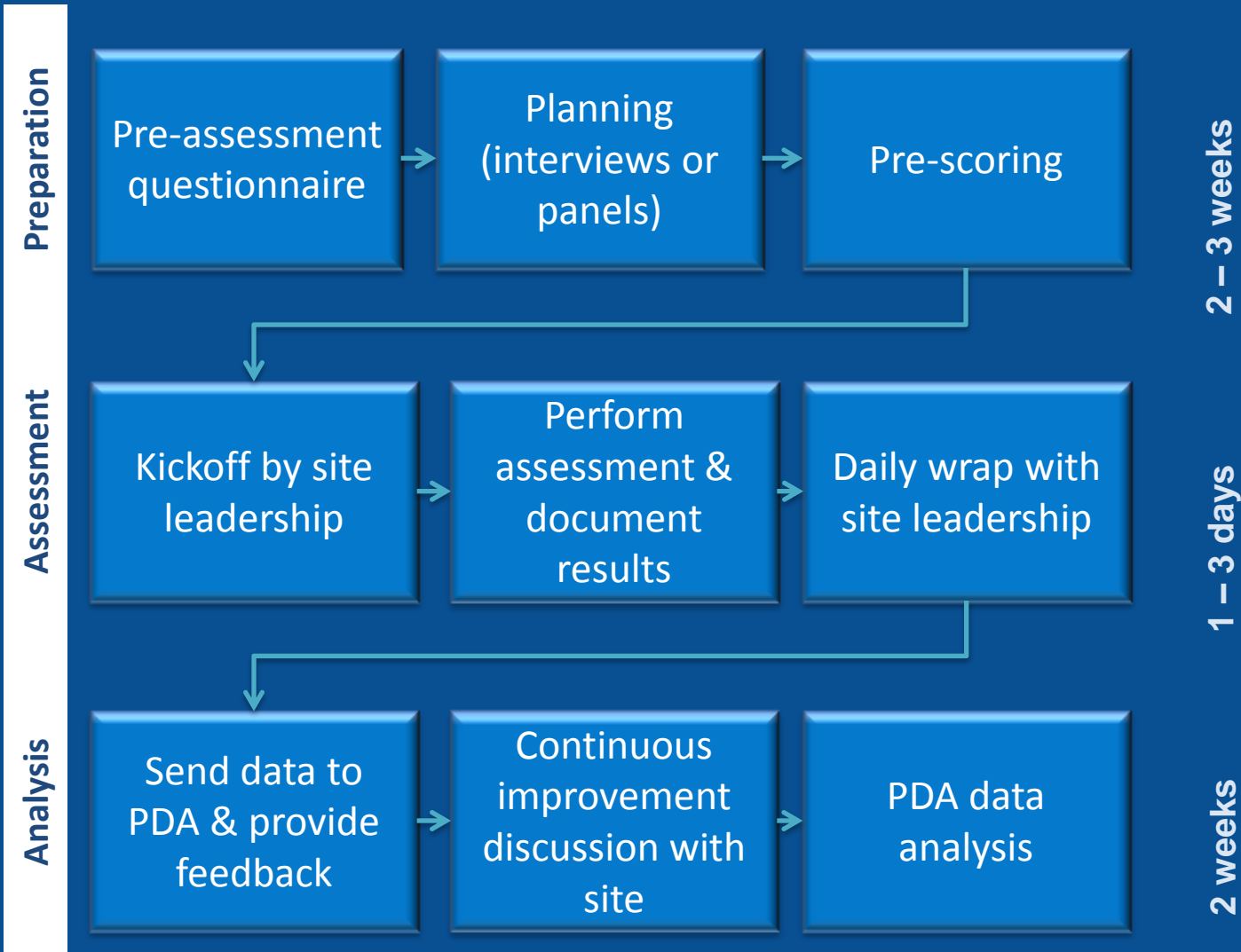


## 5. Understanding Quality Goals Impact on Product Quality Patient Impact

### Employee Ownership: Understanding Quality Goals

1	2	3	4	5
<p><b>Impact on Product Quality</b></p> <ul style="list-style-type: none"> <li>• Associates <u>can't</u> clearly explain their role and impact on quality goal</li> </ul>	<ul style="list-style-type: none"> <li>• Associates <u>can</u> clearly explain what they have to get done, not necessarily what's <u>important to general quality</u></li> </ul>	<ul style="list-style-type: none"> <li>• Associates can clearly explain what they have to get done and what the <u>critical process parameters</u> are</li> </ul>	<ul style="list-style-type: none"> <li>• Associates can clearly explain the specific <u>critical quality attributes</u>, their importance and <u>linkages</u> to the operations / processes they oversee</li> </ul>	<ul style="list-style-type: none"> <li>• Associates at all levels can explain <u>process capabilities</u> and their <u>impact</u> on specific product critical quality attributes</li> </ul>
<p><b>Patient Impact</b></p> <ul style="list-style-type: none"> <li>• Associates <u>don't understand</u> how the product impacts the patients. (e.g. product indication, population)</li> <li>• Management <u>doesn't communicate</u> how the product impacts patients</li> </ul>	<ul style="list-style-type: none"> <li>• Associates <u>understand</u> how the product is used in patients but <u>don't</u> understand how Quality impacts <u>clinical outcomes</u></li> <li>• Only <u>occasional communication</u> from Management on the importance of Quality and how that can affect patients</li> </ul>	<ul style="list-style-type: none"> <li>• Associates understand how the product is used in patients and how Quality impacts <u>clinical outcomes</u></li> <li>• Management <u>communicates frequently</u> in meetings and other forms of communication the importance of Quality and how that can affect patients</li> </ul>	<ul style="list-style-type: none"> <li>• Associates understand how the product is used in patients and <u>specific CQA</u> impact on clinical outcomes</li> <li>• 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.</li> </ul>	<ul style="list-style-type: none"> <li>• Associates understand the <u>patient expectations</u> and how product is used in patients and specific CQA impact on clinical outcomes</li> <li>• <u>Associates share with each other</u> the importance of Quality on clinical outcomes</li> </ul>

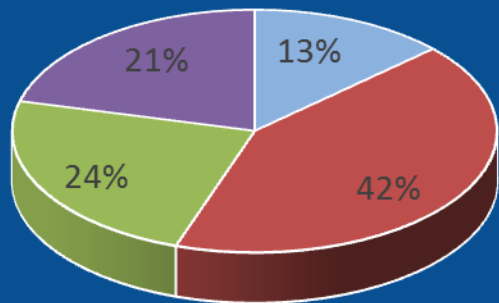
# Quality Culture Assessment Process



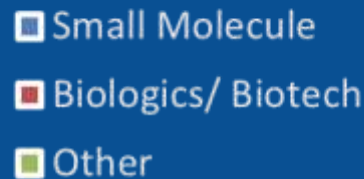
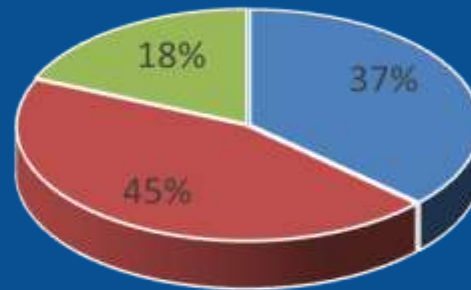
# Pilot Program Participants

A cross Section of the Pharma Industry:  
~40 sites from 20 firms, 64 assessors

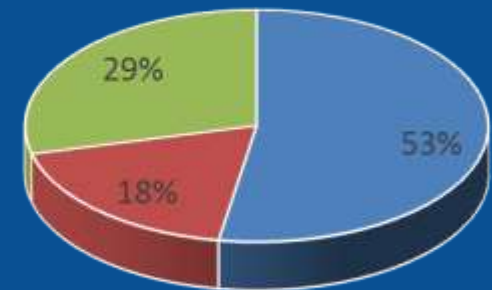
Business Function



Product Class



Site Locations



# Feedback from participants



- Quality culture assessment without audit mindset **encouraged openness**
- The tool provided **clear framework** and scoring method
- Enable firms to follow a **structured way** to assess quality culture
- Tool is valuable to **align expectations** between CMO and firms
- Tool provides **roadmap for improvement**

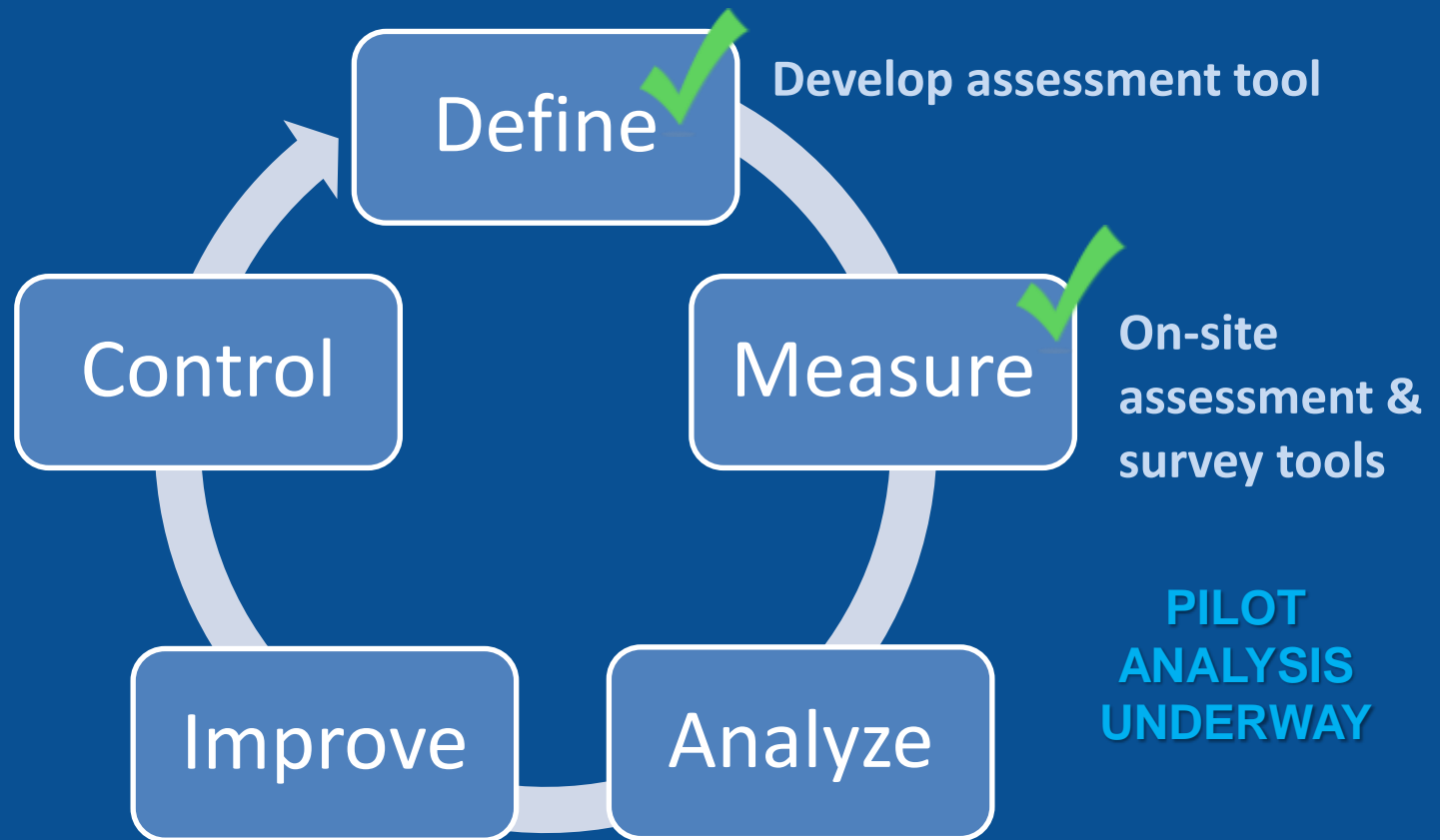
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# Lessons Learned Through The Pilot

- **Site leadership** to set expectation of the assessment
- Differentiate the quality culture **assessment vs. GMP audit**
- Advance **planning** is key!
- **Assessor's skill** sets the tone
- **Survey Translation** for sites that don't speak English
- Best to have **more than one** assessor at the site



# Where is PDA in the Quality Culture Program?





- Wrap up pilot and present findings at September PDA/FDA Joint Conference
- Launch tool Q4 2017
- PDA database with assessment data for benchmarking
- Expand assessment tool for suppliers and corporate functions
- Workshop/Users Group for sharing practical experiences in driving improvement using the tool.



# PDA Quality Culture Team

Cylia Chen (Amgen) – Team Lead

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