

# PDA Quality Culture Program Overview

**Are you ready to assess your site's quality culture?**

Cylia Chen, PDA Quality Culture team

PDA SoCal Chapter

Nov. 2016

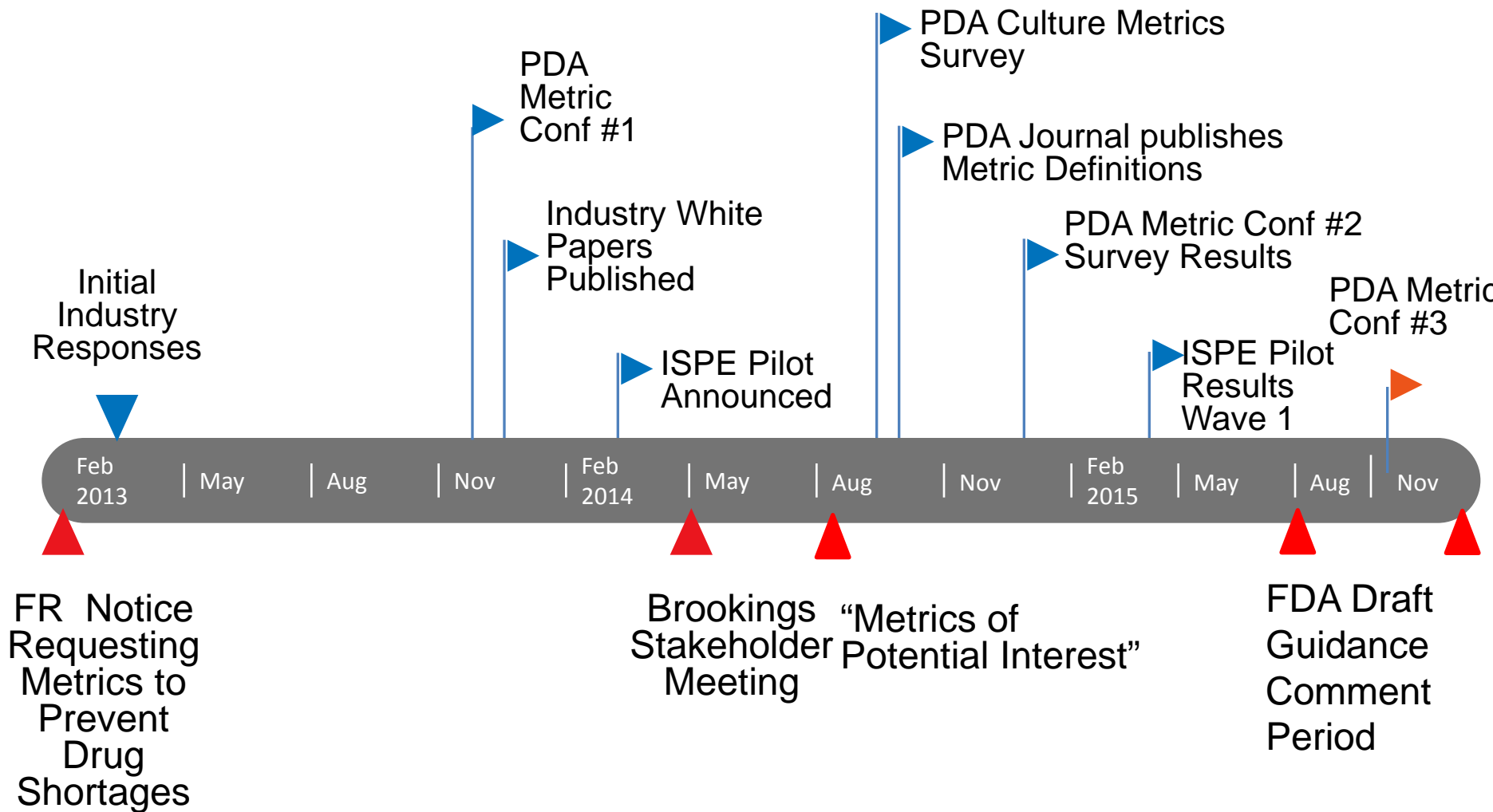
# What is FDA (and industry) Striving for?

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

Janet Woodcock, October 5, 2005

This is driving a number of changes in CDER

# FDA Metrics Journey 2013- 2015



# What is quality culture?

The **behaviors** and **beliefs** characteristic of a particular social group. (Webster's dictionary)

Culture/values indicate what is important to the enterprise, thus, impacts their decision making

The importance of culture:

- The root cause of many of quality problems.
- Essential for continuous improvement of the quality systems.

# PDA's Program to Enhance Quality Culture

## Vision / 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.

# 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?



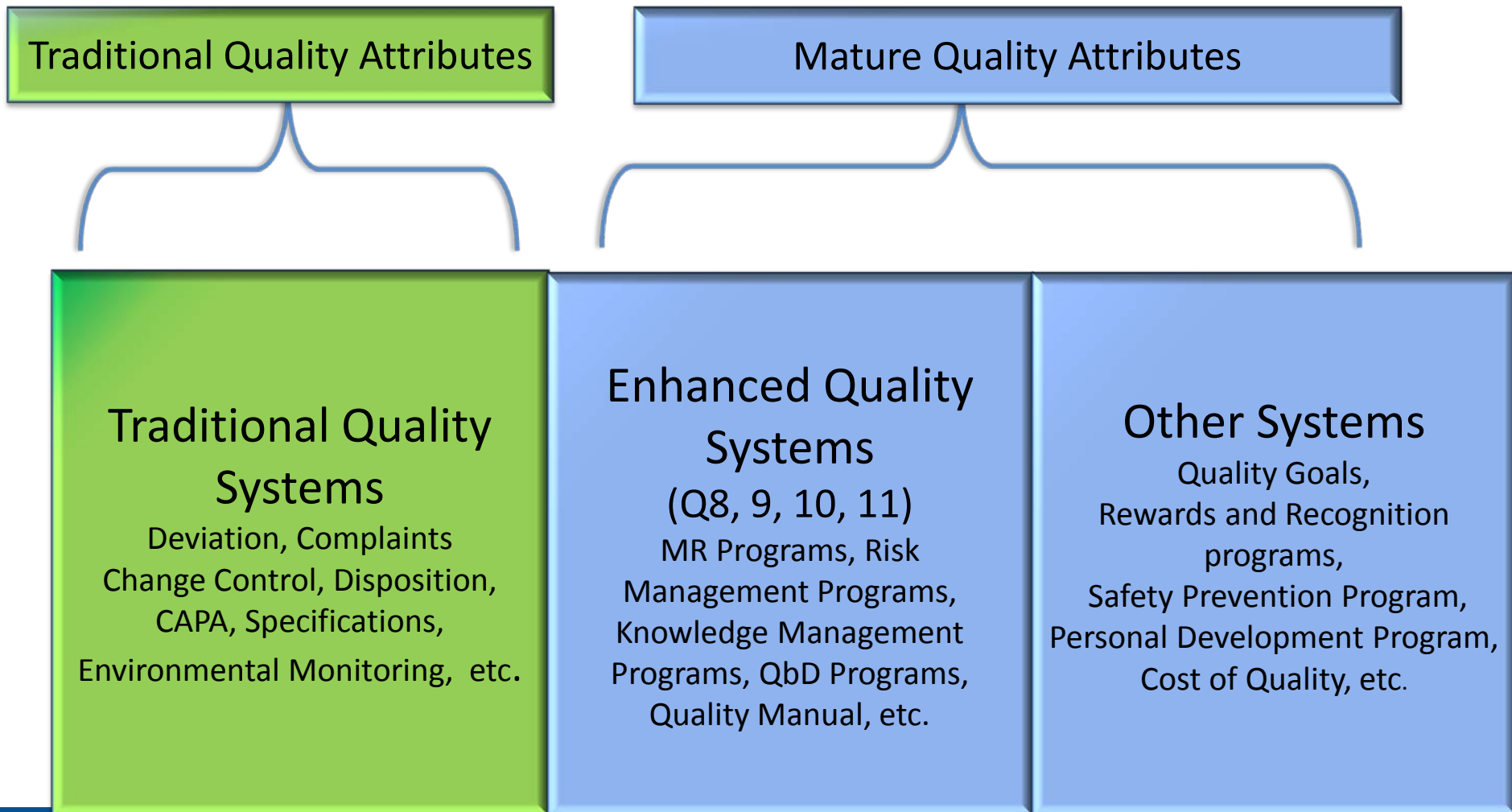
# PDA's Quality Culture Survey Conducted

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



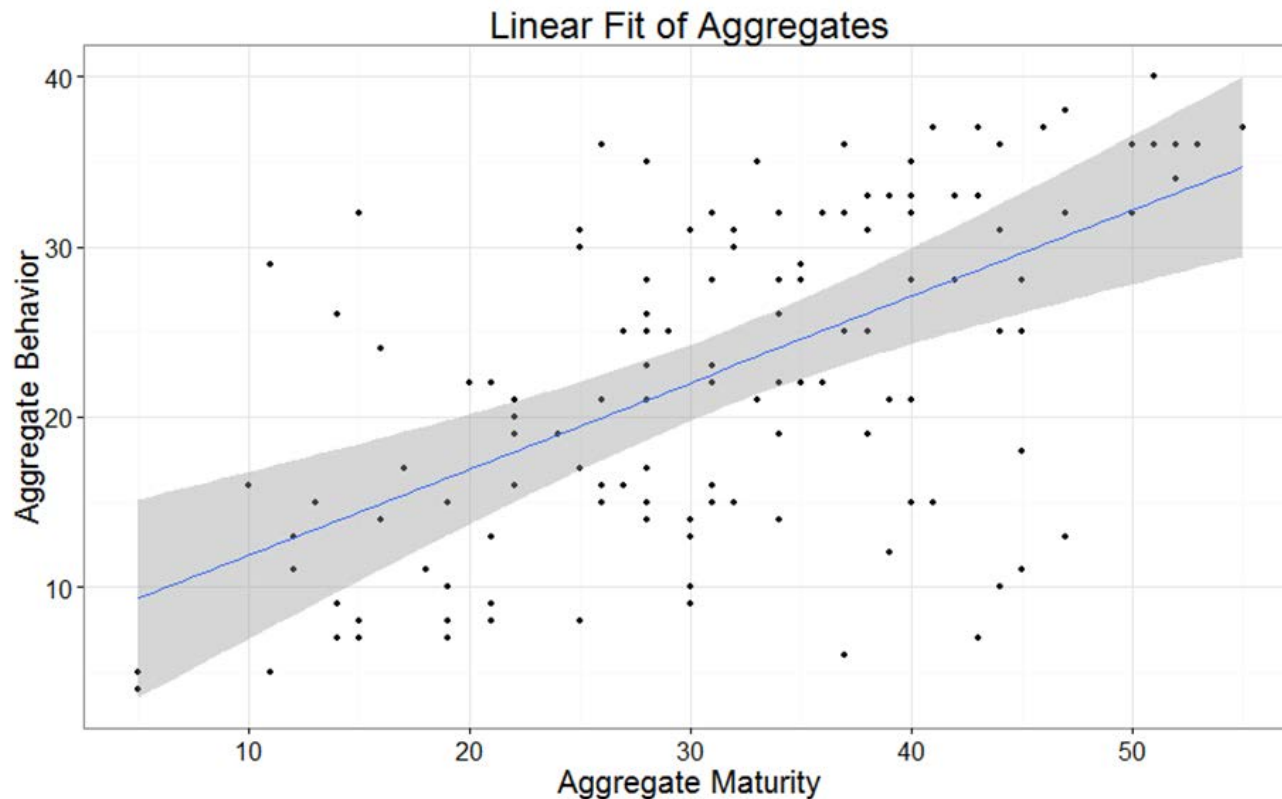
137 Global Responses Received from the Survey

# Section C: Mature Quality Attributes





# Is our hypothesis confirmed?



Higher MQA score the higher the behavioral score

Given this is a Social Science Analysis, this is a strong relationship

PDA Quality Culture Survey analysis  
<http://journal.pda.org/content/69/5/631.full.pdf+html?sid=1d68365b-c441-4c68-943f-eb0f39ce084e>

**Yes! There is a relationship between Quality Culture Behavior and Mature Quality Attribute**

# 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



# Five Additional Mature Quality Attributes

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*



**Leadership  
Commitment**

**Communication  
& Collaboration**

**Employee  
Ownership**

**Continuous  
Improvement**

**Technical  
Excellence**

## 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

## Leadership Commitment

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

## 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

## 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  
EH&S Program  
Targets

## Technical Excellence

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

## Example of Employee Ownership

### 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 how</u> the product is used in patients but <u>don't understand</u> 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 communicates <u>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>

**Goal of pilot:** obtain hands on experience with assessment tools and collect feedback to improve and ensure readiness for launch

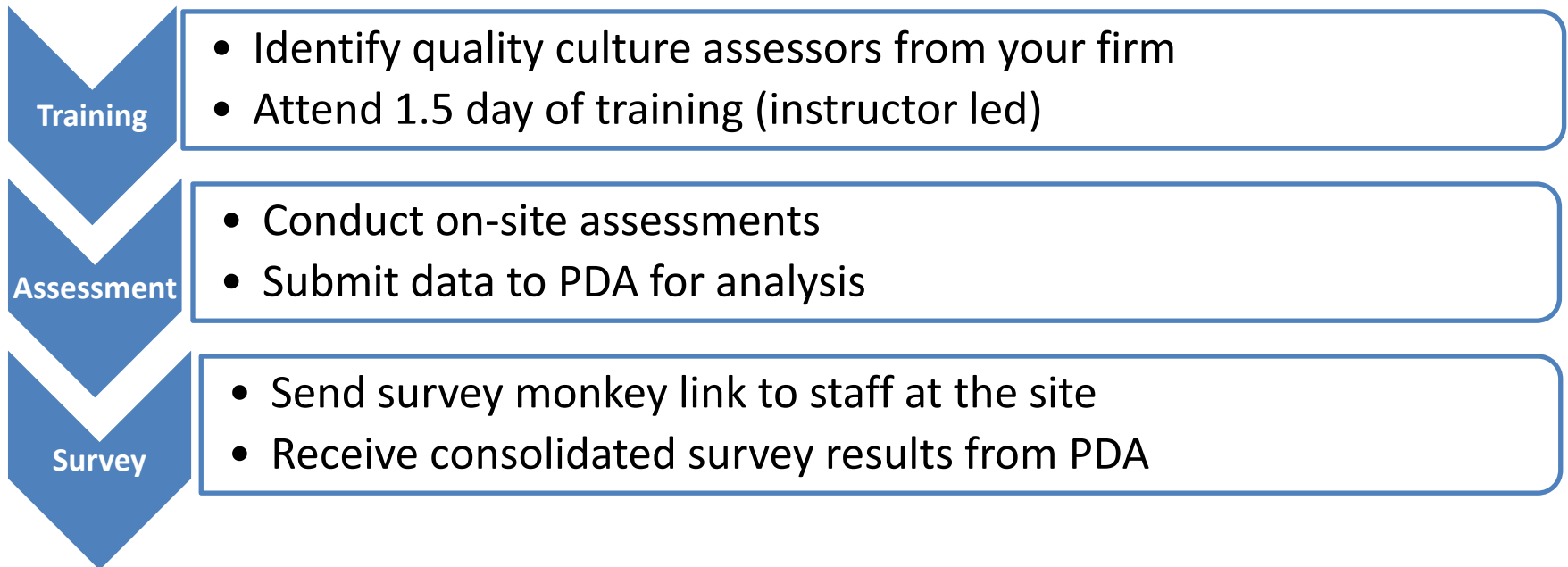
- Total of 20 firms to participate
  - minimum 2 sites where assessment will be conducted
- PDA will analyze results and provide aggregate data to pilot participants

**Success criteria:**

- No major gaps identified based on participants feedback



## What does the pilot entail for participants?



## Why Should I Participate in the Pilot?

Provide your input to both regulators and industry on how quality culture can be best assessed

Test this unique tool that is specific to pharma industry and understand your site's quality culture maturity

The tool can serve as a framework and guide for improvement towards higher quality culture maturity

# Timeline

Activities	Target completion date
Finalize assessment tool and survey	March 31 2016
Confirmation of pilot participants	March - June 2016
First training (sandbox testing)	May 16 - 17
First execution	May/ June
Lessons learned from beta testing	Beginning of July
Kickoff meeting with remaining participants & training	Q2 2016 – Q1 2017
Pilot execution	May 2016 – June 2017
Read out meeting (focus groups)	July – June 2017
Data analysis	Q3 – Q4 2017

# We are looking for more participants in the pilot!

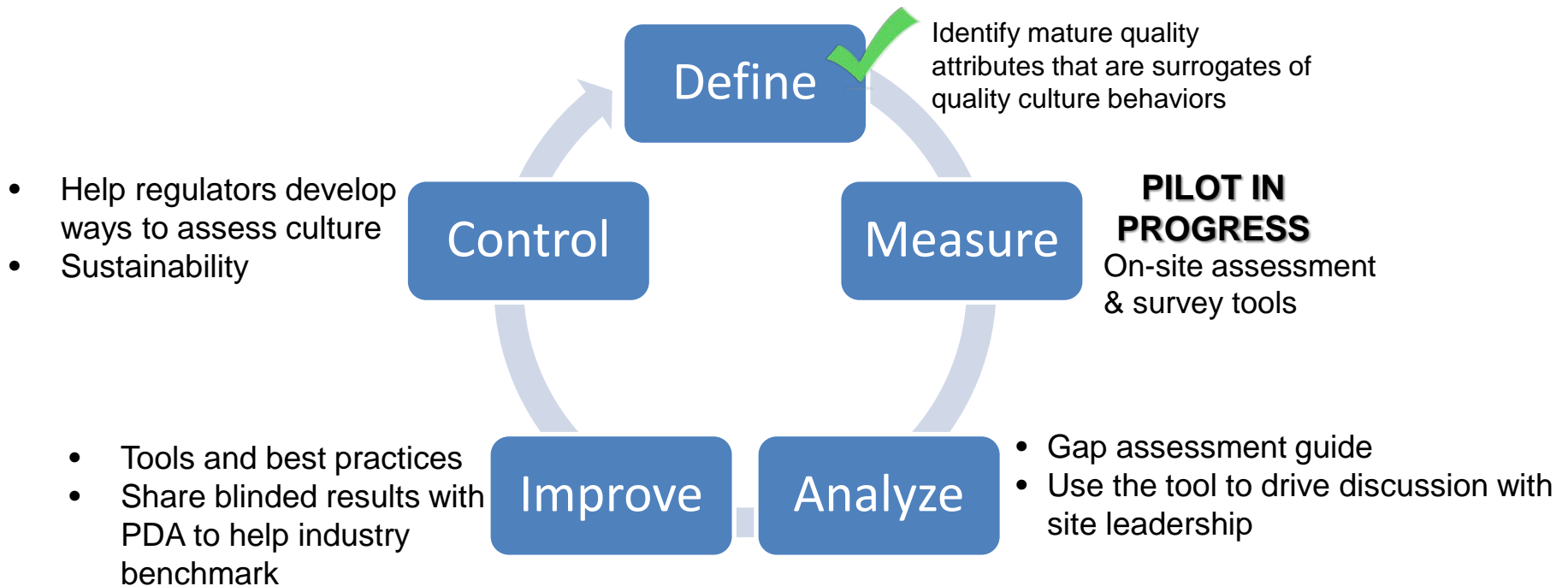
- More firms
- Sites in more geographical locations



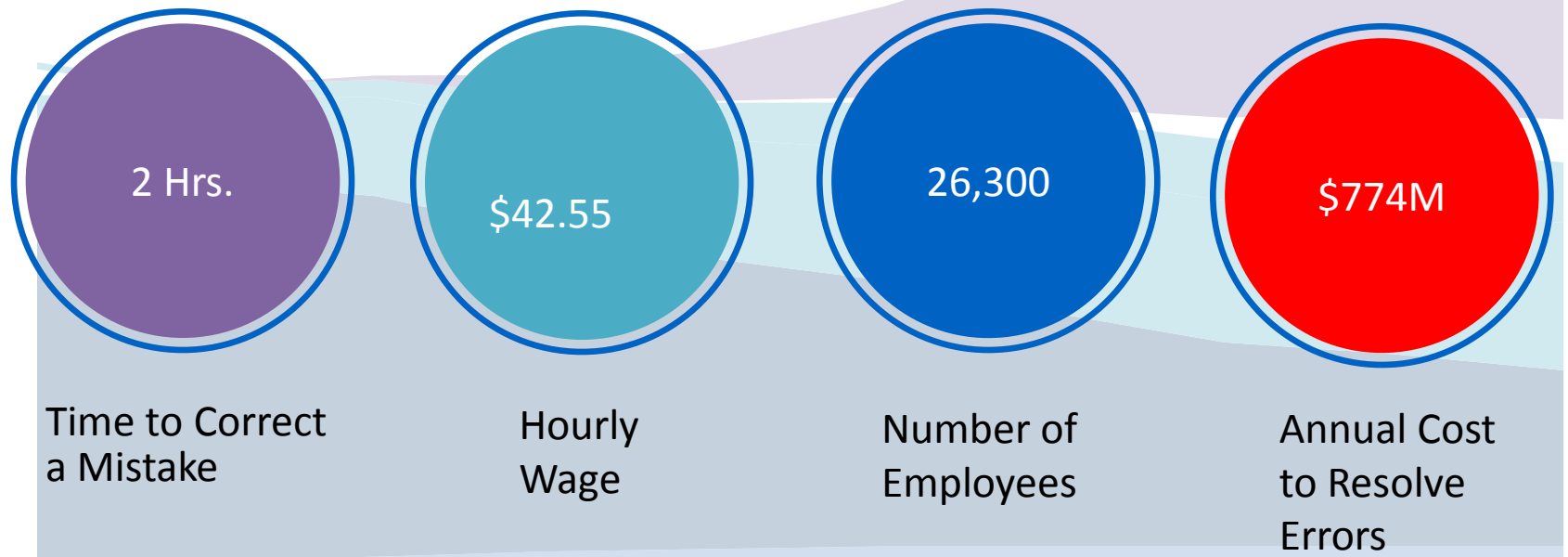
Upcoming training session (Last one!)

- Jan. in Southern California

# Future Aspirations



# The Business Benefits



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

# PDA Quality Culture Team

**Cylia Chen (Amgen) – team lead**

Steve Mendivil (Amgen)

Machelle Eppler (Patheon)

Pritesh Patel (Novartis)

Sue Schniepp (Regulatory Compliance Associates)

Chuck Bornhoeft (Upshire Smith Lab)

Anne Eickhoff (GSK)

Matija Gabrovsek (Novartis)

Joseph Kuntz (Pfizer)

Briana Peterson (BI)

Jan Paul Zonnenberg (PwC)

Sandra Lueken (MedImmune/AZ)

Tara Goen (FDA)

Gerald Heddell (MHRA)

**PDA Staff:** Denyse Baker, Rich Levy

Special thanks to Robert Kieffer

backup



# There are several existing quality maturity models

FOUNDATIONAL ELEMENT	SUB-ELEMENT
1. Employee Empowerment	1.1 Enabling Performance
	1.2 Knowledge, Skills and Abilities
2. Teamwork and Collaboration	2.1 Team Performance
	2.2 Learning Communities
3. Leadership	3.1 Planning and Structure
	3.2 Understanding the Customer
4. Customer Focus	4.1 Satisfying the Customer through the Value Chain
	4.2 Reprioritizing and Creating Programs and Services
5. Quality Improvement Infrastructure	5.1 Strategic Planning
	5.2 Systems

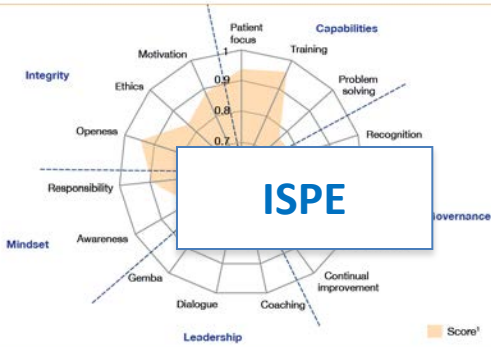
**NACCHO**

**DuPont**

Key element	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
How are results achieved? (Monitoring & measurement)	Results are achieved in a random manner. Corrective actions are <i>ad hoc</i> .	Some predicted results are achieved. Corrective and preventive actions are performed in a systematic way.	Predicted results are achieved, especially for identified interested parties. There is consistent use of monitoring, measurement and improvement.	There are consistent, positive, predicted results, with sustainable trends. Improvements and innovations are performed in a systematic way.	The achieved results are above the sector averages for the organization, and are maintained in the long term. There is implementation of improvement and innovation throughout the organization.
How are results monitored? (Monitoring & measurement)	Financial, commercial and productivity indicators are in place.	Customer satisfaction realization of the performance suppliers are	Key performance indicators are aligned with the organization's strategy and are used for monitoring.	Key performance indicators are aligned with the organization's strategy and are used for monitoring.	Key performance indicators are integrated into the real-time monitoring of all processes, and performance is efficiently communicated to relevant interested parties.
How are improvement priorities decided? (Improvement, innovation & learning)	Improvement priorities are based on errors, complaints or financial criteria.	Improvement priorities are based on customer satisfaction data, or corrective and preventive actions.	Improvement priorities are based on the needs and expectations of some interested parties, as well as those of suppliers and the organization's people.	Improvement priorities are based on trends and inputs from other interested parties, as well as analysis of social, environmental and economic changes.	Improvement priorities are based on inputs from emerging interested parties.
How does learning occur? (Improvement, innovation & learning)	Learning occurs randomly, at an individual level.	There is systematic learning from the organization's successes and failures.	A systematic and shared learning process is implemented in the organization.	There is a culture of learning and sharing in the organization that is harnessed for continual improvement.	The organization's processes for learning are shared with relevant interested parties, and support creativity and innovation.

highest level achieved up to that point with no preceding gaps in the criteria.

### 12 Quality Culture Attributes (& Maturity Matrix)



- Employee Ownership**
    - Clearly understand quality fit with job
    - Empowered to make quality decisions
    - Communicate quality violations
    - Communicate directives for better quality
  - Leadership Emphasis on Quality**
    - Told that quality is a leadership priority
    - Manager "walks the talk" on quality
    - Manager emphasize quality's importance
- CEB**

Measurement Categories	Crosby Maturity Grid				
	Stage 1: Uncertainty	Stage 2: Awakening	Stage 3: Enlightenment	Stage 4: Wisdom	Stage 5: Certainty
Management Understanding and Attitude	No comprehension of quality as a management tool. Tend to focus on cost.	Recognizing that quality management may be of value but unwilling to provide resources.	While going through quality improvement program learn more about quality management.	Participating, understand absolutes of quality management. Recognize their role in continuing emphasis	Consider quality management as an essential part of company system
Quality Culture	Quality is an afterthought.	Quality is a goal.	Quality is a management philosophy.	Quality manager is an officer of the company, effective status reporting and preventive action. Involved with customer affairs and special assignments.	Quality manager on board of directors. Prevention is main concern. Quality is a thought leader.
Problem Handling	Problems are fought as they occur, no resolution, inadequate definition, yelling and accusations	Teams are set up to solve problems. Long range solutions are most solicited	Corrective action communication established. Problems are faced and resolved in an orderly way	Problems are identified early in their development. All functions are open to suggestion and improvement	Except in the most unusual cases, problems are prevented
Quality Improvement Actions	No organized activities. No understanding of such activities	Trying obvious "motivational" short-range efforts	Implementation of multi-step program. With a thorough understanding and establishment of each step	Continuing the multi-step program and starting other proactive/preventative product quality initiatives	Quality improvement is a normal and continued activity
Company Quality Posture	"We don't know why we have quality problems"	"Is it absolutely necessary to always have problems with quality?"	"Through management commitment and quality improvement we are identifying and resolving our problems"	"Defect prevention is a routine part of our operation"	"We know why we do not have problems with quality"

**Crosby**