PDA Quality Culture Assessment Training

April 2018

Introduction & Icebreaker

- Tell us about yourself
- Describe your experience with quality culture
- What do you want to get out of this training?

- What is your aviator call sign or nickname?

Agenda Day 1

Agenda Topics	Duration
Welcome & icebreaker (breakfast)	9 — 9:30
Vision & Background	9:30 —10
Break	10 – 10:30
Group Exercise	10:30 – 11:30
Audit Logistics and Tools	11:30 – 12
Lunch	12 – 13:00
Intro to Case Study and Mock Assessment	13:00 – 13:30

Mock Assessment
• Employee Ownership and Engagement
  • Understanding quality goals
  • Staff Empowerment and Engagement
• Continuous Improvement
  • CAPA Robustness
  • Clear Quality Objectives
• Technical Excellence
  • Utilization of new technologies
  • Maturity of systems
	13:30- 17:00
	(break 20 mins)

Team dinner	18:00

Agenda Day 2

Agenda Topics	Duration
Case Study Assessment Continues •Leadership Commitment • Commitment to Quality • Enabling Resources •Quality Communication and Collaboration • Quality Communications • Management Review and Metrics • Internal Stakeholder Feedback • Collaboration with Assessors *(optional)*	• 8:30 – 12:00 • (break 20 mins)
• Lunch	• 12 – 13:00
• Characteristics of a Successful Assessor	• 13:00 – 13:30
• Learning from Previous Site Participants – Understanding Scores	• 13:30 – 14:30
• Getting Site Management Involved and Setting Expectations	• 14:30 – 15:00
• Wrap Up -- Feedback	• 15:00 – 15:30

Goals of the training

- Aligned understanding of the Quality Culture Assessment Program
- Understand the assessment process & your role as assessors
- Understand scoring and reporting of assessment results
- Prepare for a successful site assessment
- To have fun and connect with new colleagues

What is Quality Culture?

- "True Quality Culture – 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."
- "A culture in which employees "live" quality ….. as a personal value rather than simply obeying an edict from on high"

"Roughly 60% said they work in an environment without a culture of quality, especially when it comes to having peers who go above and beyond"

From **Harvard Business Review April 2014**: Creating a Culture of Quality. Ashwin Srinivasan and Bryan Kurey of CEB

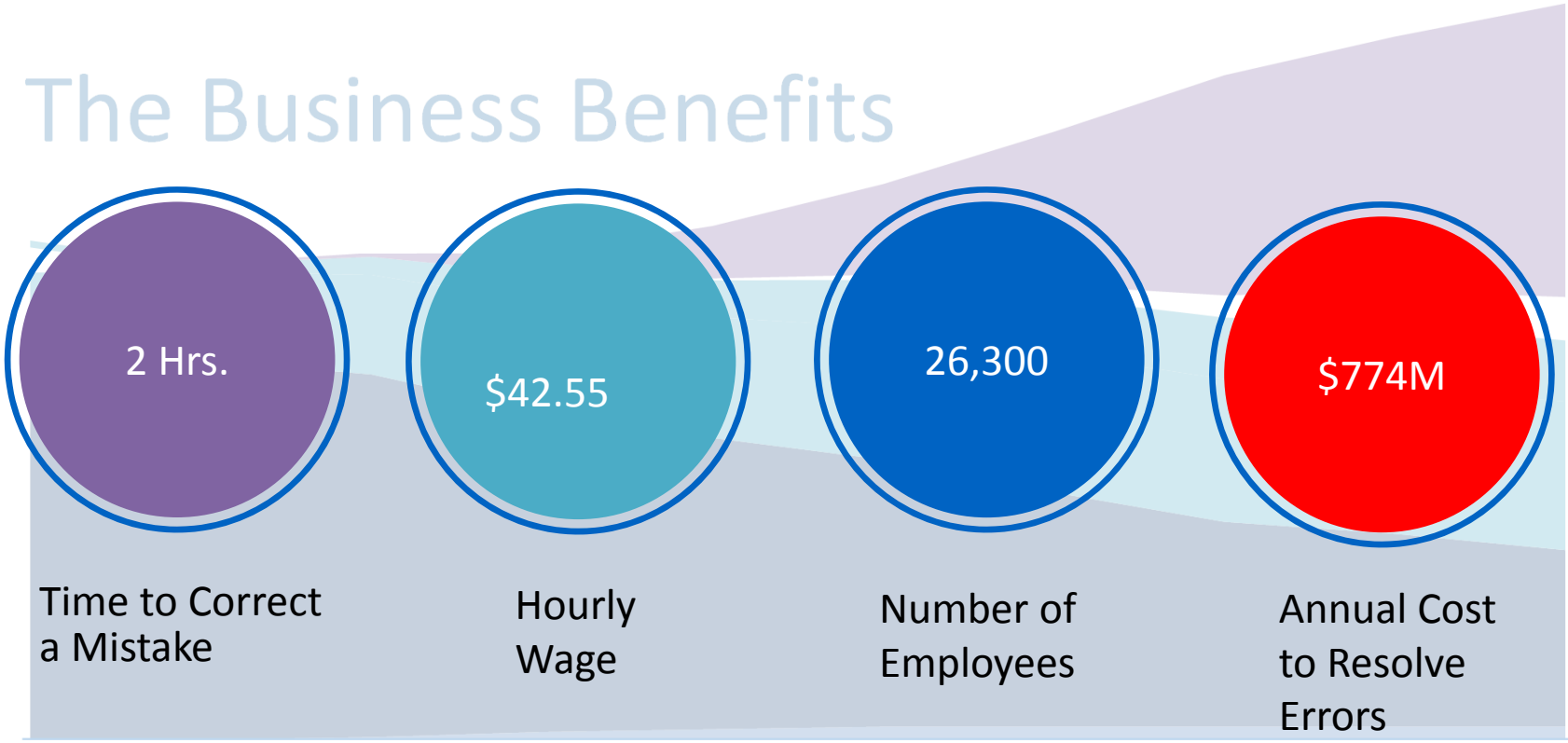
Quality Culture is:

- A set of “behaviors, beliefs, and values” of a particular enterprise, impacting their decisions.
- Is the root cause of many quality problems
- Essential for continuous improvement of quality systems

Companies ranked in the top 20% in terms of quality culture reported 46% fewer mistakes in their daily work resulting in a saving of $67M per 5K employees

From **Harvard Business Review April 2014**: Creating a Culture of Quality. Ashwin Srinivasan and Bryan Kurey of CEB

The Business Benefits



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

Culture is not the culprit

Culture is not something you "fix", cultural change is what you get after you put in new processes or structures in place.

Makes intuitive sense to look at culture as an outcome – not a cause or a fix.

Reworking fundamental practices will inevitably lead to some new values and behaviors.

Harvard Business Review April 2016 – Change management "Culture is not the culprit"

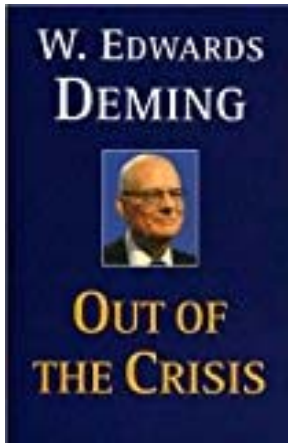
PDA Task Force Vision and Background

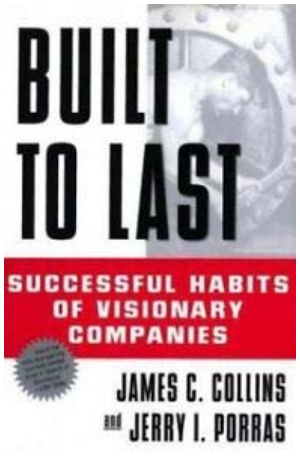
PDA's Program to Enhance Quality Culture

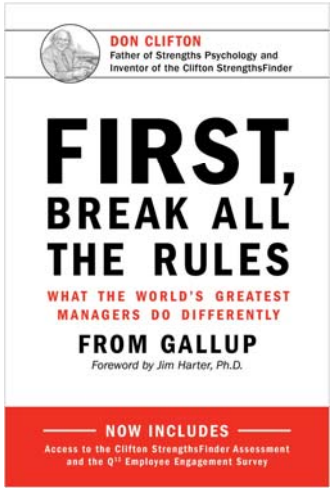
Vision / Mission:

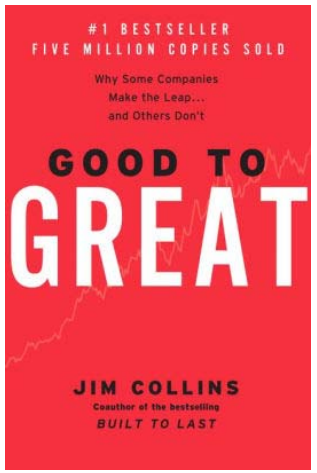
Promote Quality Culture, its understanding, assessment and improvement within the Pharmaceutical / Biopharmaceutical Industry by providing tools and knowledge to enable continuous improvement. The ideal state is to ensure a quality mindset and behaviors are imbedded into the daily work of all functions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

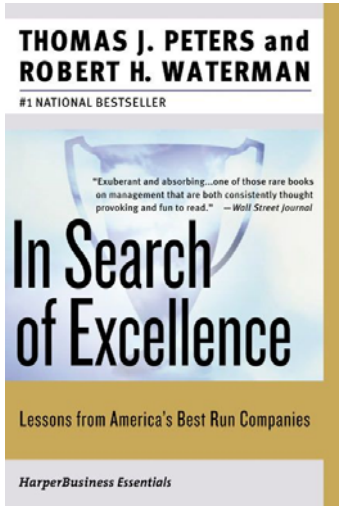
In 80's & 90's Business Focused on Tools and Strategies

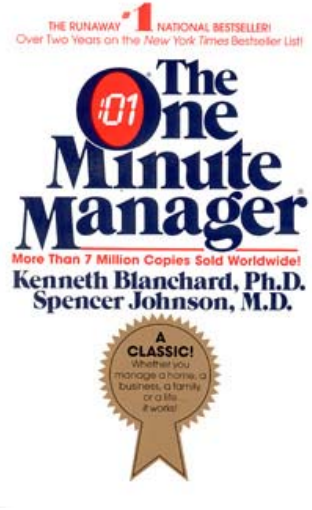


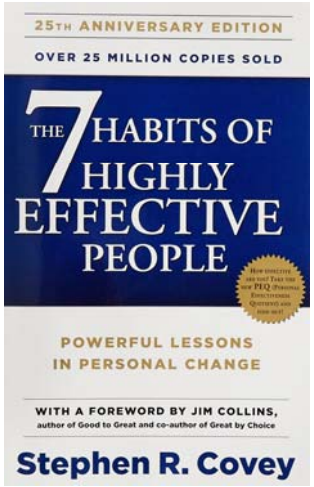


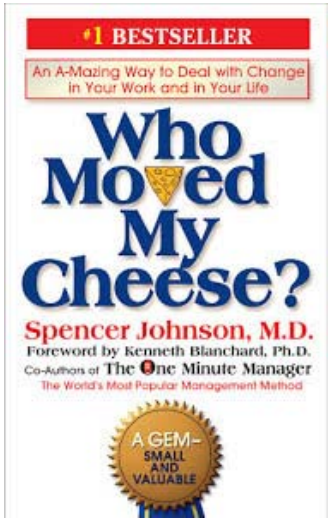




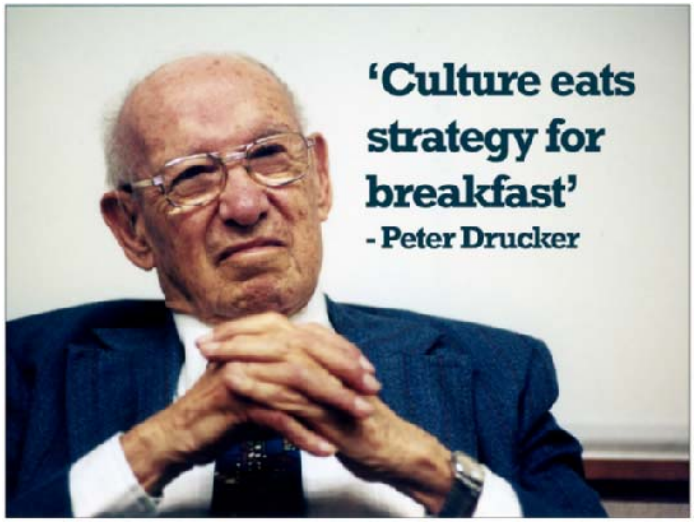


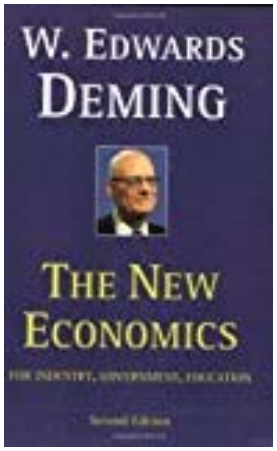


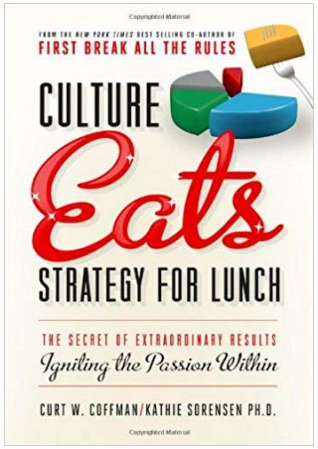


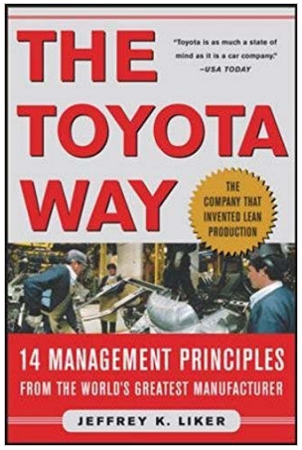


2000's The Importance of Culture was Realized





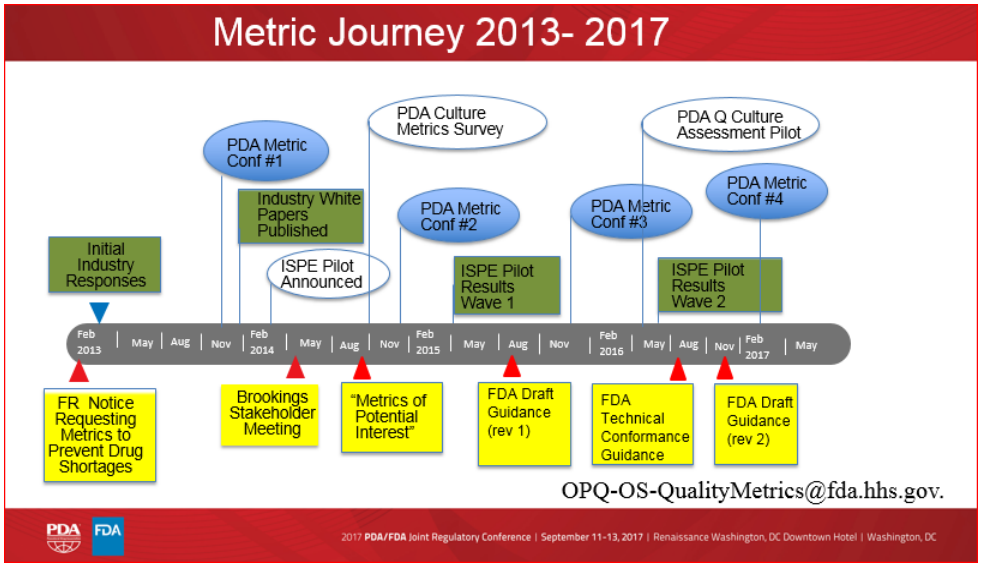


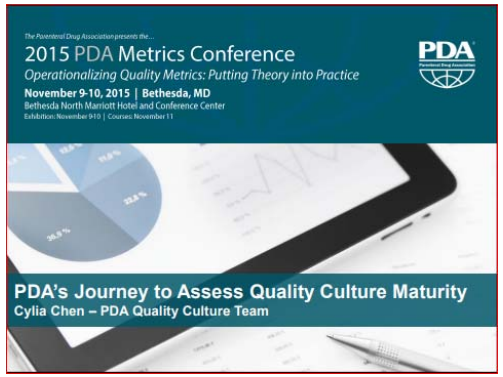


Why the focus on Quality Culture now?

- Pharmaceutical Industry is finally realizing what other industries have known about root cause of human errors and continuous improvement.
- Quality Metric programs must be balance with strong Quality Culture to be valuable

PDA's Journey to Quality Culture





The importance of Quality Culture was Clear after first PDA Metric Conf (2013)

Can you objectively measure Quality Culture?

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

1. Is there a relationship between Desired Behavior scores and Mature Quality Attribute scores?
2. Which Mature Quality Attributes have the strongest relationship to Desired Behavior?

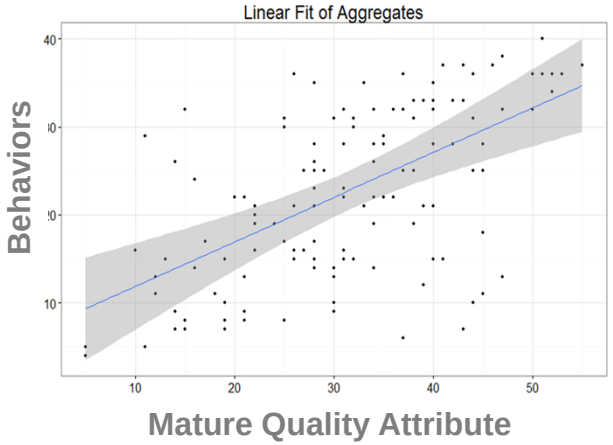
Is it possible to measure quality culture?

42 Behaviors

Seven Areas of Behavior Questions

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

Relationship established!



55 Mature quality attributes

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 objective measures for quality culture behaviors were identified

Higher Quality Maturity is accompanied with Higher Quality Behavior

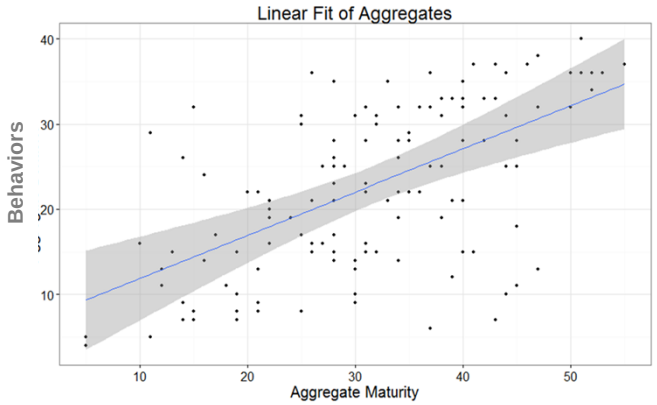
St. Gallen confirms PDA's Quality Culture Survey outcome

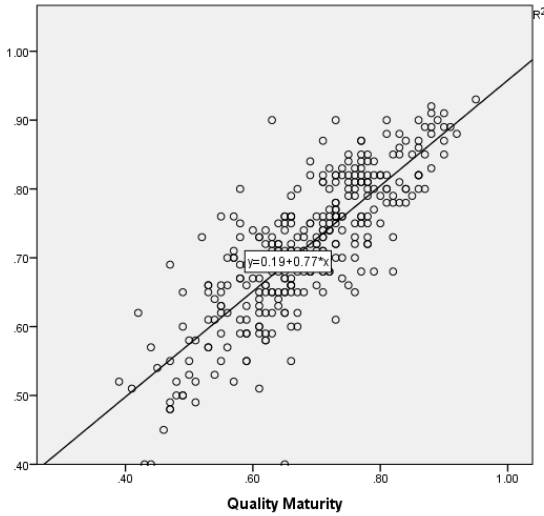
PDA Survey Analysis 2014

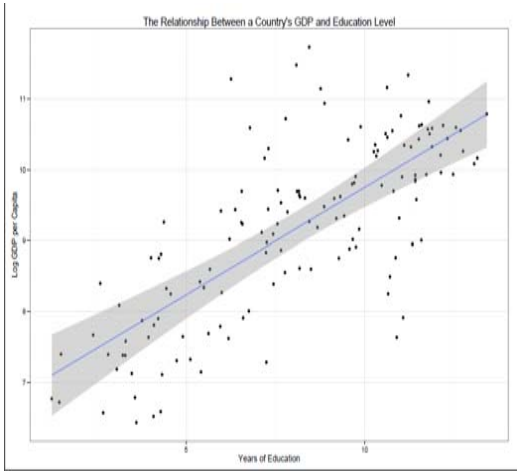
St. Gallen Analysis 2017

Social Science Analysis

Education vs. Income







$R^2 = 0.34$ → $R^2 = 0.66$

- 326 pharmaceutical sites 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

There are several existing quality maturity models

Analysis

FOUNDATIONAL ELEMENT	SUB-ELEMENT
1. Employee Empowerment	1.1 Enabling Performan
	1.2 Knowledge, Skills ar
2. Teamwork and Collaboration	2.1 Team Performance
	2.2 Learning Communit
3. L	
4. C	cing and Stru
	standing the
	4.2 Satisfying the Custo
	4.3 Reprioritizing and C
5. Quality Improvement Infrastructure	5.1 Strategic Planning

NACCHO

Leadership

Safety-oriented leaders demonstrate a visible commitment; embrace clear, meaningful policies and principles; challenge all goals and plans from a safety perspective; and demand high standards of performance. **The survey's Leadership questions relate to**:

- the priority individuals give to safety
- the priority respondents think others give to safety
- the extent that safety is built in
- the presence and influence of safety values
- the extent line management is held accountable for safety
- involvement in safety activities
- the extent safety rules are enforced
- recognition for safety achievements

Structure

The structure element of safety management requires line management which is accountable, a supportive safety staff, an integrated committee structure, performance measurement and progressive motivation. **The survey's Str**

- the belief that injuries can
- the effect of a drive for sa
- the level of safety where t
- the quality of safety rules
- knowledge of safety perfo
- rating of the safety organi
- rating of the safety depart
- satisfaction with the safety performance of the organization

DuPont

Processes and Actions

ment of safety management requires thorough investigations and
luation, effective communication processes, and safety management
Actions questions relate to:

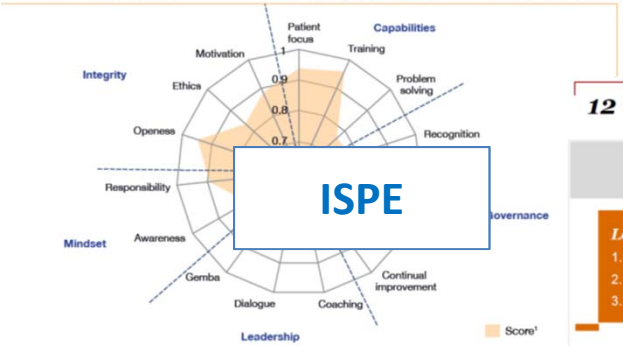
wered to take action in safety

ty meetings

ey element	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
results d? ring & ement)	Results are achieved in a random manner. Corrective actions are ad hoc.	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 average for the organization, and are maintained in the long term. There is implementation of improvement and innovation throughout the organization.
results ed? ring & ement)	Financial, commercial and productivity indicators are in place.	Customer sa realization pr the performa suppliers are	f the ple and es is	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.
improvement s decided? ement, ion & 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.
es learning ement, ion & 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.

ISO



ISPE

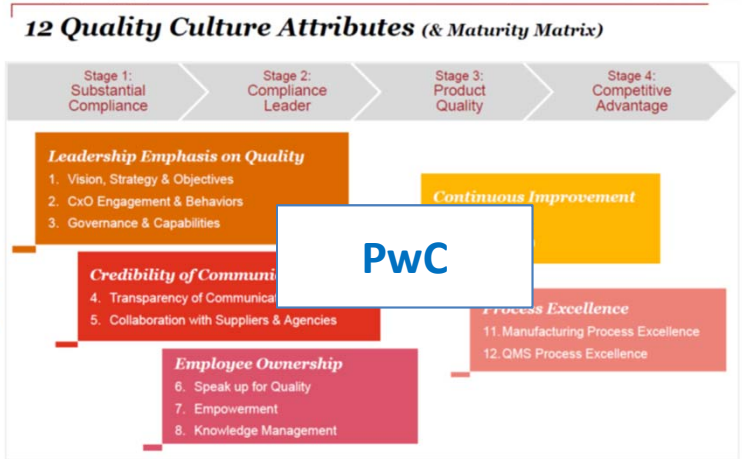
Employee Ownership

- Clearly understand quality fit with job
- Empowered to make quality decisions
- Com
  conc
  viola
- Com
  directives for better quality

Leadership Emphasis

- Told that quality is a leadership priority
- Manager "walks the on quality
  anager emphasize
  uality's importance

CEB



PwC

understand.
- Easy to make sense of leadership priorities

involved in quality efforts.
- Peers are held accountable for quality performance.

Crosby Maturity Grid

Measurement Categories	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	Recognizing that quality management may be of value but not willing to provide	While going through quality improvement program learn more about quality	Participating, understand absolutes of quality management. Recognize their role in continuing emphasis	Consider quality management as an essential part of company system
Quality	of organization. Emphasis on appraisal and sorting	of manufacturing or other	management of company	Quality manager is an officer of 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 attack major problems. Long range solutions are not solicited	Corrective action communication established. Problems are faced openly 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 pro-active/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

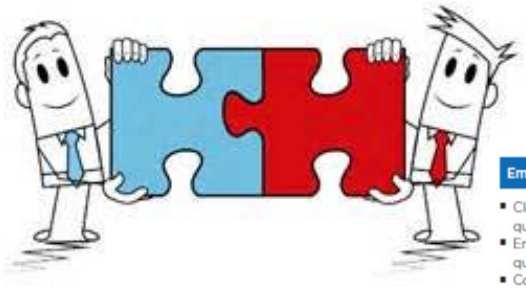
Driving Quality Culture to the Next Level

- Multi Year Effort that building on knowledge and understanding of Quality Culture with each stage brings awareness of the importance of Quality Culture and brings objective measures into the discussion.
- You can only improve what you measure
- The journey has a path forward but there may be turns along the way
- Let's begin the journey

PDA Developed Quality Culture Assessment Tool

- Specific to pharma industry
- Simple, objective and **verifiable**
- Could be used in conjunction with existing maturity models
- Intended for internal and external assessment (CMOs or suppliers)

PDA Assessment Tool



Crosby Maturity Grid

Measurement Categories	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 blame quality department for "quality problems"	Recognizing that quality management may be of value but not willing to provide money or time to make it happen	While going through quality improvement program learn more about quality management; becoming supportive and helpful	Participating, understand absolutes of quality management. Recognize their role in continuing emphasis	Consider quality management as an essential part of company system
Quality Organization Status	Quality is hidden	A stronger quality	Quality department	Quality manager is	Quality manager on board

CEB

Employee Ownership
- Clearly understand quality fit with job
- Empowered to make quality decisions
- Comfortable raising concerns over quality violation
- Comfortable challenging directives for better quality

Leadership Priority
- Manager "walks the talk" on quality
- Manager emphasizes quality's importance

Message Credibility
- Messages are delivered by respected sources.
- Communications appeal to me personally.
- Messages are easy to understand.
- Easy to make sense of leadership priorities

Peer Involvement
- Have a strong network of peers for guidance.
- Peers raise quality for team discussion.
- Peers are directly involved in quality efforts.
- Peers are held accountable for quality performance.

2 years to develop with a team of 17 members

The Task Force defined five categories

Leadership Commitment

Communication & Collaboration

Employee Ownership

Continuous Improvement

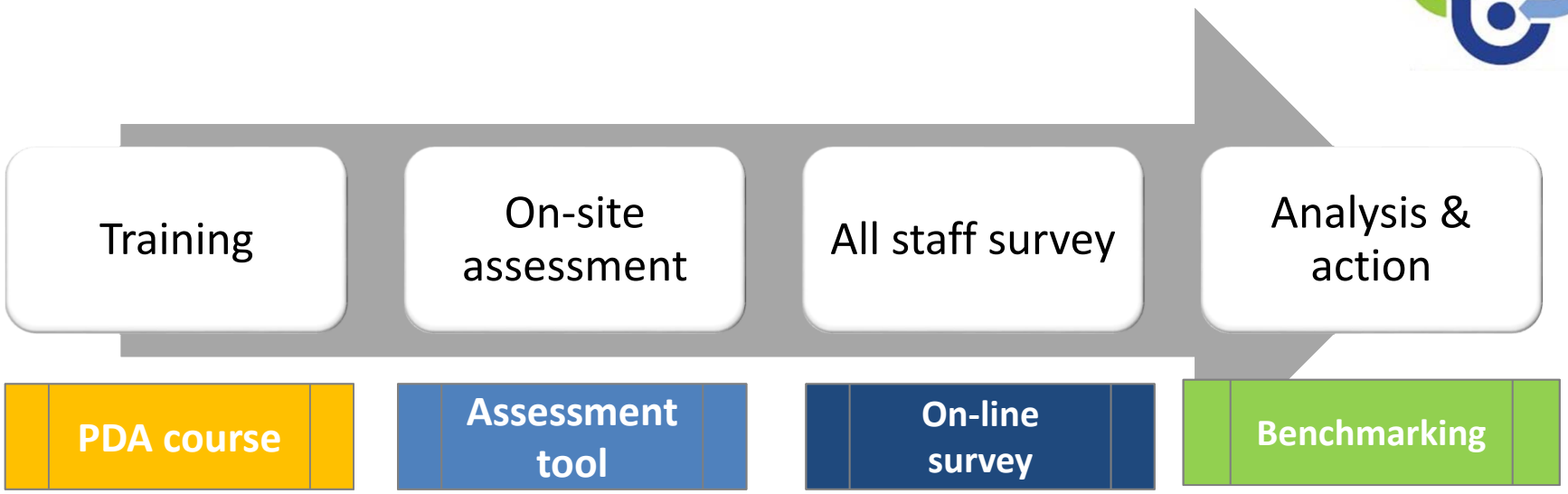
Technical Excellence

Capturing your experiences

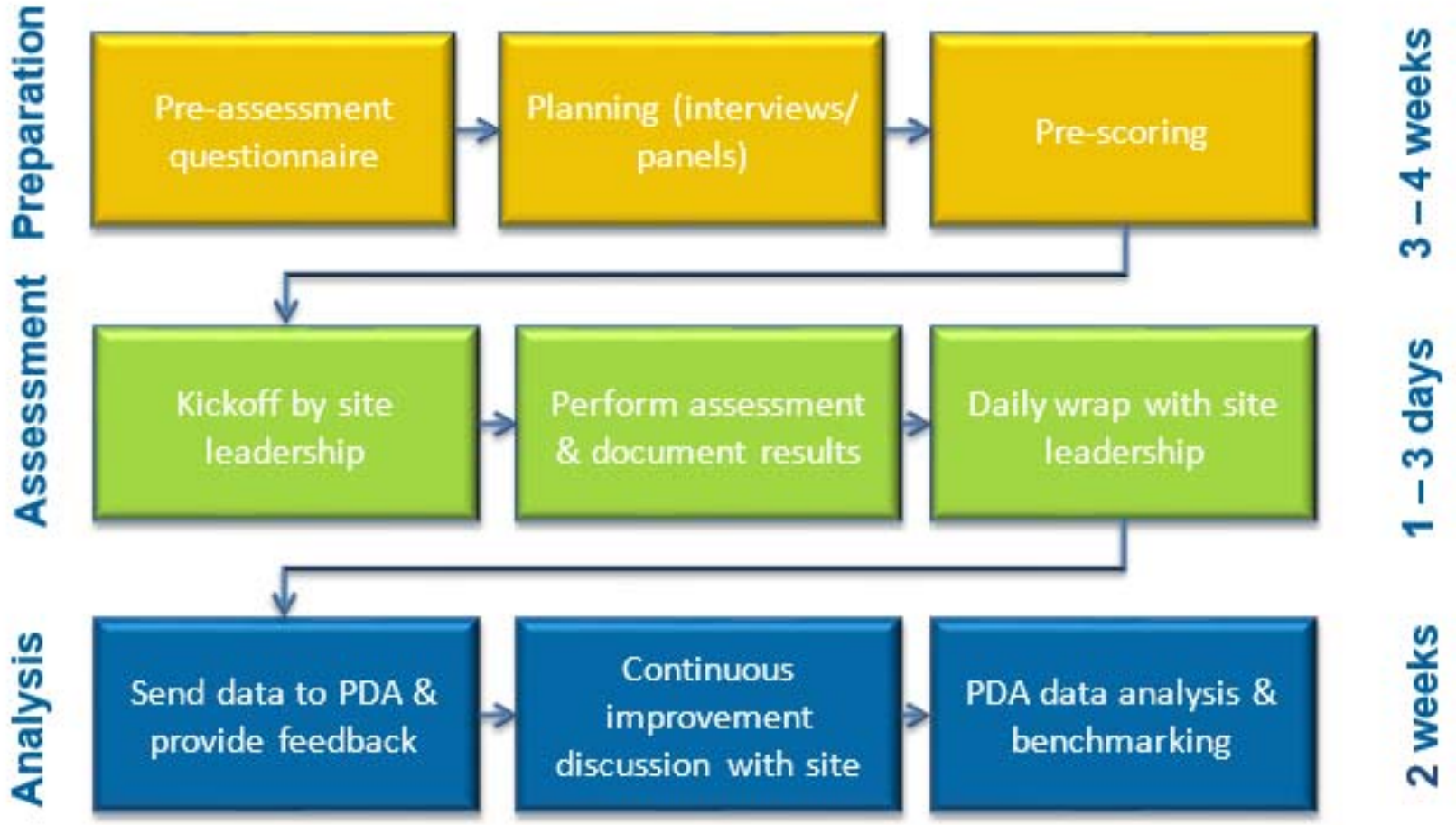
Thinking about your past experiences, share specific examples of how you **knew** a company had a Quality Culture.

PDA Quality Culture Self Assessment Logistics and Tools

What does the PDA Quality Culture program involve?



PDA Recommended Process Flow and Timing for Self Assessments



PDA Quality Culture Assessment Tools Provided

- **Guided Self-Assessment Tool**
  - Definitions and Process Flow
- **Matrix and Example Interview Questions**
  - Guide to help plan for on-site interviews
- **Site Kick Off/Leadership Presentation**
  - Sample Slide Deck for you to Customize
- **Pre-audit Questionnaire**
  - Sent to the site in advance to help assessors plan for interview questions and assessment duration
- **Scoresheet**
  - Used to document interview observations, site demographics, and results
  - Scores returned to PDA for Benchmarking
- **Quality Culture Survey**
  - PDA send link to on line survey and collects results anonymously
  - You distribute link to all site staff to complete

Method of assessment

- Options:
  - Walkthrough mfg floor & discussion with staff
  - Panel discussions (middle and floor staff)
  - One-on-one (leadership team)
- Duration:
  - Range from 1.5 days to 3 days on site
    - Include discussion and documentation review

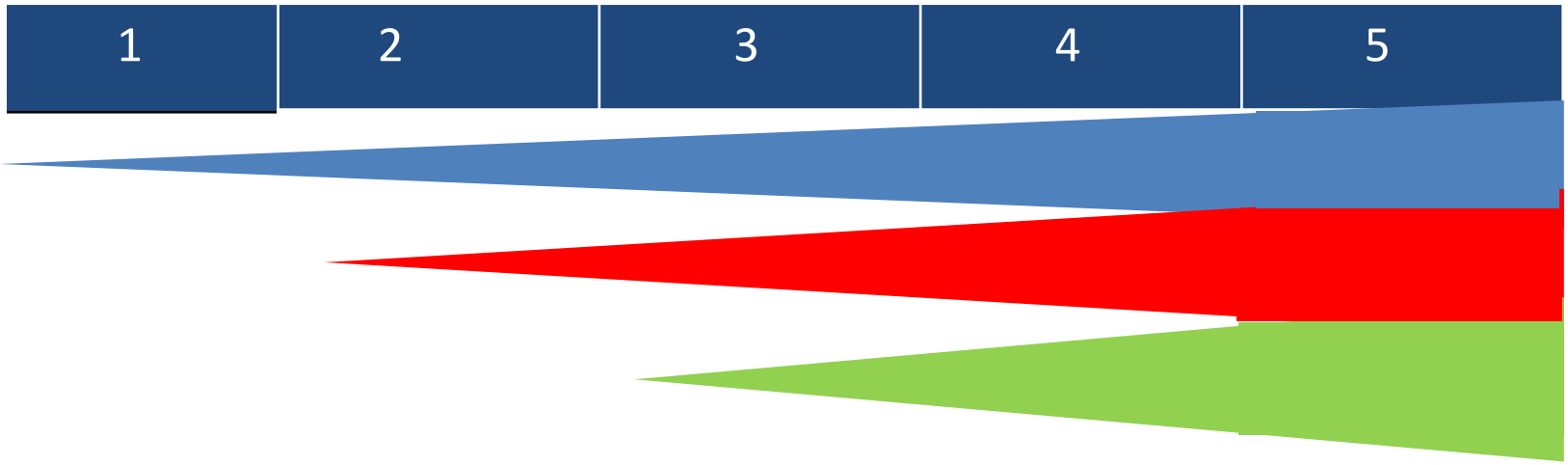
General guidance using the self-assessment tool

- Each metric may be at a different maturity level
- Use your judgement when getting conflicting information from staff interviews – generally lean towards the lower maturity level
- Take into account how familiar they are with the subject you are asking about

General Principles for scoring each metric

Three basic elements that build and combine for full maturity

1. Development of the Framework (blue)
2. Implementation cascaded down thru all levels (red)
3. Effectiveness of program demonstrated (green)



Case study – Mock Assessment

- You are assessing a CMO site for your firm

- Process:
  - 20 minutes to read case study for each category
  - 20 minutes to conduct interview for each attribute and score the metrics
    - Steve – Site Head and/or Quality Leader
    - Cylia – Quality and/or Manufacturing Management
    - Denyse – Centrifuge Operator
  - 20 minutes to review assessment result for each attribute

Ground Rules

- Actively participate - share ideas, ask questions
- Share your honest feedback
- Share your unique experience
- Stay open to new ways of doing things
- Seek common ground and understanding (not problems and conflict)

Quality Culture Attributes and Metrics in PDA Tool

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

Employee Ownership and Engagement

A. Understanding Quality Goals

1. Impact on Product Quality

- Process Understanding – none, limited, CCP, CQA, process capability
- Quality Goals – none, limited & general, specific & cascaded down

2. Patient Impact

- Patient's Use – no understanding, clinical outcomes, patient expectations
- Connection to Patients – none, thru management, directly

Employee Ownership and Engagement

B. Staff Empowerment and Engagement

1. Process Ownership & Engagement
   - Ownership - None, immediate workspace, program responsibility, continuous improvement authority, industry thought leader
2. QMS Processes
   - Ownership – unclear, clear, multifunctional, resolution of issues
   - Measurement & improvement – none, limited, showing CI

Case Study Session 2
Key Issues for Continuous Improvement

Continuous Improvement

A. CAPA Robustness

1. Root Cause
   - limited tools, standardized tools, CAPA effectiveness
2. Human Error
   - limited understanding, formal training on human factors, proactive error prevention,

Continuous Improvement

B. Clear Quality Objectives and Targets

1. Continuous Improvement

- Corrective actions only, preventative action, CI projects, utilization of formal CI tools, six sigma or advanced level achieved
- Resources none, ad hoc, assigned, cross functional, dedicated

Technical Excellence

A. Utilization of New Technologies

1. Manufacturing Technologies

- Outdated equipment (resulting in supply issues) – utilization of new technologies
- Programs and capital to review and assess new technologies

B Maturity of Systems

Technical Excellence

1. Training
   - SOP driven, career development, prevention skills, advanced training
2. Business Conduct
   - Data Integrity – no program, basic policy, audit program / hot lines, Compliance Committee and BOD involvement
   - Community impact, involvement and support
3. Quality Risk Management
   - QRM program – none, ad hoc, defined, proactive tools, risk profile awareness
   - Risk communication – none, ad hoc, defined, risk register

Leadership Commitment

A. Commitment to Quality

1. Accountability and Quality Planning

- Accountability – solely within Quality, shared Sr. Leadership, cascaded down
- Quality Manual & Policies – frequency of updating, integrated with MR, long term Quality Plan

B Enabling Resources

Leadership Commitment

1. Safety Program

- EH&S program – reactive, formal safety program, prevention of serious incidents, focus on all behaviors, ergonomic focus

2. Rewards & Recognition

- Regarding Quality – none, compliance focused, company values, focus on prevention

3. Feedback & Staff Development

- Performance Management System - unclear goals no feedback system, clear goals, collaboration expectation, company values programs and formal feedback, coaching, cascaded, formal mentoring programs

Communication & Collaboration

A. Quality Communications

1. Quality Communications

- None, informal general, customized, formal and ongoing
- Issue escalation – none, formal escalation, hotline, ombudsman, open discussions on quality at all levels

Communication & Collaboration

B. Management Review and Metrics

1. Management Reviews

- MR – ad hoc, formal, CI focus, accountability outside Quality, demonstrated product / process improvements

2. Metrics

- efficiency, compliance, prevention, six sigma achievement

Communication & Collaboration

C. Internal Stakeholder Feedback

1. Internal Stakeholder Feedback

- Feedback – passive, active, formal, tracking & follow up
- Shop Floor walk throughs – rare, occasional, regular, Gemba

2. Quality Culture Survey

- Survey – none, limited data, robust data, demonstrated improvement

Communication & Collaboration

D. Collaboration with Assessors

1. Operations Readiness & Knowledge

- Responses – missing, require follow-up, lacking specifics, timely and scientific,
- Associates Process Knowledge –none, needing clarification, technical, thought leadership

Characteristics of a Successful Assessor

- Open and approachable
- Emotionally intelligent
- Able to see beyond the surface
- Inquisitive and respectful

Learning from Previous Participants

Keys to a successful assessment:

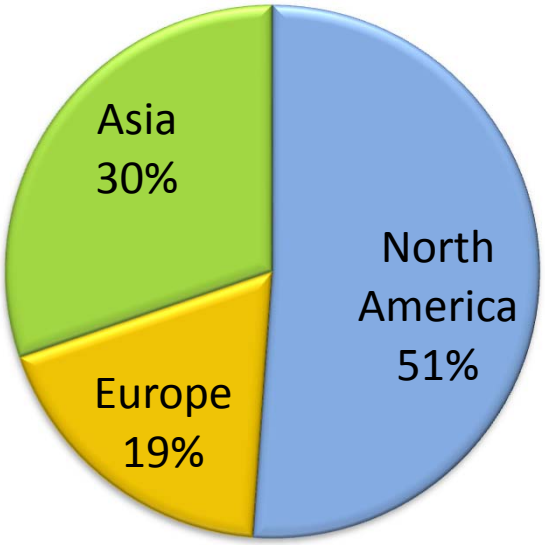
- Important to create a sense of partnership and a positive environment with the people being assessed
- Understand the components of a good culture
- Understand how to score the metrics using the tool
- Flexible in following leads to collect the required facts
- Open and honest dialogue with senior management to communicate results

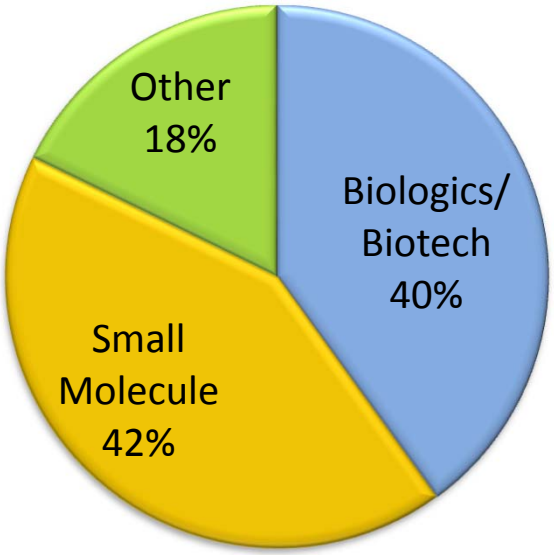
Some learnings from previous assessment

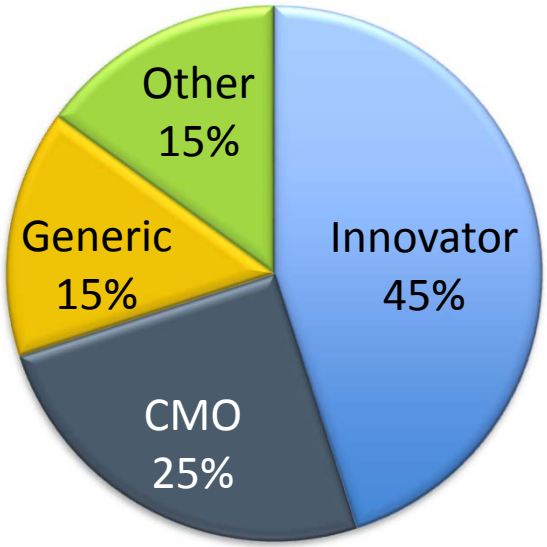
- Pre-scoring was done and found helpful
- Intro opening presentation by site leadership was important to set the stage and expectation
- Verbatim comments were very helpful for site leadership
- Closeout meeting triggered good discussions
- Best to perform assessment with 2 assessors – one person can manage the questions while the other document & organize data

Tool Results and Benchmark Data

Profile of Benchmarking Database



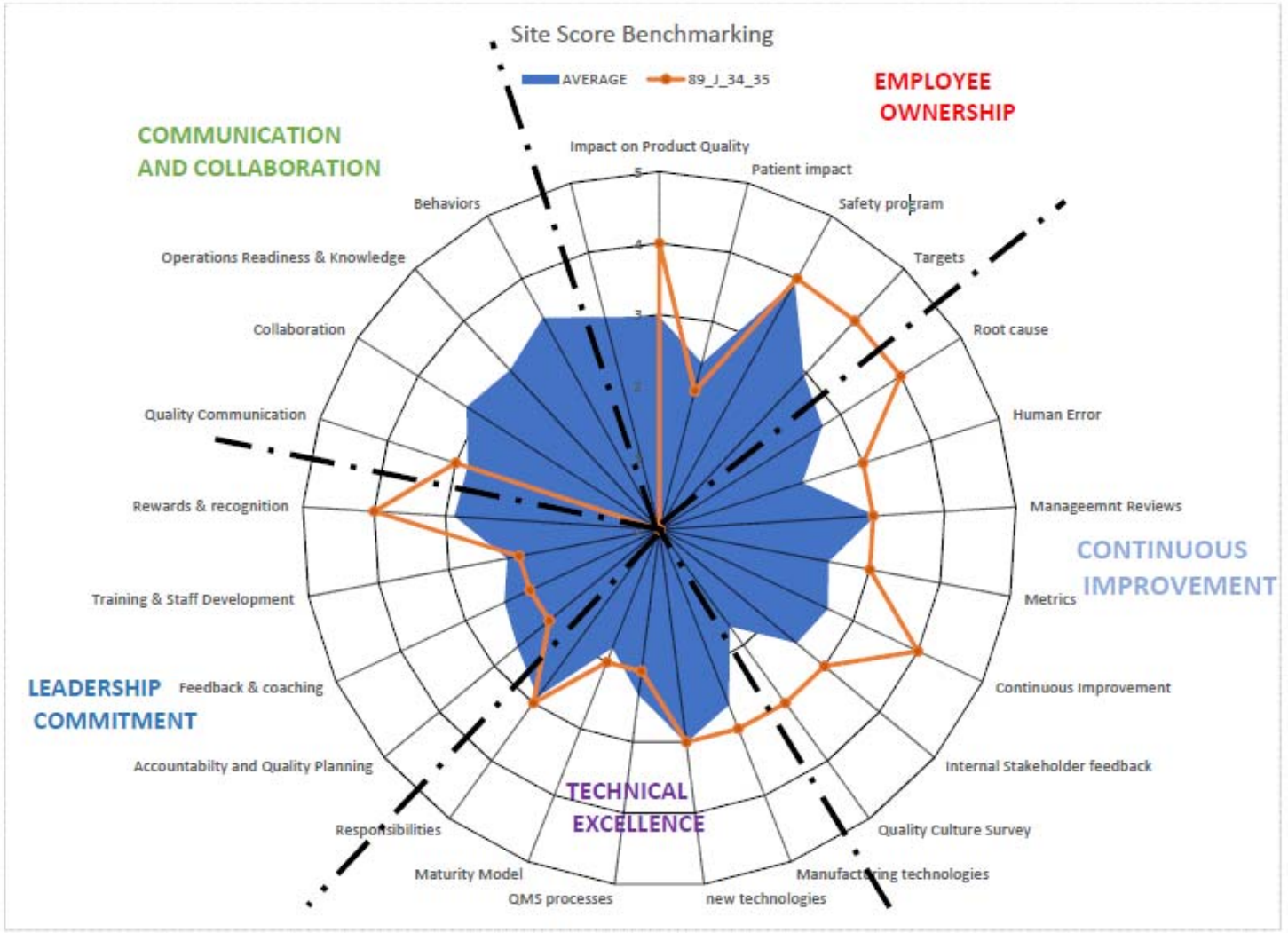




Pilot collected scores from 24 companies and 43 sites

Total of 63 assessors trained; 9000+ survey respondents

Example of site benchmarking results



PDA Quality Culture Program for 2018

April Mainz, Germany June Bethesda September Washington D.C.

Course — Understand the importance of quality culture

Tool — Assess your site with quantitative results

Survey — Examine behaviors vs. attributes

Benchmark — Compare results with other similar sites

Quality Culture Transformation Resources

New Research:
How does improving Quality Culture change OPEX or business metrics?

Quality Culture and Performance Assessment
Joint Project of University of St. Gallen and PDA

University of St.Gallen

Getting Site Management Involved and Setting Expectations

Group Discussion

Thank you for your participation!

Feedback and Questions?