Aspiring to Measure Quality Culture

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PDA Director of Science and Regulatory Affairs

Pharmaceutical Quality Congress
The Unintended Consequences of Quality
June 14-16, 2017 - Bethesda, MD
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 serving 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
Higher Quality Maturity is accompanied with Higher Quality Behavior.
St. Gallen confirms PDA’s Survey Outcome

- 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

Thomas Friedli, PDA 2017 Metrics Conference
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

1. Leadership Commitment to Quality
2. Enabling Capable Resources
3. Quality Communications
4. Collaboration with Auditors
5. Understanding Quality Goals
6. Safety Culture
7. CAPA robustness
8. Management Review and Metrics
9. Clear Quality Objectives
10. Internal Stakeholder Feedback
11. Utilization of new proven technologies
12. Maturity of Systems
On-site assessment tool – 24 Sub Attributes

1. Leadership Commitment to Quality
   Accountability and Quality Planning
2. Enabling Capable Resources
   Feedback and Coaching
   Training & staff development
   Rewards and Recognition
3. Quality Communications
   Quality Communications
4. Collaboration with Auditors
   Collaboration
   Operations Readiness & Knowledge Behaviors
5. Understanding Quality Goals
   Impact on Product Quality
   Patient Impact
6. Safety Culture
   EHS Program
   Targets
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
11. Utilization of new proven technologies
    Manufacturing Technologies
    New Technology
12. Maturity of Systems
    QMS Processes
    Maturity Model
    Responsibilities

Connecting People, Science and Regulation®
### 5. Understanding Quality Goals

**Impact on Product Quality**
- Associates can clearly explain what they have to get done, not necessarily what’s important to general quality
- Associates can clearly explain what they have to get done and what the critical process parameters are
- Associates can clearly explain the specific critical quality attributes, their importance and linkages to the operations / processes they oversee
- Associates at all levels can explain process capabilities and their impact on specific product critical quality attributes

**Patient Impact**
- Associates don’t understand how the product is used in patients but don’t understand how Quality impacts clinical outcomes
- Associates understand the importance of Quality and how that can affect patients
- Associates understand how the product is used in patients and how Quality impacts clinical outcomes
- Associates understand how the product is used in patients and specific CQA impact on clinical outcomes
- Associates share with each other the importance of Quality on clinical outcomes

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Quality Culture Assessment Process

Preparation
- Pre-assessment questionnaire
- Planning (interviews or panels)
- Pre-scoring

Assessment
- Kickoff by site leadership
- Perform assessment & document results
- Daily wrap with site leadership

Analysis
- Send data to PDA & provide feedback
- Continuous improvement discussion with site
- PDA data analysis

Timeframes:
- Preparation: 2–3 weeks
- Assessment: 1–3 days
- Analysis: 2 weeks
Pilot Program Participants

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

Business Function
- Generic: 42%
- Innovator: 21%
- CMO: 13%
- Other: 24%

Product Class
- Small Molecule: 45%
- Biologics/Biotech: 18%
- Other: 37%

Site Locations
- North America: 53%
- Europe: 29%
- Asia: 18%
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**

![Employee Ownership: Understanding Quality Goals](chart)
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?

- Define: Develop assessment tool (PILOT ANALYSIS UNDERWAY)
- Control
- Measure: On-site assessment & survey tools
- Improve
- Analyze
Future work

- 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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