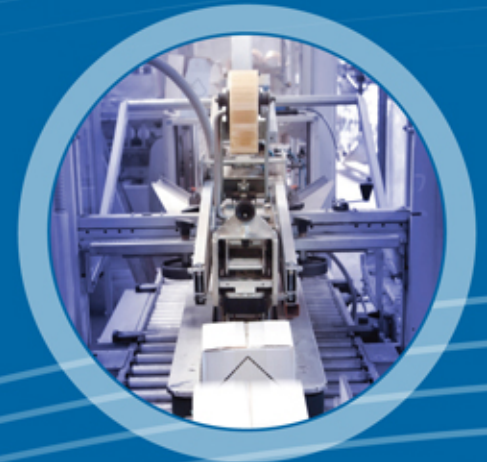




*Connecting People, Science and Regulation®*

# Quality Culture Metrics? PDA's Seeking Answers

Steven Mendivil  
PDA Quality Metric Task Force Leader





# FDA is Interested in Quality Metrics

- FDASIA (7/12) - Section 706
- Opportunity to help with Drug Shortages while also assessing quality and compliance risk
- FDA is exploring Quality Metrics as an input into their Inspectional Risk Model
- PDA Commented on “FDA’s Drug Shortage Strategic Plan” 3/13/13



One of PDA 's Strength is their work on Quality Systems



# Quality Metric Proposals

- FDA requested input on potential Quality Metrics by 12/20/13.
- At least four Quality Metric proposals submitted to FDA



- And a special meeting

BROOKINGS

QUALITY. INDEPENDENCE. IMPACT.



# Highlights from Brookings

- “Consensus set of metrics are somewhat rudimentary, and provide limited information about the culture of quality at a given organization.”
- “Many remarked that a strong quality culture is a critical component in driving the system and processes that underpin the quality control and assurance infrastructure at an organization”
- “However, Quality culture is also difficult to capture through metrics.”



PDA believes the next step is focusing on  
Objective Quality Culture Metrics



# What is Quality Culture

## and how can you measure it

“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.”

From **Harvard Business Review April 2014**: Creating a Culture of Quality. Financial incentives don't reduce errors. Employees must be passionate about eliminating mistakes. Ashwin Srinivasan and Bryan Kurey of CEB

Financial incentives don't reduce errors  
People must be passionate about eliminating mistakes



# Quantifying Quality Culture

December 2013 PDA Quality Metric Conference breakout session identified key factors for Quality Culture

1. Communication & Transparency
2. Commitment & Engagement
3. Technical Excellence
4. Standardization of Criteria or Requirements
5. Cross Functional Vision

PDA will focus on Quality Culture at Quality Metric Workshop in Dec 2014



# Objective Quality Culture Metrics

PDA has launched a Quality Culture Surveys

1. Help identify attributes of Quality Culture and Quality System Maturity
2. Correlate Quality Culture behavior scoring (subjective) to Quality System maturity scoring (objective)
3. Can Quality System Maturity scoring differentiate sites?

Objective quality culture metrics must be verifiable



# PDA's Quality Culture Survey

## Three Survey Sections:

1. Demographic
2. Observed Quality Culture behavior (management and co-workers)
  - Subjective assessment at the work site
3. Quality System Maturity scoring
  - Objective attributes



Quality System Maturity  
as Surrogate for Quality Culture





# PDA's Quality Culture Survey

## Section 2: Quality Culture Behavior Scoring

Assessment of behaviors observed for co-workers and management over last 6-18 months for:

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





# PDA's Quality Culture Survey

## Section 3: Quality System Maturity Scoring

Objective scoring of attributes in 6 areas

1. Prevention Programs
2. Quality Management and Issue Escalation
3. Training and Personnel Development
4. Quality Management Systems
5. People and Communication
6. Continuous Improvement



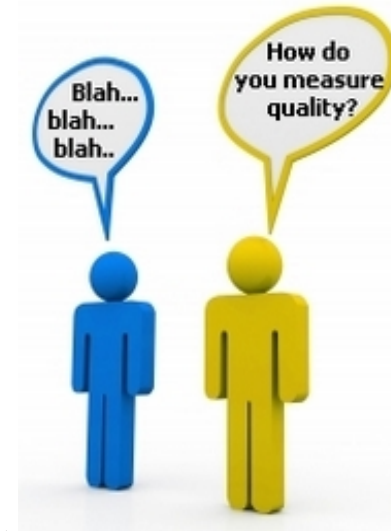
Survey Questions Score the Maturity  
of these Quality System Attributes



# Survey Results to Seed Discussion

## Survey results to be presented at PDA 2014 Quality Metric Workshop

- Plenary Presentations on Quality Culture
- Three Breakout Sessions Planned
  1. Quality Culture Attributes in Pharma Industry
  2. Measuring the Maturity of Quality Systems
  3. Objective Measures for Quality Culture and Quality System Maturity



Use of Voting Clickers to Determine Participants Input



# PDA's Points for Consideration

## Recommended Metrics for Consideration

### Trend Metric per Product

1. Complaint rate
2. Batch Reject rate (DS & DP)
3. Confirmed OOS rate (DS & DP)

### Trend Metric per Site

1. Confirmed OOS rate
2. Batch Reject rate

Use external (commonly understood) vs. internal (defined by company or site) metrics



# PDA's Points for Consideration

## Alternative Approach for Direct Comparison

1. Confirmed OOS (Site and Product)
2. Recall Rate (Product)
3. OOS Rate (Site)

Direct Comparison was specific request from FDA



# FDA's Consensus Metrics

Consensus Quality Metric at Brookings Meeting	PhRMA	PDA	ISPE
Lot Acceptance Rate - One minus number lots rejected / number lots attempted)	✓	✓	✓
Product Quality Complaint Rate - Number of quality complaints / number units released	✓	✓	✓
Confirmed OOS - Number of confirmed OOS / Number of release tests	✓	✓	✓
Recall Rate - Number of product recalls / number of lots released	✓	✓	



# FDA's Metric of Potential Interest

Recent FDA Presented Proposal	PhRMA	PDA	ISPE
Lot Acceptance Rate - Number lots rejected / number lots attempted)	✓	✓	✓
Product Quality Complaint Rate - Number of quality complaints / number lots released	✓	✓	✓
Right First Time Rate - Any batch without a deviation			
In-Valid OOS Rate			✓
APR On Time Rate			✓
CAPA's as a result of APR			
Management Level Approval of APR			
Process Performance / Process Capability Questions			



# Final Thoughts

- No perfect quality metrics; determining trade offs.
- First, carefully consider a “do no harm” and prevent unintended consequences approach
- Balanced Meaningful Metric Scorecard including Quality Culture
- Quality Culture / Quality System Maturity metrics will go beyond cGMP requirements
- Data trending is more valuable than direct comparison
- Can globally applicable metrics be developed?

FDA's use of Quality Metrics can be a game changer





# PDA Quality Metric Task Support

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