Quality Metrics
Journey to Excellence

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Journey to ...
Journey Mileposts

1. FDA Quality Metrics
2. ISPE QM Pilots
3. Metrics that Matter
4. Industry Next Steps
FDA Quality Metrics Overview
Industry Comments – Initial Draft

- Start small
  - Phased approach – don’t include APIs or Optional Metrics
- Voluntary during learning period
- Report metrics by site
- Allow grouping of formulae
  - Improve and clarify definitions
- CMOs report directly
- Context
Q Metrics Program Timing

- Revised Draft Comment Period – Mar 27, 2017
- Reporting Period – CY 2017
- Revised Tech Conf Guide – TBD
- Data Submission – JFM ’18
- Finalized Guidance – TBD
FDA QM Program Update

The Parenteral Drug Association presents the...

2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference

February 21-22, 2017 | Bethesda, MD
Bethesda North Marriott Hotel & Conference Center
Exhibition: February 21-22
#2017Metrics
Key Takeaways

- Q Metrics is a long-term program, will improve over time & become mandatory

- The voluntary program will launch with the current revised draft out but FDA will work with us on questions

- The initial 3 metrics are a starting point – lot of interest in Q Culture

- Reporters List will show company name & location

- CMOs want brand owners to report Q metrics

- Participation provides the opportunity to engage with FDA on the future of the program

- FDA understands they don’t have good incentives for participation currently and want input
ISPE Quality Metrics
Quality Metrics Timeline

2012
- Industry Whitepapers

2013
- Launch Wave 1 Pilot

2014
- Quality Metrics
- Brookings Institute

2015
- FDA FRN/Draft Guidance

2016
- Launch Wave 2 Pilot

Beyond...

July 2012
- FDASIA signed into law
ISPE Quality Metrics Wave 2 Pilot Timeline

Wave 2 Pilot enrollment → Data collection and submission → Industry analysis → Individual reports

Jun 2015 → Jun 2016

83 Sites, 28 Companies
Enhanced geographic, technology and product type representation
## Wave 2 Metrics

### External Quality Outcomes
- Total complaints rate
  - Per million packs, incl. LOE
  - Per million packs, excl. LOE
  - Per '000 attempted lots released, incl. LOE
  - Per '000 attempted lots released, excl. LOE
- Critical complaints rate
  - Per million packs
  - Per '000 attempted lots released
- Total recall events per year

### Internal Quality Outcomes
- Lot acceptance (%)
  - Per finally dispositioned lots
  - Per attempted lots
- Invalidated OOS rate
  - Per '000 lots tested
  - Per '000 tests performed
  - Per total OOS per tests performed
- Right first time (%) per released lots attempted
- Deviations rate
  - Per '000 finally dispositioned lots
  - Per '000 attempted lots
- Recurring deviations rate (%)
- Lots pending disposition more than 30 days (%) per lots attempted

### Culture Indicators
- Culture survey scores (% top boxes)
  - Total score
  - Leadership score
  - Integrity score
  - Mindset score
  - Governance score
  - Capabilities score
- CAPAs with preventive actions (%)
- Planned maintenance rate (%)
- Employee turnover rate (%)
- Human error deviations (%)
- Deviations with no assigned root cause (%)
- CAPA requiring retraining (%)

**SOURCE:** ISPE Quality Metrics Initiative
Wave 2 Correlations Overview

Correlations with p-value < 0.05

FRN metrics

External
Quality
Outcomes

Internal
Quality
Outcomes

Culture
Indicators

- Total Complaints (per pack)
- Total Complaints (per Released Lots)
- Planned Maintenance Rate
- CAPA with Preventative Actions

SOURCE: ISPE Quality Metrics Initiative
Planned Maintenance Rate & Product Q Complaints Rate

**Planned maintenance rate to total complaints** (n=15 solids sites)

- **Total complaints rate (including LOE)** per million pack

R² = 46%
P = 0.00

- Planned maintenance rate explains ~45% of the variability in total complaints per million packs
- This relationship may be related to the common factors that influence both planned maintenance rate and total complaints – such as focus on prevention, operational excellence, quality improvement mindset

Note: Major outliers excluded – more than 2 interquartile ranges away from sample median – 2 sites excl. on total complaints both with very high LOE rates

R² measures to what extent metric Y (dependent variable) is explained by the variability of metric X (independent variable)
P- value is probability that correlation between X and Y is zero, value below 0.05 indicates statistically significant results.

SOURCE: ISPE Quality Metrics Initiative
FDA Guidance Metrics Definitions

Product Quality Complaint Rate – proposed normalization by packs released

— When normalized by released lots attempted has no connection to other quality metrics

— When normalized by packs there is correlation to cultural metrics

SOURCE: ISPE Quality Metrics Initiative
ISPE Quality Metrics Initiative

Available from ISPE
Metrics that Matter
Pursue the Red
OTC Complaint Reality

- Wide variability in the Quality of information
- Only 50% of consumers have product at time of reporting
- Financially motivated fraud artificially inflates the numbers
- New product launch and product changes result in an increase in complaints
Consumer Comment Journey
P&G Approach to FDA Q Metrics

- Leadership role in Industry initiatives
- ISPE Pilots: 2 sites
- Developing IT solutions – $$$$*
- Internal FDA Quality metrics reporting program
- Leadership reviews -> Quality Council integration
Internal FDA Q Metrics Reporting

Lot Acceptance Rate

Product Quality Complaint Rate

Invalidated OOS Rate

CAPA Retraining Rate
Top-Level Learning

- FDA Q Metrics have provided new insights
- Product grouping approach
- Challenging to align on definitions and adapt to supply chain differences
- Manual reporting burden high at start – improves over time
- Mapping data between internal and external systems can be difficult (OTC)
CULTURE EATS STRATEGY FOR LUNCH

PETER DRUCKER
ASQ Quality Culture Workshop

Cultureofquality.org/assessment
Quality Culture Assessment

Average Scores

Overall

By Theme

- Customer Engagement
- Risk Management Culture
- Quality Vision and Values
- Pursuit of Performance Excellence
- Performance Metrics and Measurement
- Employee Engagement
- Investment in Performance Improvement
- Adapting Across Geographies/Cultures
- Leadership Commitment to Excellence
- Understanding Customer Needs

P&G
Consumer Products
All Respondents
ASQ Culture of Quality Roadmap

1. Evaluate Current Performance
2. Identify How Culture Plays a Role
3. Clarify Improvement Vision
4. Define Values and Expected Behaviors
5. Clarify Strategies and Goals
6. Engage Team to define SMART Goals
7. Clarify & Track Key Measures
8. Maintain a Management System for Priorities/Goals
9. Manage Communication Habits
10. Build Motivations Throughout

Define
Align
Manage

Define & Track Key Measures
Industry Next Steps
Conference on Quality Culture and Quality Metrics

Powerful Tools to Shape Quality Excellence

25 - 26 April | Bethesda Marriott | Bethesda, MD
Group Discussion

- What can industry associations do to help your company prepare?

- How can you leverage the FDA Quality Metrics program to accelerate your journey?
Where is Your Journey Headed
... Compliance or Excellence?