Connecting People, Science and Regulation

PDA Quality Metric Activities and Plans

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FDA is Interested in Quality Metrics

- FDAISA (7/12)
  - Section 706 – allows for records to be requested in advance or in lieu of inspections
- FDA sees Quality Metrics as an 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
- FDA issued and PDA Commented on "FDA's Drug Shortage Strategic Plan" 3/13/13

PDA 's Strength is their work on Quality Systems

Quality Metric Proposals

- FDA requested input on potential Quality Metrics by 12/20.
- At least four Quality Metric proposals submitted to FDA
  1. GPhA (Generic Pharmaceutical Association)
  2. PhRMA (Pharmaceutical Research and Manufacturers of America)
  3. ISPE (International Society of Pharmaceutical Engineers)
  4. PDA (Parenteral Drug Association)

Brookings Institute meeting with Key Industry Leaders

2013 PDA Quality Metrics Workshop

- Co-Chaired with FDA including FDA facilitation of breakout sessions
  - Metric can drive continuous improvement within a company
  - However, development of meaningful Metrics within a company requires overcoming a number of **challenges**
  - The challenge: Adopting common metrics across the industry are huge.
  - Direct comparison of raw metric data is problematic
  - Comparing trends would promote continuous improvement
- PDA submitted a Points to Consider document on Quality Metric on 12/20/13
- PDA is supportive of FDA's efforts to find Quality Metrics as a potential input into FDA's Inspectional Risk Model

Which Quality Metrics are best suited for FDA's Inspectional Risk Model

Quality Metrics Encompass Significant Challenges

Benefits

- Drives consistency of metrics that are measured for products and sites across the industry
- **Greater visibility/transparency** between industry and regulator
- **Drives continuous improvement**
- Audits and inspection schedules can be driven off of trends
- **Prioritize and focus** on the most important issues
- Facilitates **proactive** discussion and action
- Allows for an **early identification** of drifts and the prevention of problems and losses
- Promotes that **quality is everyone's job**
- Help **prevent drug shortages**
- Facilitates industry sharing of common metrics definitions, collection and use

Risks

- Could drive wrong behaviors and lead to **unintended consequences**
- Any attempt to impose a one size fits all could lead to failure of initiative
- Excess or complex metrics **take resources away** from daily activities (both industry and FDA)
- Resources needed to execute metrics may outweigh the benefit (setting, monitoring, and reacting) -ensure we select *metrics that matter*
- Comparing data that is not comparable and interpretation of single data instead of aggregates/ trends may lead to **wrong interpretations**
- **Inappropriate responses to metrics**
- Using compliance metrics as Quality surrogate

There is no single set of metrics that can act as a surrogate to reliably reflect Quality across different sites and companies

PDA is Focusing on Two Types of Quality Metrics

- There are literally thousands of metrics that can be established, monitored and reviewed
- Key Quality metrics fall into two main areas
  1. Product Specific Quality Metrics
  2. Site Quality System Metrics
     - should relate to FDA Six System approach to inspections

Target : Identify a handful objective metrics

Identifying Key Quality Metrics

1. Closely related to product quality
2. Include some forward looking or leading indicators
3. Metrics should be **objective** for appropriate trending and comparison as potential risk inputs
4. GMP vs. Non GMP Metrics

Challenge to define specific metrics as GMPs focus on "what" Metrics focus on the "how"

PDA's PtC Document

- PDA's Recommended Metrics focus on Trends rather than Direct Comparison
  - Trend Metrics per Product (via license holder)
    - (Confirmed) Product Compliant Rate by Product
    - Batch Reject rate by product
    - Confirmed OOS Rate (DS & DP) by product
  - Trend Metrics per Site (via each registered site)
    - Confirmed OOS Rate (DS & DP) by site
    - Batch Reject Rate by site

Trending allows for slight different interpretation of the metric between companies

PDA Proposal

- Alternative Approach
  - Direct Comparison
    - Confirmed OOS by product
    - Recall Rate by product
    - OOS rate by site

Identical metric interpretation is required for direct comparison

PDA's Next Steps

PDA's Quality Metric Task Force

1. Work stream finalizing PDA's metric definitions
2. Work stream planning a second Quality Metric Conference with FDA Co-Chairs scheduled for December
3. Work stream developing a Quality Culture Survey to report out and facilitate discussion at Dec Quality Metric Conference