Medical Device Quality Metrics

FDA/Xavier University Metrics Initiative

MDIC Case for Quality Forum
October 26, 2016
Identify Meaningful Metrics for Industry

To provide a system of metrics across the Total Product Lifecycle that:

1. Informs internal company decisions and triggers action

2. Shifts the Right-First-Time mentality closer to the initial days of development
Assessment Across the TPLC

Enterprise-Wide Continual Improvement

Pre-Production

Production

R&D Continual Improvement & Risk Mgmt.

Transfer

Production Continual Improvement & Risk Mgmt.

Post-Production
### Top 3 Metrics Finalized

<table>
<thead>
<tr>
<th>Phase/Metric Name/Goal</th>
<th>Metric Calculation</th>
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<tbody>
<tr>
<td><strong>Pre-Production:</strong> Design Robustness Indicator</td>
<td>Total # of product/process changes across projects Total # of projects</td>
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<tr>
<td>Assess the number of product changes that are related to product or process inadequacies or failures</td>
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<tr>
<td><strong>Production:</strong> Right First Time Rate</td>
<td># of units mfg. Right-First-Time within or across lots # of units started</td>
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<tr>
<td>Assess the number of production failures related to product and process inadequacies or failures</td>
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<tr>
<td><strong>Post-Production:</strong> Post-Market Surveillance</td>
<td>1. Basic Level: We provide proven calculations for many post-market indicators. 2. Advanced Level: We provide an example of how to factor risk scores into the post-market indicators.</td>
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<tr>
<td>Assess an aggregate of post-market indicators with root causes of product or process inadequacies or failures</td>
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Purpose: To help organizations understand how best to use the output from the metrics to inform decisions and trigger actions

- Metric output can be used to understand root causes
- Combine metric output with other metrics to understand a more holistic picture and analyze trends
- Goal is to provide a feedback loop to improve systems from the earliest point possible that allowed the failure to occur originally

http://xavierhealth.org/device-measures-initiative/
Enterprise-Wide Assessment

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Imagine: TPLC Risk Analysis

**Y-axis = Internal Risk Score**

“Internal” includes pre-production and production metric total risk score

**X-axis = External Risk Score**

“External” includes the total post-production risk score of appropriate indicators
No need to identify and pilot additional metrics

– Our Best Practices Document provides guidance on how to use metrics to inform decisions

– We believe the 3 metrics chosen provide great insight on product risk when used as we describe (including the Enterprise-Wide roll-up), but companies will have many more they are monitoring or alternate versions of these 3 that make sense for their business operations
Focus on quantititating the strength of an organization’s Culture of Quality

• **Why?** Recognition that lowering risk to product quality can only be sustained in a strong Culture of Quality

• **How?** Use the Xavier/PwC Culture of Quality Alignment Optimization Assessment
  – What would you have to see in action to know a company has a strong culture of quality?
  – Schellingpoint process uses complex algorithms determine alignment and sentiment through a 2-step process that takes a total of 15 minutes
  – Results are verifiable
  – Provides the state of maturity of the organization
We continue to believe these and all performance metrics need to be assessed in context

– This can be accomplished on inspection

– Otherwise could lead to false conclusions and unintended consequences
Collaborative Effort
(multiple relevant sources of info)
1. List of 97 Gold and Silver activities that are above compliance across 11 critical systems and 3 phases of production

2. Identification of 17 measures linked to impact to patient safety, design robustness, process reliability, quality system robustness, and failure costs

3. Conversion of 3 measures into defined metrics

4. 2 year Retrospective Pilot Study completion and analysis

5. “Best Practices” Metric Output Documents
Questions

Kristin McNamara
Senior Advisor to DACRA
Office of Regulatory Affairs
FDA

Marla Phillips
Director
Xavier Health
Xavier University