



XAVIER  
HEALTH



MEDICAL DEVICE INNOVATION CONSORTIUM

ALIGN | ACHIEVE | ACCELERATE

# Medical Device Quality Metrics

## FDA/Xavier University Metrics Initiative

MDIC Case for Quality Forum  
October 26, 2016





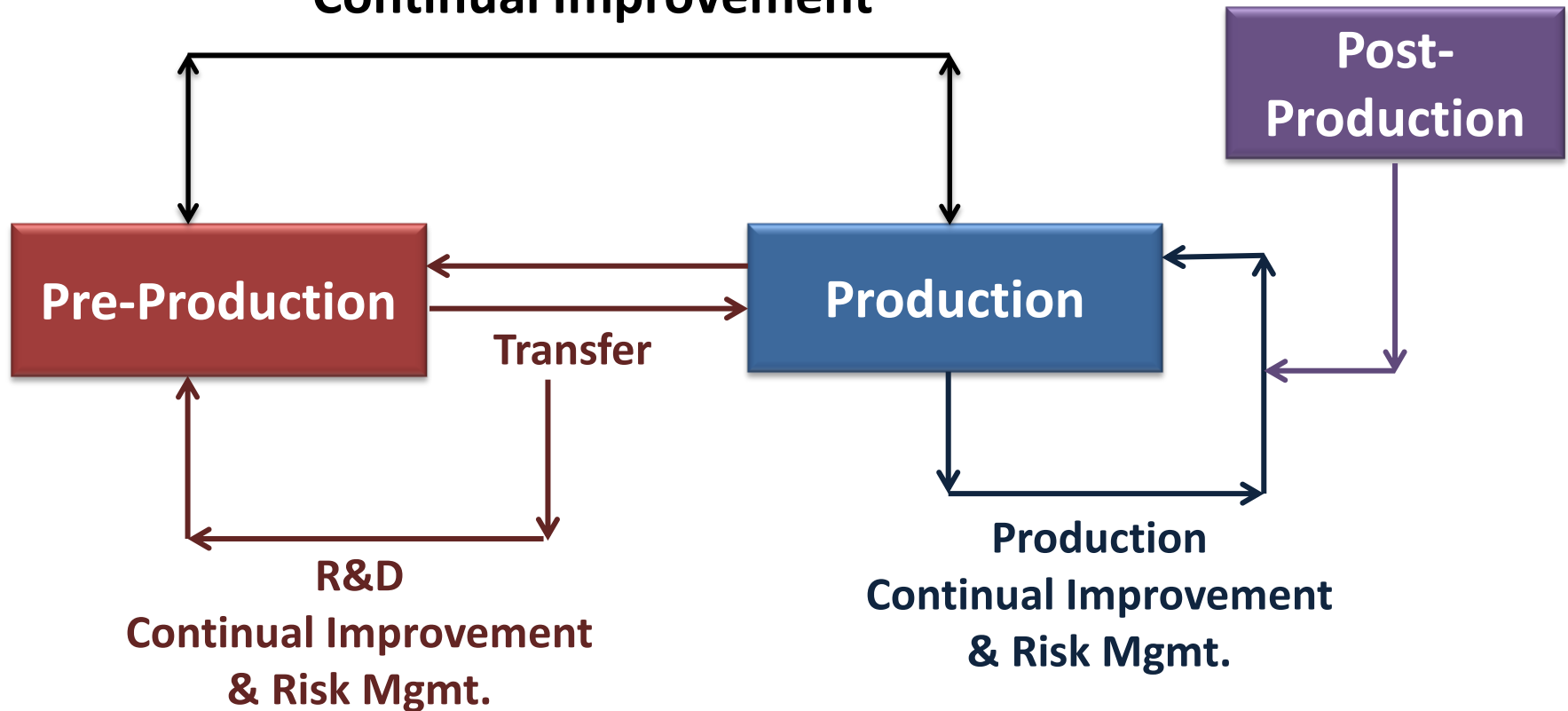
## Identify Meaningful Metrics for Industry



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

## Enterprise-Wide Continual Improvement

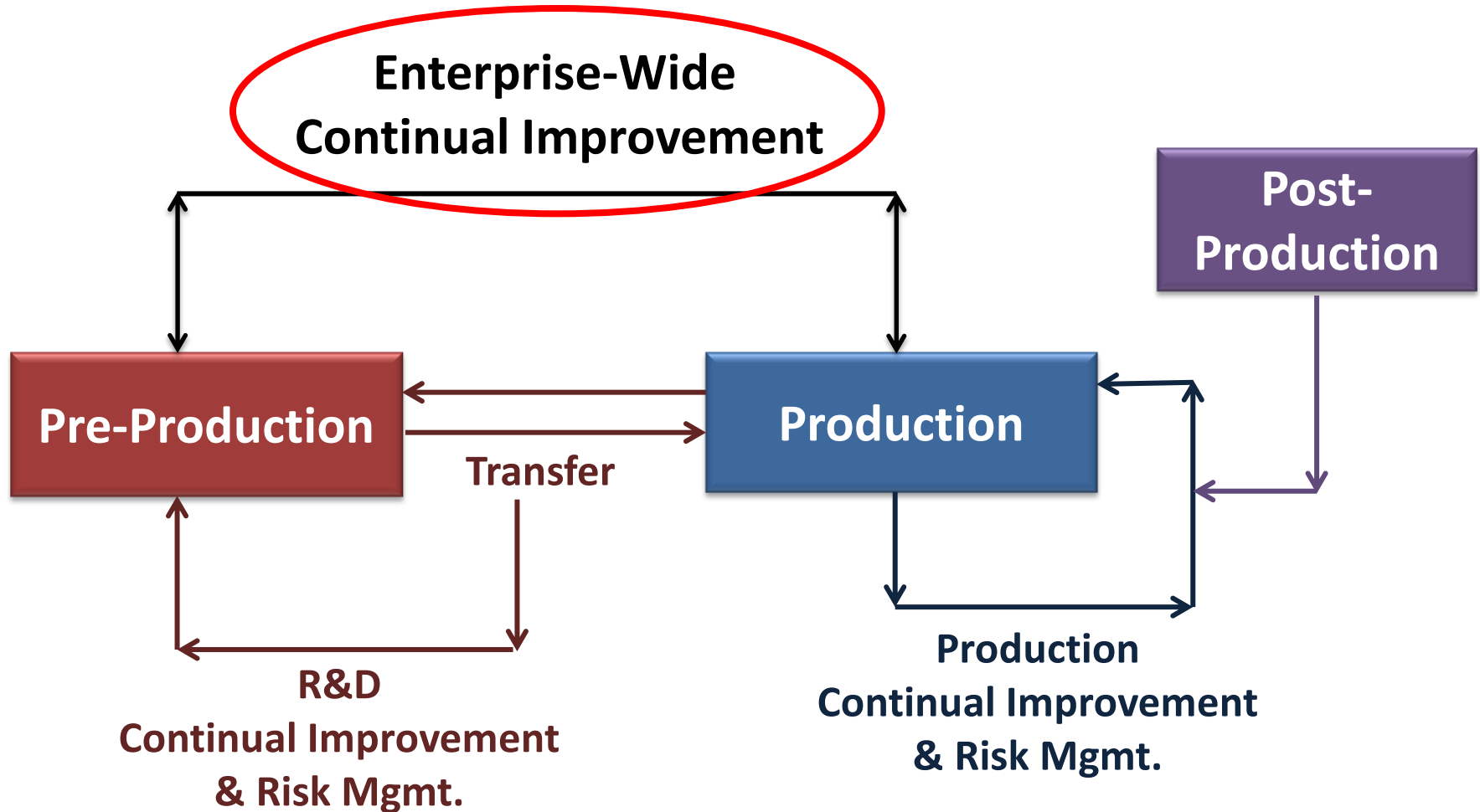


Phase/Metric Name/Goal	Metric Calculation
<p><b>Pre-Production:</b> Design Robustness Indicator</p> <p>Assess the number of product changes that are related to product or process inadequacies or failures</p>	$\frac{\text{Total \# of product/process changes across projects}}{\text{Total \# of projects}}$
<p><b>Production:</b> Right First Time Rate</p> <p>Assess the number of production failures related to product and process inadequacies or failures</p>	$\frac{\text{\# of units mfg. Right-First-Time within or across lots}}{\text{\# of units started}}$
<p><b>Post-Production:</b> Post-Market Surveillance</p> <p>Assess an aggregate of post-market indicators with root causes of product or process inadequacies or failures</p>	<ol style="list-style-type: none"> <li>1. Basic Level: We provide proven calculations for many post-market indicators.</li> <li>2. Advanced Level: We provide an example of how to factor risk scores into the post-market indicators.</li> </ol>



**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



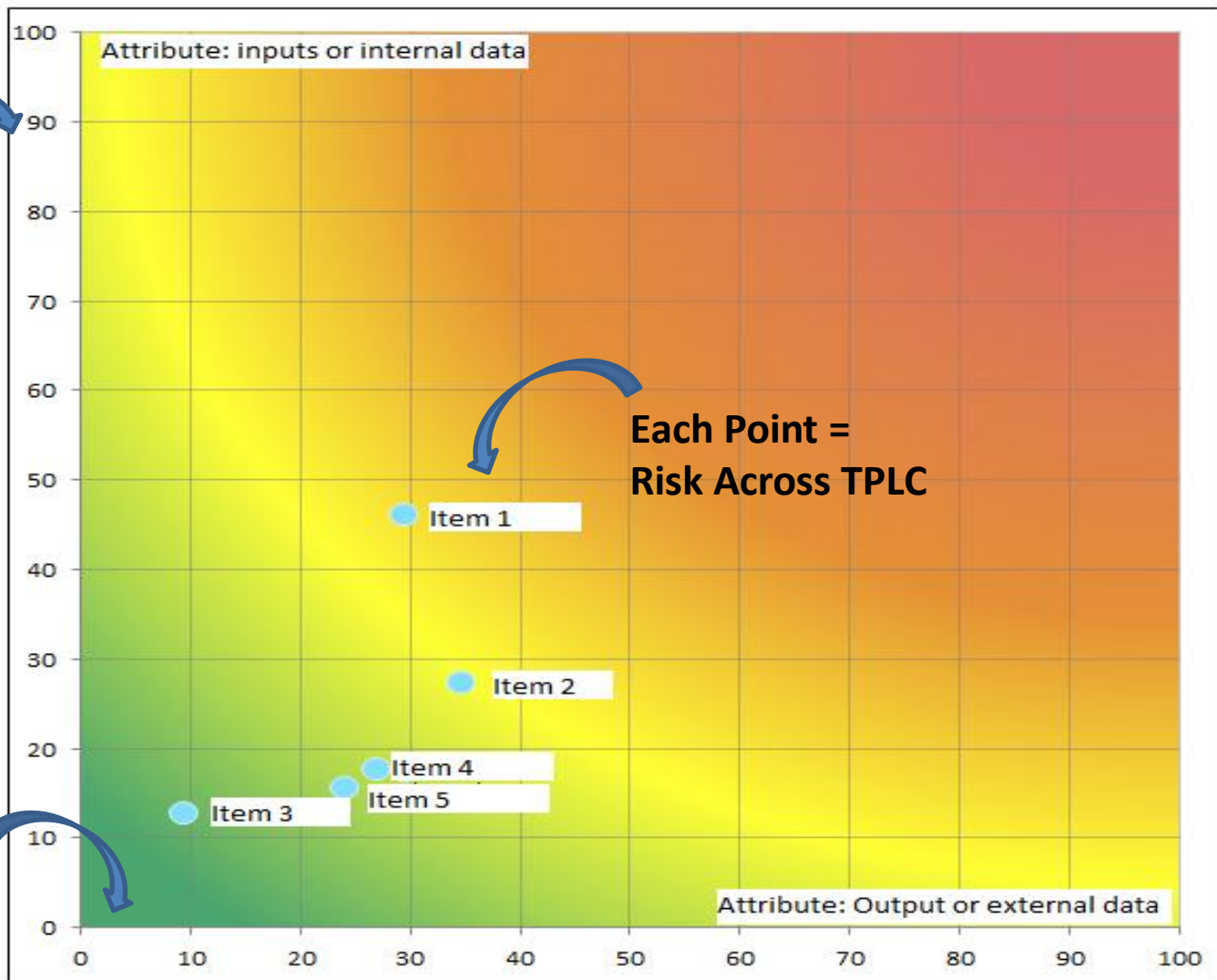
# Imagine: TPLC Risk Analysis

**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 quantitating 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**

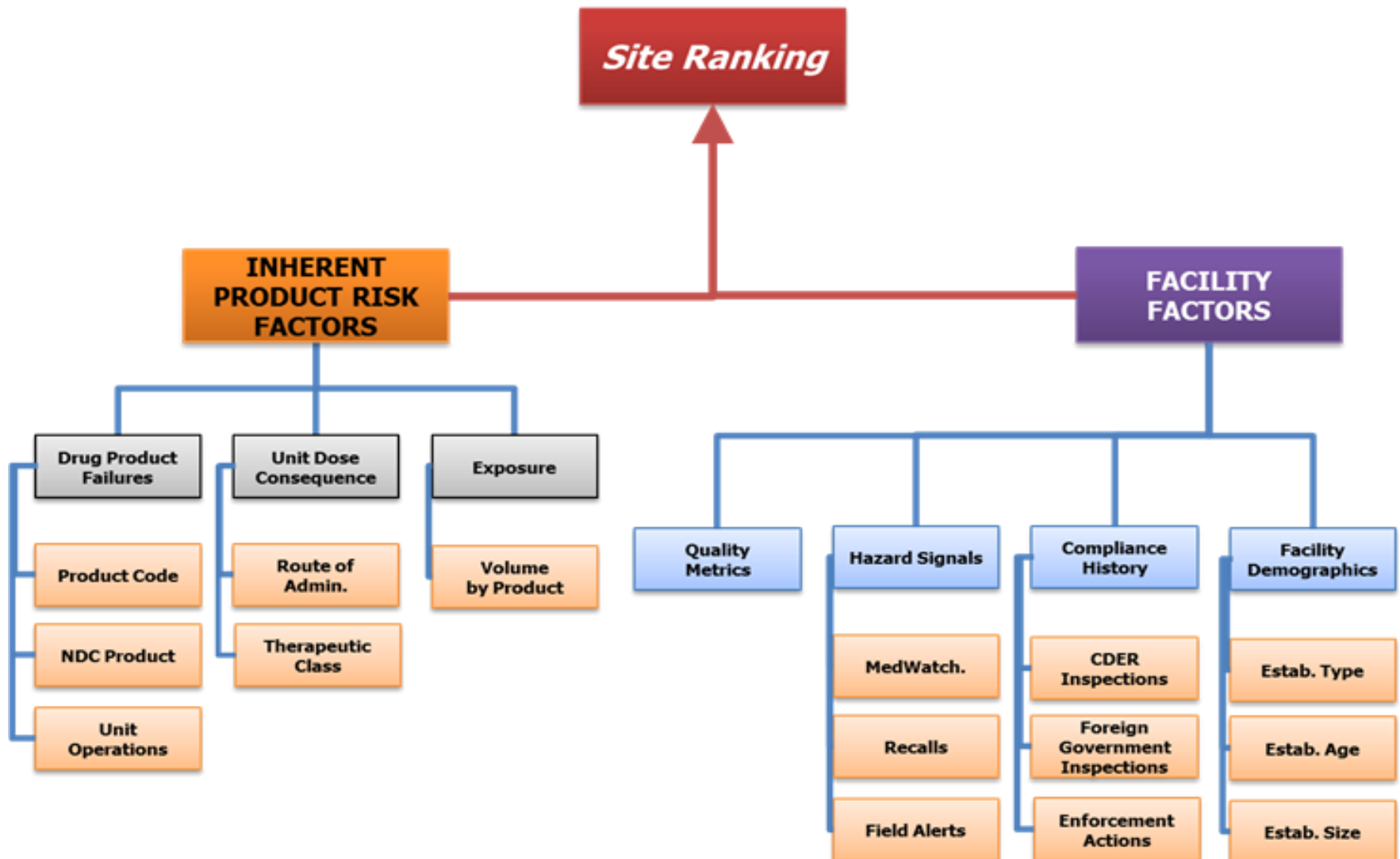
- This can be accomplished on inspection
- Otherwise could lead to false conclusions and unintended consequences

\*Presented by Ellen Morrison at FDA/Xavier PharmaLink Conference, March 2016.



**Collaborative Effort**  
(multiple relevant sources of info)

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- ✓ 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



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# Questions



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