XAVIER HEALTH

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
ALIGN | ACHIEVE | ACCELERATE

# Medical Device Quality Metrics

## FDA/Xavier University Initiative

MDIC Case for Quality Forum

June 28, 2016

# Purpose and Outcome

## Purpose:

To provide a system of metrics that

- Supports the Case for Quality
- Spans the Total Product Lifecycle
- Enables the assessment and reduction of risk to product quality

## Outcome:

Identification of quality system metrics to

- Inform internal company decisions and trigger action
- Shift the Right-First-Time mentality closer to the initial days of development

# XAVIER HEALTH 2014 – 2016 Team Members (1 of 5)

| First | Last | Company |
|---|---|---|
| Paul | Andreassi | Fisher & Paykel Healthcare |
| Karen | Archdeacon | FDA |
| Pat | Baird | Baxter Healthcare |
| Kathy | Bardwell | Steris |
| Anupam | Bedi | AtriCure |
| Pankit | Bhalodia | PwC |
| Kankshit | Bheda | PwC |
| Steve | Binion | BD |
| Robin | Blankenbaker | W.L. Gore & Associates |
| Rafael | Bonilla | ScottCare |
| Gina | Brackett | FDA |
| Kate | Cadorette | Steris |

# XAVIER HEALTH 2014 – 2016 Team Members (2 of 5)

| First | Last | Company |
|---|---|---|
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| Tony | Carr | Boston Scientific |
| Kara | Carter | Abbott Vascular Division |
| Vizma | Carver | Carver Global Health |
| Ryan | Eavey | Stryker |
| Joanna | Engelke | Boston Scientific |
| Tom | Haueter | Clinical Innovations |
| Chris | Hoag | Stryker |
| Jeff | Ireland | Medtronic |

# XAVIER HEALTH 2014 – 2016 Team Members (3 of 5)

| First | Last | Company |
|---|---|---|
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| Greg | Jones | BSI |
| Bryan | Knecht | AtriCure |
| Jonathan | Lee | PwC |
| Bill | MacFarland | FDA |
| Kristin | McNamara | FDA |
| Rhonda | Mecl | FDA |
| Brian | Motter | J&J MD&D |
| Ravi | Nabar | Philips |

# XAVIER HEALTH 2014 – 2016 Team Members (4 of 5)

| First | Last | Company |
|---|---|---|
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| Scott | Nichols | FDA |
| Pete | Palermo | CR Bard |
| Luann | Pendy | Medtronic |
| Marla | Phillips | Xavier University |
| Greg | Pierce | Engisystems |
| Susan | Rolih | Meridian Bioscience, Inc. |
| Barbara | Ruff | Zimmer Biomet |
| Joe | Sapiente | Medtronic |
| Gin | Schulz | CR Bard |
| Benjamin | Smith | Biomerieux |

# 2014 – 2016 Team Members (5 of 5)

| First | Last | Company |
|---|---|---|
| Isabel | Tejero | FDA |
| Shelley | Turcotte | DePuy Synthes |
| Sam | Venugopal | PwC |
| Marta | Villarraga | Exponent |
| Monica | Wilkins | Abbott |

Steering Committee Representative: Joe DuPay (CVRx)

# Process Overview

# How?

- Lead a diverse team of industry professionals and FDA officials
- Assume the desired metrics do not exist
- Use a methodical and rigorous process to dive deep, in Pre-Production, Production, Post-Production subgroups
- Link the metrics to impact on:  patient safety, design robustness, process reliability, quality system robustness, and failure costs

11

# Critical Systems

Focused on 11 critical systems for risk to product quality measures

| | | |
|---|---|---|
| 1. CAPA | 5. Design Controls | 9. Production and Process Controls |
| 2. Change Control | 6. Distribution | 10. Servicing |
| 3. Complaint Handling | 7. Management Controls | 11. Supplier Controls |
| 4. Customer-Related/VOC | 8. Post-Launch Surveillance | |

97

# Gold and Silver Activities

- Goal: to identify activities beyond compliance that could reduce the risk to product quality
  - Think of: “Best in Class”
  - Identified 97 activities across the 11 critical systems
  - Next step to identify ways to measure how effective those activities are at reducing risk to product quality

# Step 3: Measure Activities

500+

## Ways to Measure Activities

- How can the effectiveness of each of the 97 activities be measured?
  - 208 survey responses were received, yielding 500+ ideas
  - Finalized 125 ideas to take forward

- Why go through this process to get here?
  - To open our minds to the world of possibilities
  - To focus in on measures that are tied to impact to product quality

125

# Cause and Effect Matrix

- Assessed all 125 measurement ideas against the ability of that measurement to provide an indication of impact to:
  - Patient Safety
  - Design Robustness
  - Process Reliability
  - Quality System Robustness
  - Failure Cost

# Summary: 2014 - 2015

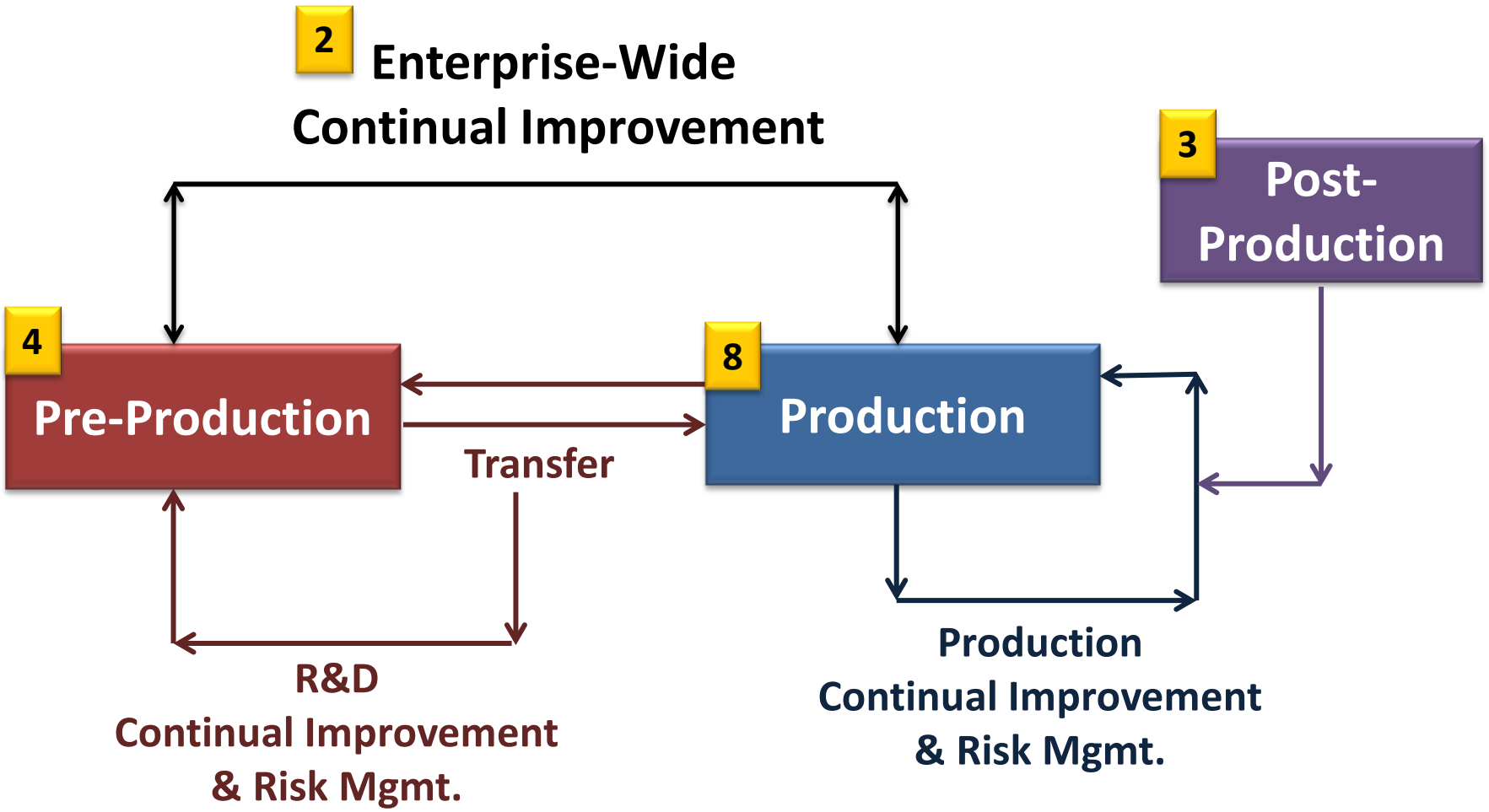
11 Critical Systems

97 Gold and Silver Activities

500+ Ways to Measure Activities

125 Cause and Effect Matrix

# 17 Measures Across TPLC




**Measures ➡ Metrics**

# Timeline and Process

| Sept 2014 | Oct 2014 – Mar 2015 | Mar – May 2015 | Jun – Sept 2015 | Oct 2015 – Jun 2016 |
|---|---|---|---|---|
| Kick-off | 11 Critical Systems | C&E Matrix of 125 Ideas | Pareto Analysis and Team Voting | |
| | 97 Gold/ Silver Activities | Finalization of 17 Measures | Selection of Top 3 Measures | Pilot Study |
| | | | Conversion of Top 3 Measures to Metrics | "Best Practices" Documents |

MDIC Adoption

# Finalized Metrics for Pilot Study

| Phase/Metric Name/Goal | Metric Calculation |
|---|---|
| **Pre- Production:** Design Robustness Indicator<br><br>Assess the number of product changes that are related to product or process inadequacies or failures | $\frac{\text{total \# of product changes}}{\text{total \# of products with initial sales in the period}}$ |
| **Production:** Right First Time Rate<br><br>Assess the number of production failures related to product and process inadequacies or failures | $\frac{\text{\# of units mfg. without non-conformances}}{\text{\# of units started}}$ |
| **Post- Production:** Post-Market Index<br><br>Assess an aggregate of post-market indicators with root causes of product or process inadequacies or failures | Index:<br><br>Complaints * (0.20) + Service Records * (0.10) +<br>Installation Failures * (0.20) + MDRs * (0.20) +<br>Recalls (units) * (0.20) + Recalls (total) * (0.10) |

# PwC Pilot Study

**Pilot Study Goal:** to demonstrate that the metrics are sensitive enough to differentiate between varying levels of product quality within a single company

- 6 companies enrolled: Baxter, Biomerieux, Boston Scientific, J&J, Meridian Bioscience, Stryker
- Each company conducted a 2 -3 year retrospective review
- Using these metrics alone allows only for in-company comparisons, since company-to-company comparisons involve variables that could lead to false conclusions

# Pre-Production: Lessons Learned

$$\frac{\text{total \# of product changes}}{\text{total \# of products with initial sales in the period}}$$

**Challenges:**

- The current denominator allows for skewing of the data by volume
- Very few companies track the number of changes that are specifically due to inadequate product and process development
- Very few companies track changes during the transfer stage
- Consistency of definition is required across a company in order to assess company-wide trends
- Difficult to segregate which of the planned changes are due to inadequacy versus improvements – this requires clear guidance and agreement
  - Also a concern that companies might reduce needed changes to improve metric

# Pre-Production: Revised Metric

$$\frac{\text{Total \# of changes (product \& process across projects)}}{\text{total \# of projects}}$$

**and/or**

Total # of changes (product & process for each project)

**Strengths:**

- Removes the risk of skewing the data by volume
- Metric is intended to bring about dialogue and improvements, as required e.g.
  - Provides an indication of the reliability of the research and development process of a company, or across R&D groups within a company
  - Increases overall awareness of R&D inadequacies such as to improve the Right First Time going forward
  - Provides an indication of the overall time and cost of getting a product to a mature state in the market

# Production: Lessons Learned

$$\frac{\text{\# of units mfg. w/o non-conformances}}{\text{\# of units started}}$$

**Challenges:**

- Not all companies can easily separate production failures by those that are due to product or process inadequacies
- Not all companies can easily trend process inadequacies
- Consistency of definition of a non-conformance is critical especially when:
  - "Unit" can refer to a finished good, in-process material, sub-component, or other
  - A finished good is an aggregation of all of its components, which may have been manufactured at a variety of facilities and/or contractors
  - Comparing across products and/or sites
  - Using a contract manufacturer
- Including planned rework and scrap is useful if it can be segregated out to track and minimize waste

# Production: Revised Metric

$$\frac{\text{\# of units mfg. Right First Time within or across lots}}{\text{\# of units started}}$$

**Strengths:**

- Tracking RFT based on product and process inadequacies continues to feed information back to R&D to improve the rigor of development
- Can track and trend within and across lots on a rolling basis to identify highest area of risk
- Apply pre-determined action limits, targets or control limits to identify when action may be needed. Different thresholds exist within company and across products
- The metric is not skewed by volume, however, the volume provides greater insight: 50 RFT out of 500 started is significantly different than 50 RFT out of 55 started.
- Can be used to monitor the start-up success across products and the timeframe needed for a product to reach a mature state.

# Post-Production: Lessons Learned

Service Records * (0.10) + Installation Failures * (0.20) + Complaints * (0.20) + MDRs * (0.20) + Recalls (units) * (0.20) + Recalls (total) * (0.10)

**Challenges:**

- Overly complicated aggregation of commonly measured indicators
- The metric is reduced to tracking complaints and MDRs for products that do not have service and installation, and have not resulted in recalls
- The weighting factor can be difficult to determine
- Not clear if measuring in aggregate is more informative than tracking separately

# Post-Production: Revised Metric

**Multi-Step Options:**

1. Calculate each post-production indicator separately with defined equations provided
2. Aggregate the post-production indicators using weighting factors that are based on product and process risk profiles
3. Comparative analysis can be conducted through mechanisms such as dashboards, score cards or heat map tools

**Strengths:**

- Provides flexibility to meet the business needs and maturity of the company and products
- Provides a mechanism to foster discussion, inform decisions and trigger actions in a way that might not be achieved by viewing the indicators in isolation
- The “how to” for each step above is provided in the Best Practices document

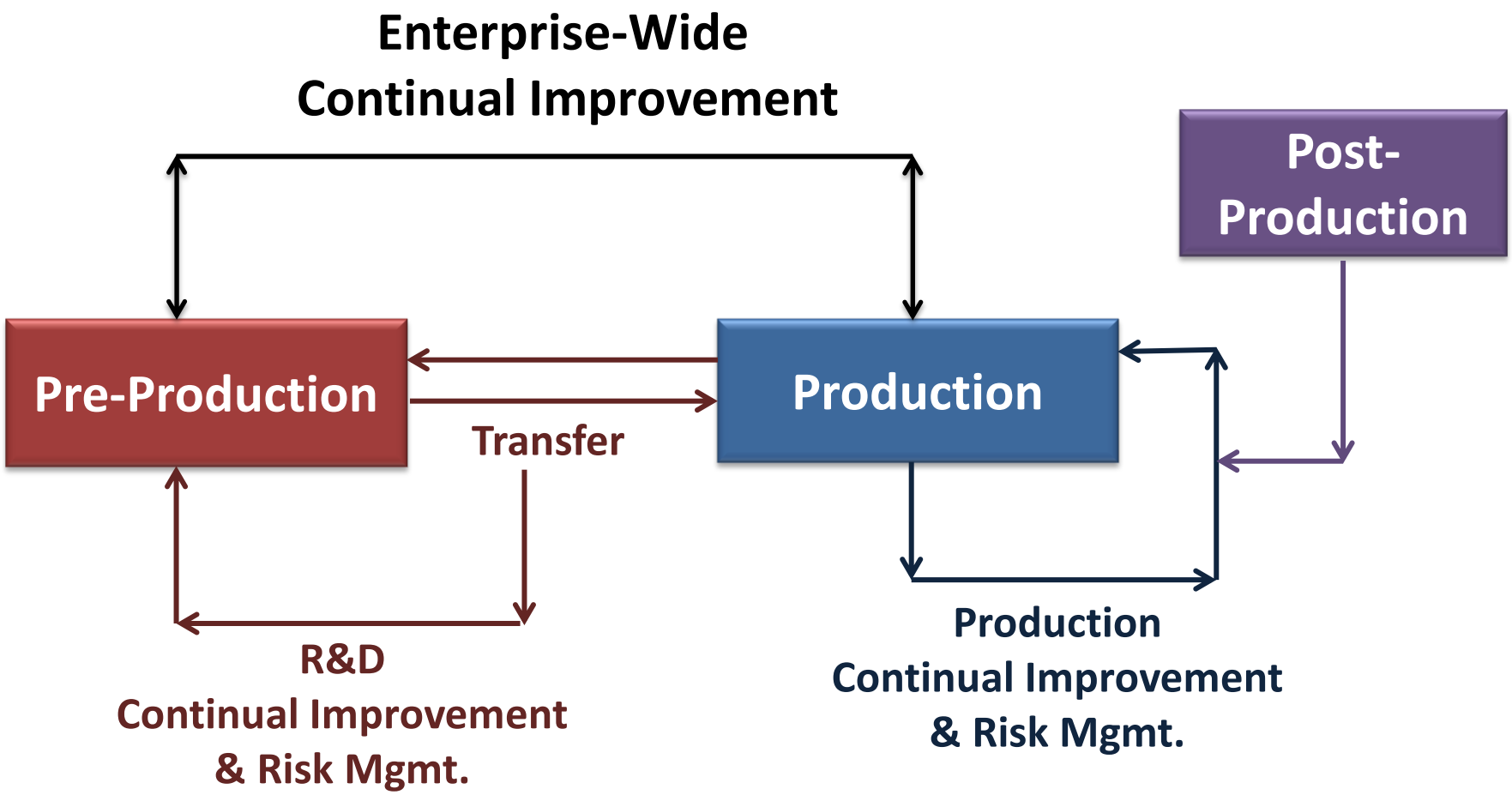
# "Best Practices" Documents

**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


| October | January | March | June |
|---|---|---|---|
| Kick-off and TPLC Champions identified | Champions presented key input received | Champions presented drafts to team | Pilot study data analyzed, and Best Practices finalized |

# Pulling it all Together



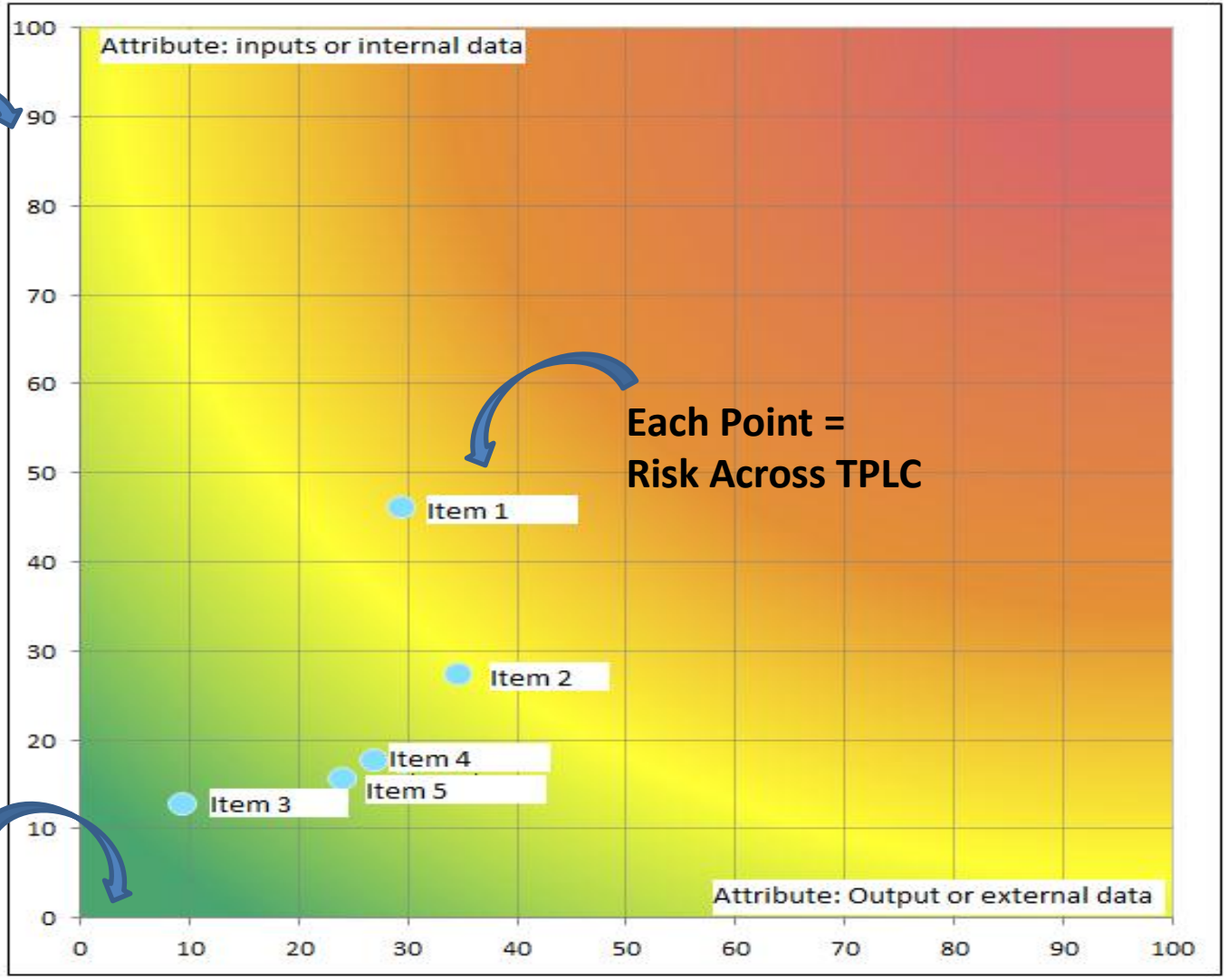
# Heat Map Correlation

**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



# Pilot Study: Lesson on Risks

Using metrics to compare one company to another can lead to unsubstantiated conclusions and unintended consequences.

- **Key contextual differences:**
  - Company culture
  - Product complexity
  - Terminology/definition
  - Historical trends


- **For discussion - potential false conclusions using the following metrics:**
  - Number of Recalls
  - Right First Time Rate
  - Complaints Rate
  - Change Rate

# 2014 – 2016 Deliverables

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

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