



Selecting Metrics For a Supplier  
Metrics & the Supplier Control Plan  
Corrective Action, GHTF, And Its Metrics  
Predictive Analysis  
Supplier Metrics and Management Review

# **SUPPLIER METRICS**

# Selecting Metrics For Supplier Management

# Material Suppliers

- For supplier's who provide material, you expect:

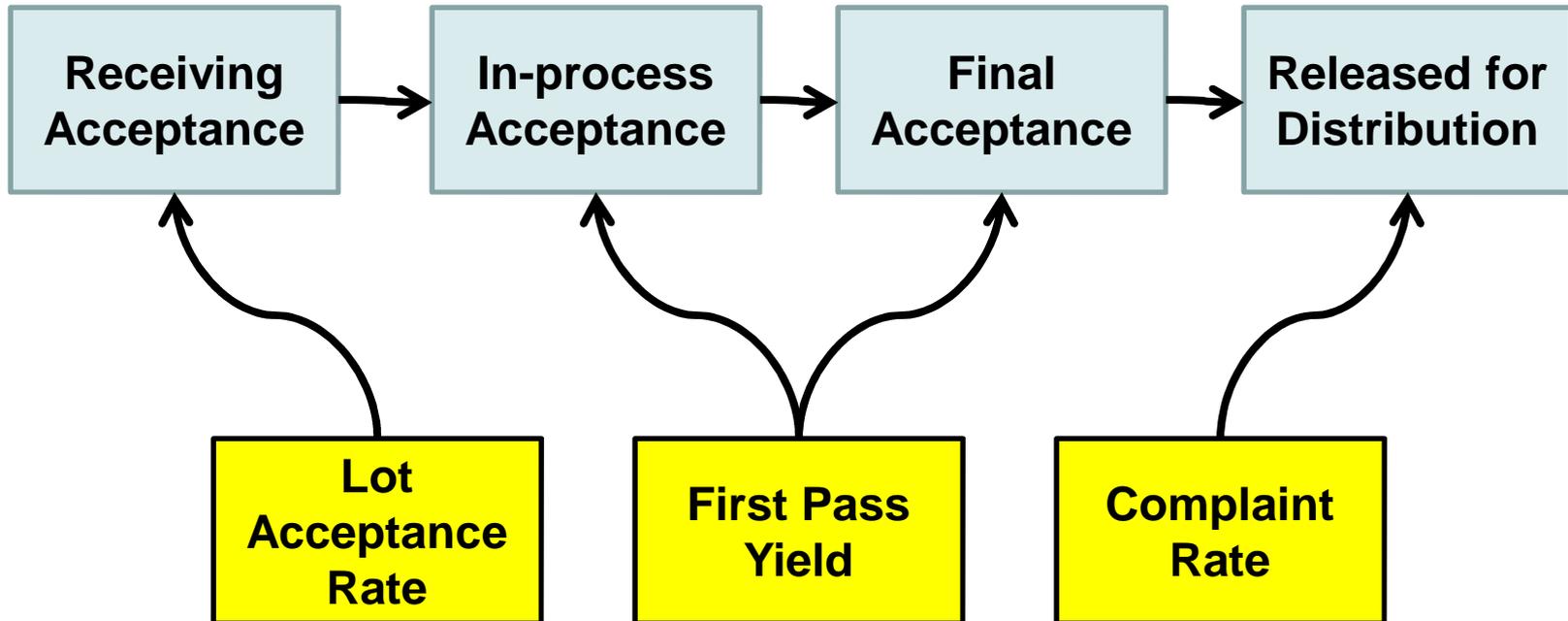
**Good stuff, on time**

- Use this as the basis of the metrics

# Good Stuff

- Think of this as material you build into your device.
- What is good stuff?
  - It is conforming material, *i.e.*, material that meets the requirements.

# Verification Points



# Lot Acceptance Rate

- The supplier submits material in lots as called out on the Purchase Order.
- Each lot is subject to Receiving Inspection
- Typically, Receiving Inspection uses lot acceptance sampling plans (Z1.4, Z1.9, or c=0).

# Lot Acceptance Rate

- The lot acceptance rate is for a specific time interval, typically 1 month, 3 months, 6 months, or 12 months.
- Implement the sampling plan's switching rules.
  - Count the proportion of a supplier's parts in Normal, Reduced, or Tightened inspection.

$$\frac{\textit{Lots Accepted}}{\textit{Lots Submitted}}$$

# Switching Rules

- Implement the switching rules in the sampling plans.
- Your target is that a supplier's parts switch to reduced inspection
  - This is your lowest cost case
  - It demonstrates good supplier process control
- Suppliers with a part on tightened inspection raise a red flag.
  - This is where you should focus your supplier management program

# First Pass Yield

- Sampling may allow nonconforming material to enter your inventory.
  - These are nonconforming items in the lot, but not in the sample.
- Your in-process or final inspection will detect the nonconforming items.
- In addition to supplier items, you may detect other nonconforming material.
  - These are nonconformances not chargeable to the supplier

# First Pass Yield

- The first pass yield is for a specific time interval, typically 1 month, 3 months, 6 months, or 12 months.
- First Pass Yield is a calculation for each individual inspection or test.
- First Pass Yield excludes items dispositioned as rework, repair, or regrade.
  - It includes only “new” items.

$$\frac{\textit{Items Accepted}}{\textit{Items Submitted}}$$

# Supplier Issues

- The First Pass Yield and Rolled Through Yield usually apply to all causes.
- Calculate separate rates for certain conditions
  - Internal v. External causes
  - By Supplier
  - By Part Number

# Complaint Rate

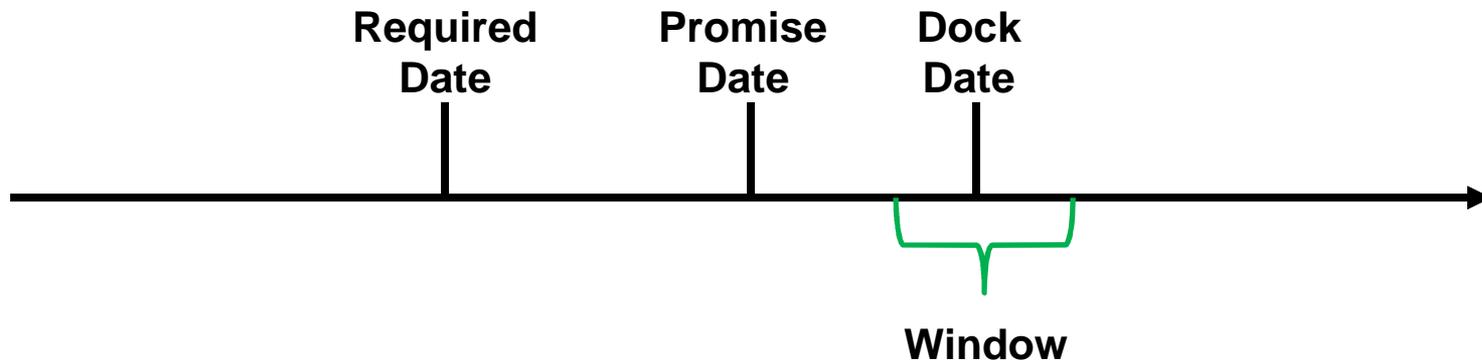
- Complaints include warranty returns and other returns.
- When investigated, classify the complaints:
  - Definitions in the regulations (identity, quality, durability, reliability, *etc.*)
  - Internal or external causes
  - Supplier
  - Part number

# Basic Supplier Quality Metrics

- Receiving Lot Acceptance Rate
- Proportion of items on Reduced Inspection
- Rolled Through Yield, Supplier Specific
- Complaint Rate, Supplier Specific

# On Time Delivery

- There are a number of ways to measure on time delivery.
- A typical MRP system generates a required date – when the item is needed on your dock.
- The supplier will respond with a promise date – when the item will ship.
- The item arrives on the dock date



# Basic Delivery Metrics

- A common practice establishes a window to account for process variability.
  - Let's assume a window of  $\pm 5$  calendar days
- A Supplier Management Effectiveness metric counts the proportion of time that Dock Date – Required Date is inside the window.
- A Supplier Performance metric counts the proportion of time that Dock Date – Promise Date is inside the window.

# Corrective Action

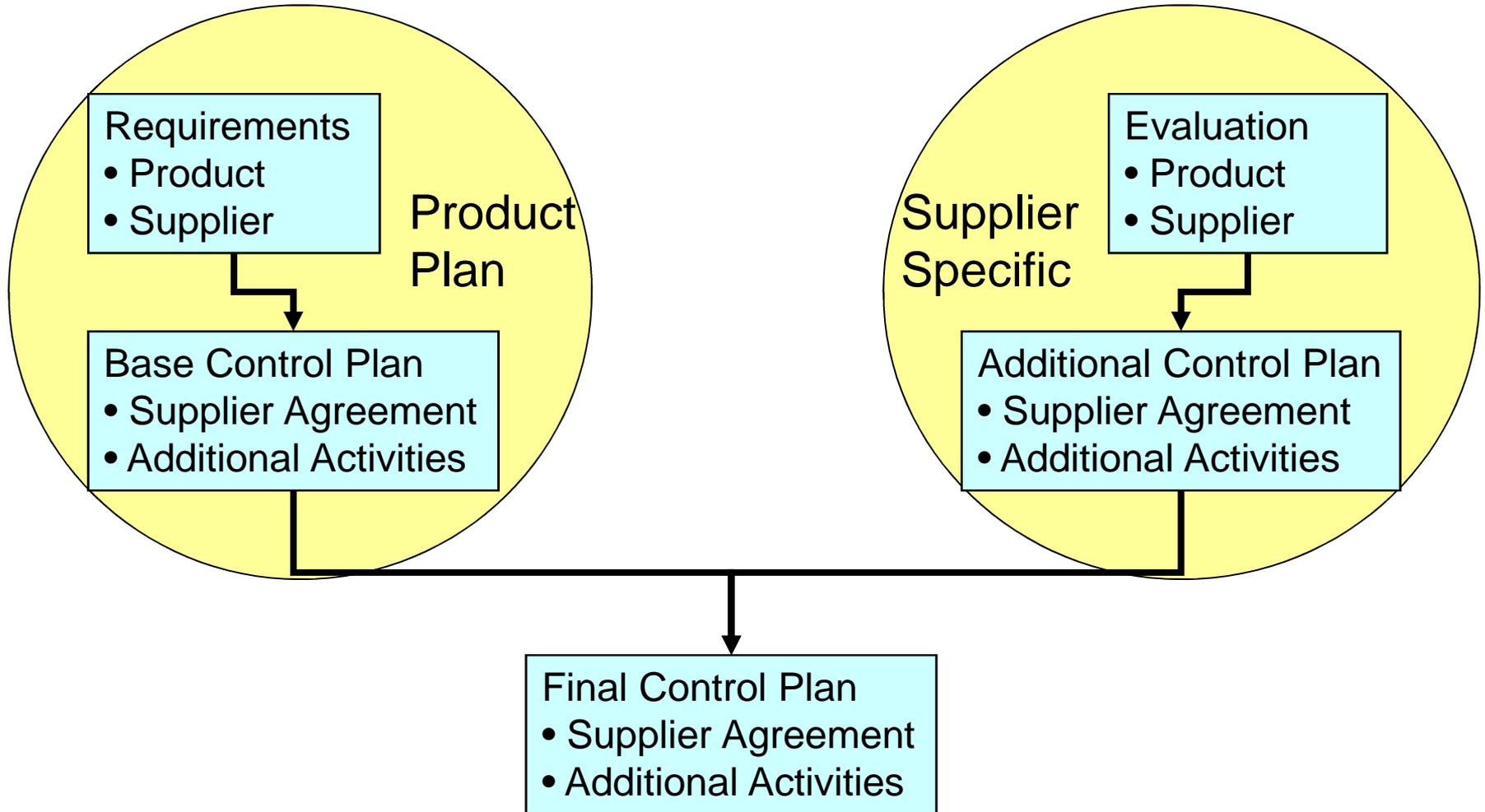
- Each lot or part rejection is a nonconformance
- Each failure to meet the Promise Date is a nonconformance
- Typically, each nonconformance will generate a request for corrective action

# **Augmenting The Metrics Using The Control Plan**

# Supplier Evaluation and Selection

- The supplier selection process typically includes the following steps:
  - Define requirements
  - Evaluate potential suppliers against the requirements
  - Identify gaps
  - Select a supplier
  - Develop a control plan for the supplier

# The Supplier Control Plan



# An Example Of A Gap

- The gap analysis may reveal supplier improvement opportunities
- For example, you may recognize that the supplier's complaint handling and corrective action processes are not robust
- This is important because you need these systems to be effective and efficient

# Metrics For The Gap Example

- The need to improve a complaint and corrective action system usually results from an audit.
- The improvement activities should be a project with a project plan, tasks, and milestones.
- A common metric is cumulative milestones completed divided by cumulative milestones planned.

# **Corrective Action, GHTF, And Its Metrics**

# Delivery, Measurement, and Monitoring

- The GHTF Guidance on supplier management includes activities related to Delivery, Measurement, and Monitoring
- The recommended objective evidence includes:
  - Receiving records
  - Inspection records
  - Acceptance records
  - Records of results of any data analysis
  - Records of any corrections

# Feedback & Communication

- The GHTF Guidance on supplier management includes activities related to Feedback and Communication
- Feedback should be both positive and negative.
- Both parties should work on open and effective communication.

# The Supplier Scorecard

- One effective communication method is the supplier scorecard
- It takes a variety of forms, but communicates the metrics the manufacturer developed and monitors
- It must be frequent enough to provide valuable information, usually quarterly

# Corrective Action

- Correction fixes a problem
- Corrective Action eliminates the cause of the problem
- A nonconforming item can be corrected and the cause determined and eliminated.
- A late delivery cannot be corrected, but the cause can be determined and eliminated

# Corrective Action

- Depending on the problem and the product, the manufacturer may delegate Corrective Action activities to the supplier in a cooperative manner.
- This is especially true for complaint investigations that involve supplier product.
- The combined Corrective Action activities of both the manufacturer and the supplier must satisfy the requirements of applicable regulations and standards.
- Even if the manufacturer delegates Corrective Actions to the supplier, the overall responsibility resides with the manufacturer.
- Corrective Action decisions and effectiveness checks reside with the manufacturer and cannot be delegated.

# Corrective Action Effectiveness

- The role of Corrective Action is to eliminate the cause of a detected nonconformity.
- A corrective action is effective when the nonconformity doesn't happen again.
- In some cases, a nonconformity could be the result of many different causes.
  - For example, a supplier late delivery could have many possible causes; eliminating one will not eliminate the others.

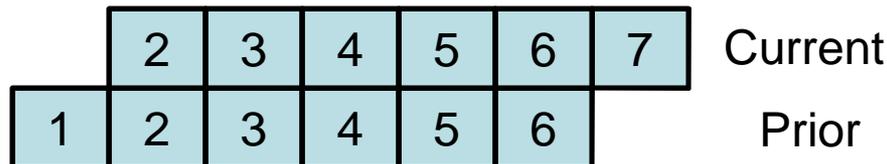
# Predictive Analysis

# Predictive Analysis

- Predictive Analysis attempts to determine if a supplier is likely to create a problem.
- The method uses supplier metrics and is one way to help identify risk.
- We look at six metrics and a traffic light system (red, yellow, or green).

# Performance

- For simplicity, use the rates (quality and delivery) at receiving
- In effect, this counts Purchase Order lines
- Calculate the current 6 month moving average
- Calculate the difference from the prior 6 month moving average

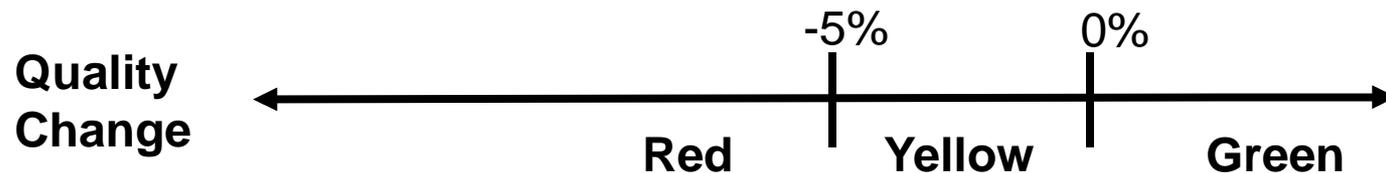


# Quality Performance

- Metrics

- Current 6 month quality score

- Change in 6 month quality score

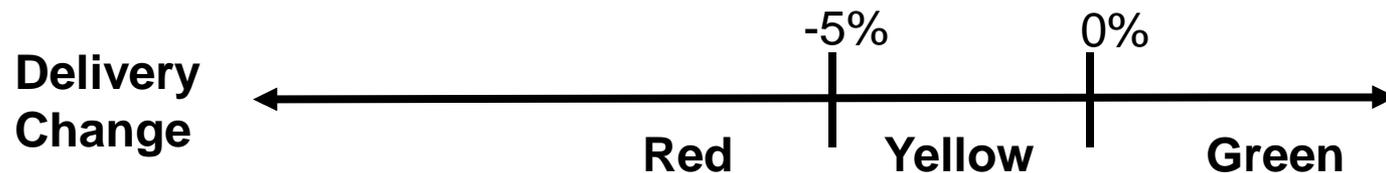
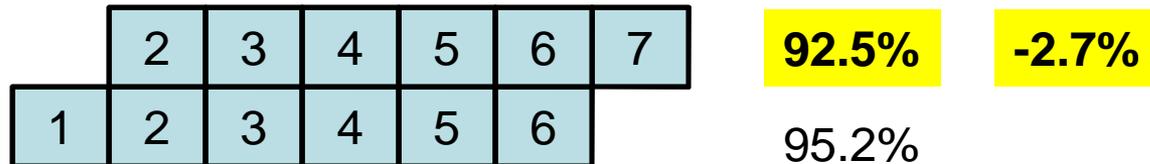


# Delivery Performance

- Metrics

- Current 6 month delivery score

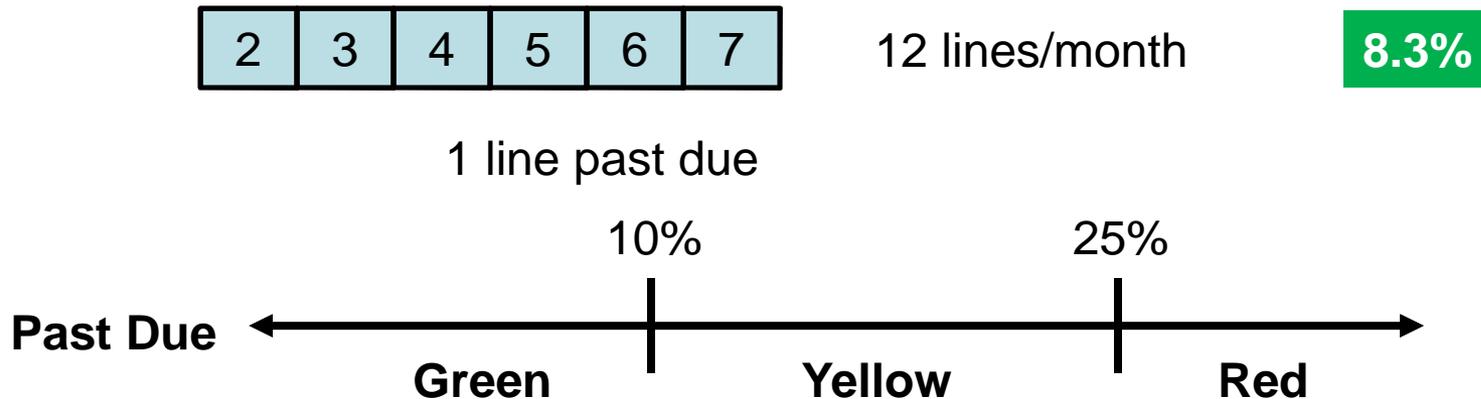
- Change in 6 month delivery score



# Past Due Performance

- Metrics

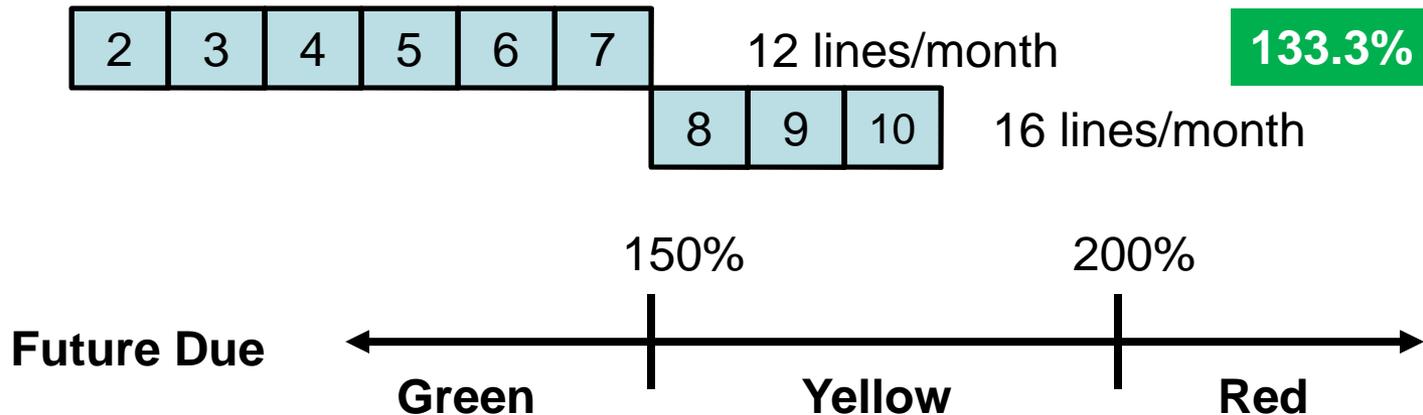
- The ratio of past due PO lines to the 6 month average PO lines received



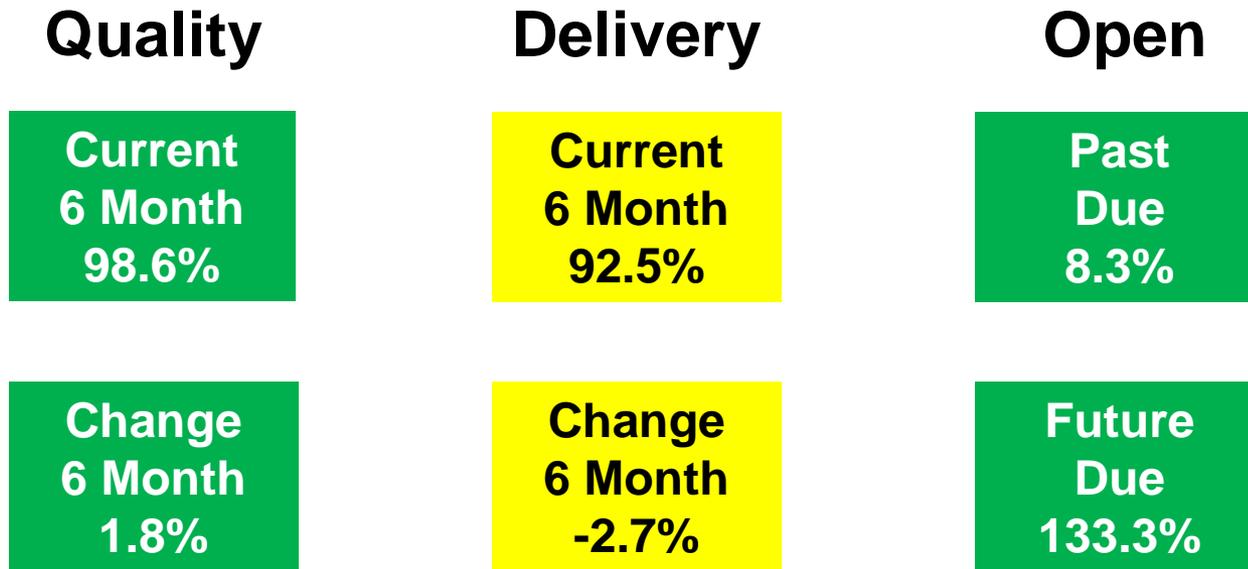
# Future Due Prediction

- Metrics

- The ratio of PO lines due in the next 3 months to the 6 month average PO lines received



# The Predictive Scorecard



## Analysis

Q: The supplier's quality is acceptable and shows improvement over the previous measurement period.

D: The supplier's delivery is marginal and has deteriorated. In addition, the supplier is late on some deliveries, but we have also planned to increase their workload.

# **Integrating Supplier Metrics Into Management Review**

# Management Review

- Management with executive responsibility reviews the suitability and effectiveness of the quality system.
- Following the QSR preamble, management review may include a review of combined information based on customer feedback, internal feedback (such as results of internal audits), process performance, and product (including servicing) performance

# Management Review

- For ISO 13485:2003 and ISO 13485:2016 the input to Management Review includes process performance (monitoring and measurement)
- Supplier management is one of the processes.
- In addition, clause 4.1 tells us that when the manufacturer chooses to outsource processes it must control them, and identify the control in the QMS.

# Metrics for Management Review

- To get a effective set of metrics for management review, utilize the things we discussed:
  - Predictive Analysis will tell you both current performance and risk
  - Special metrics from the control plan
  - Corrective Action aging
  - Corrective Action effectiveness reviews



# ***QUESTIONS***