



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:

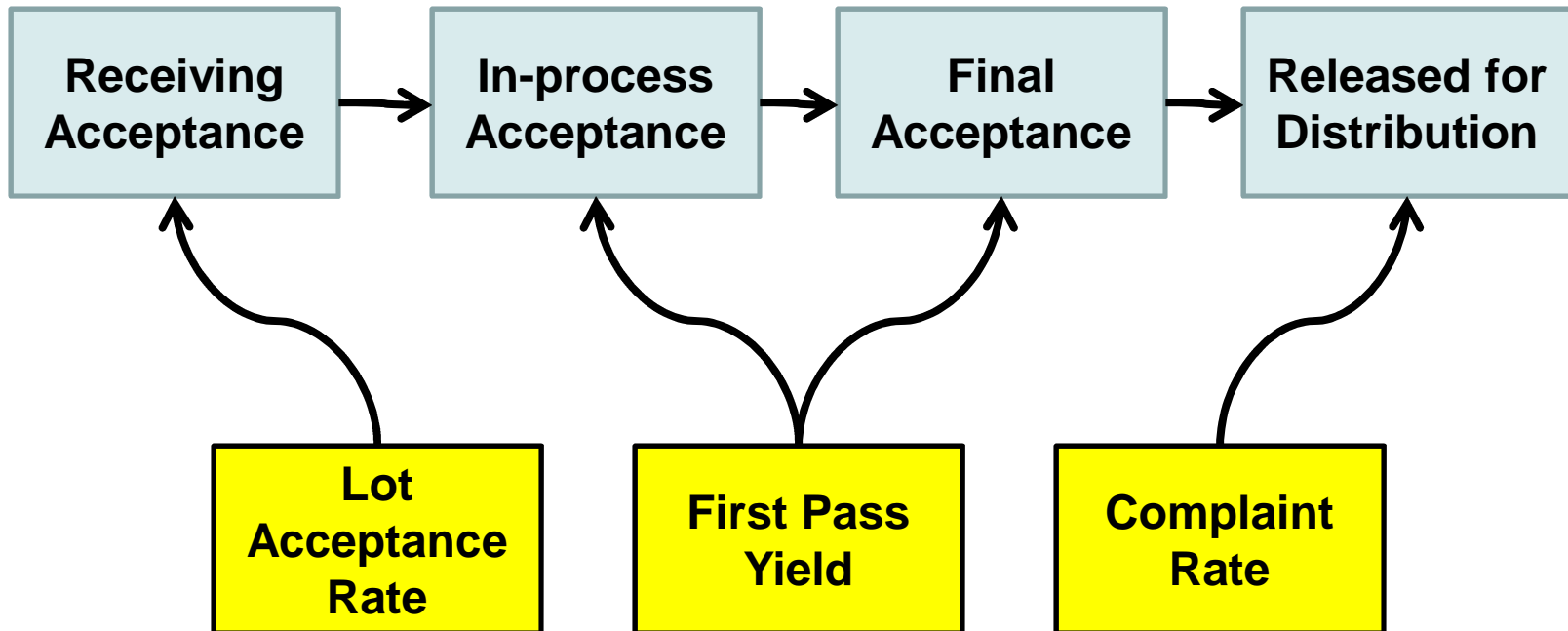
Good stuff, on time

- 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

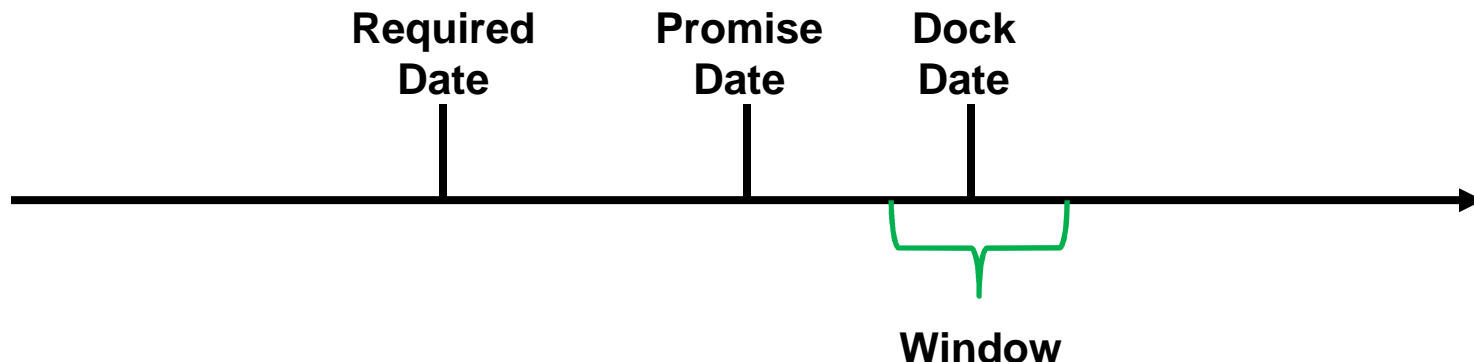
- Complaints include warranty returns and other returns.
- When investigated, classify the complaints:
 - Definitions in the regulations (identity, quality, durability, reliability, *etc.*)
 - Internal or external causes
 - Supplier
 - Part number

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 ± 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

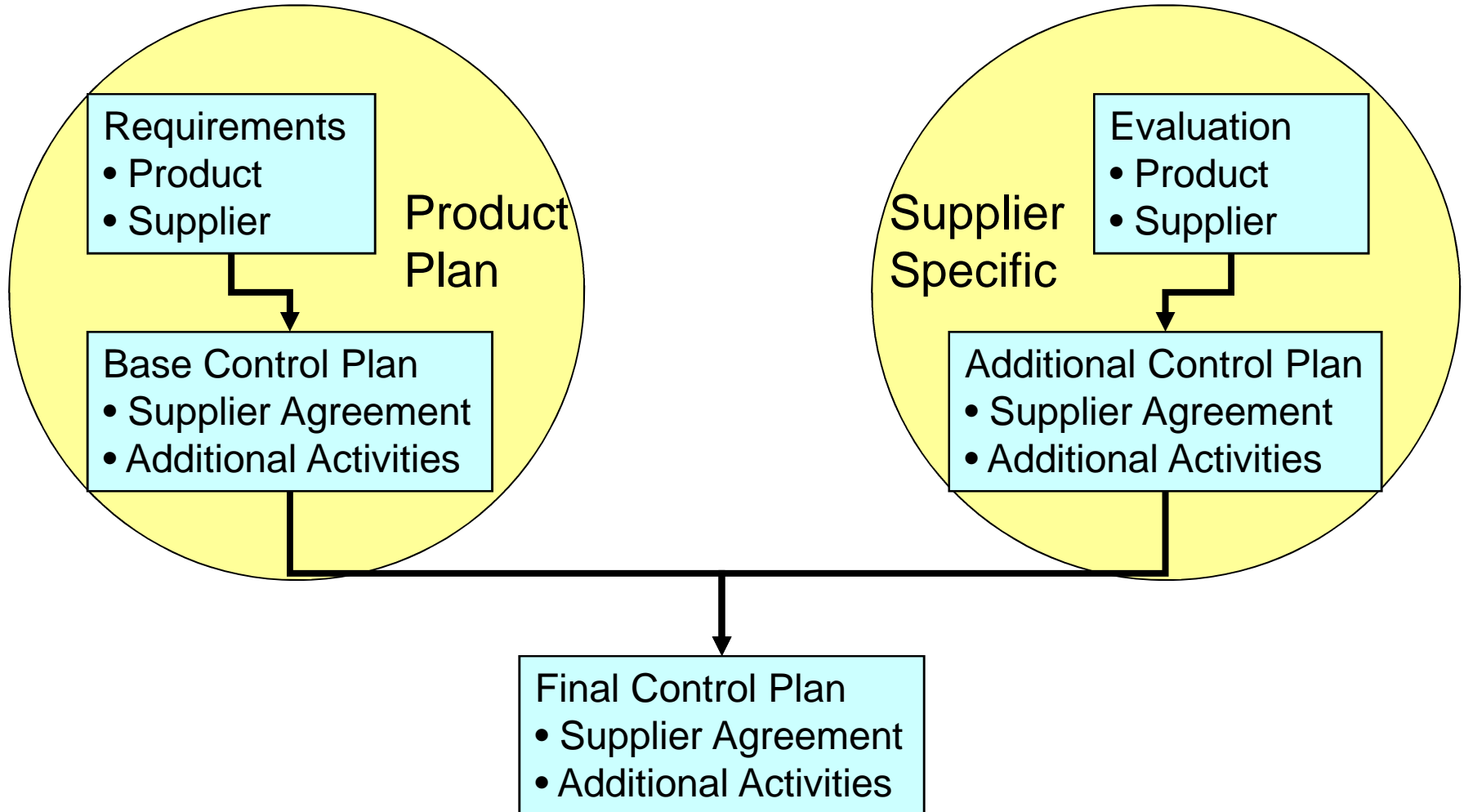
- Each lot or part rejection is a nonconformance
- Each failure to meet the Promise Date is a nonconformance
- Typically, each nonconformance will generate a request for corrective action

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.

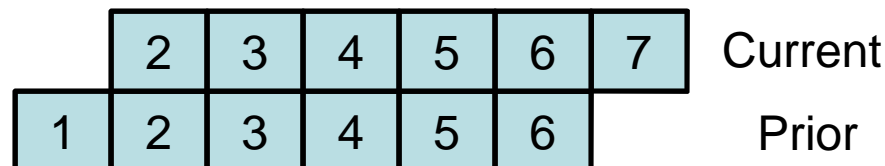
Predictive Analysis

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).

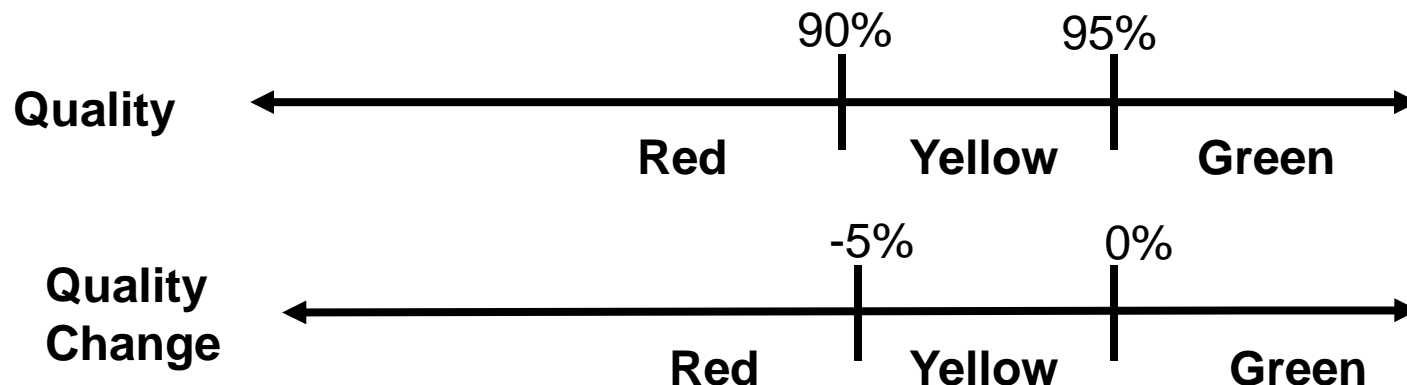
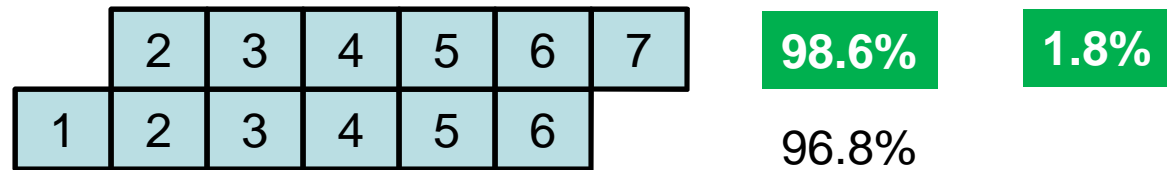
Performance

- 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

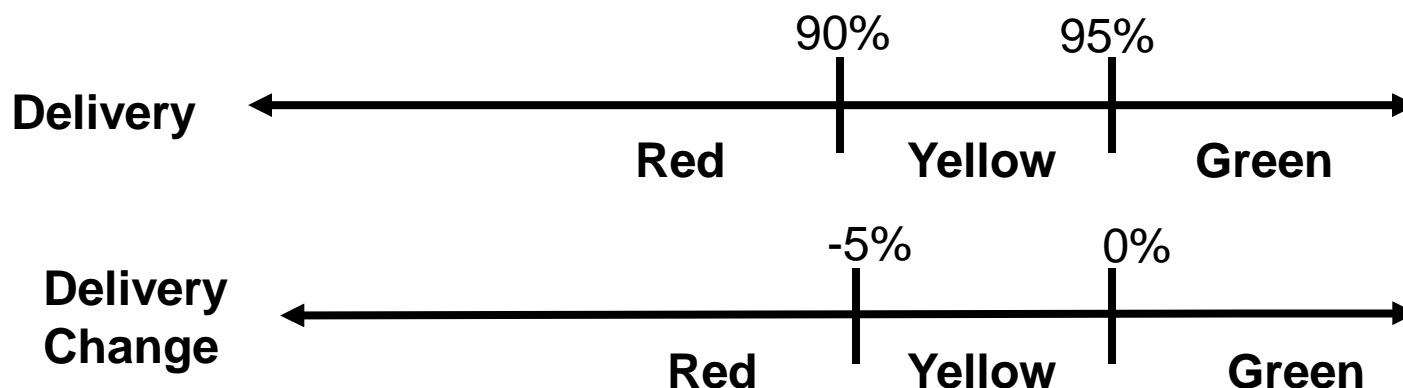
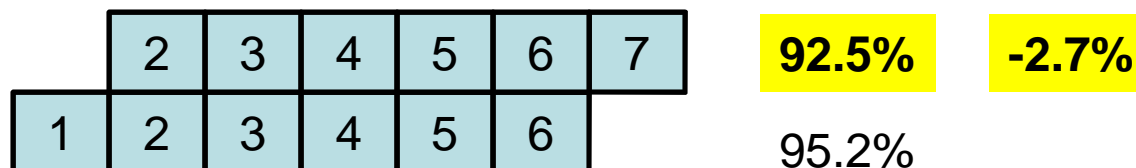
- Metrics
 - Current 6 month quality score
 - Change in 6 month quality score



Delivery Performance

- Metrics

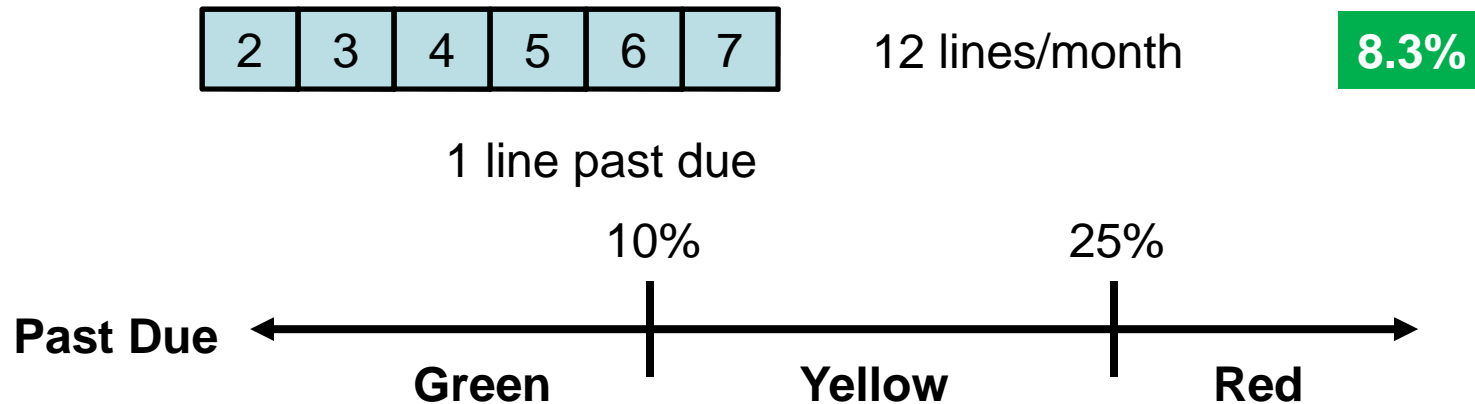
- Current 6 month delivery score
- Change in 6 month delivery score



Past Due Performance

- Metrics

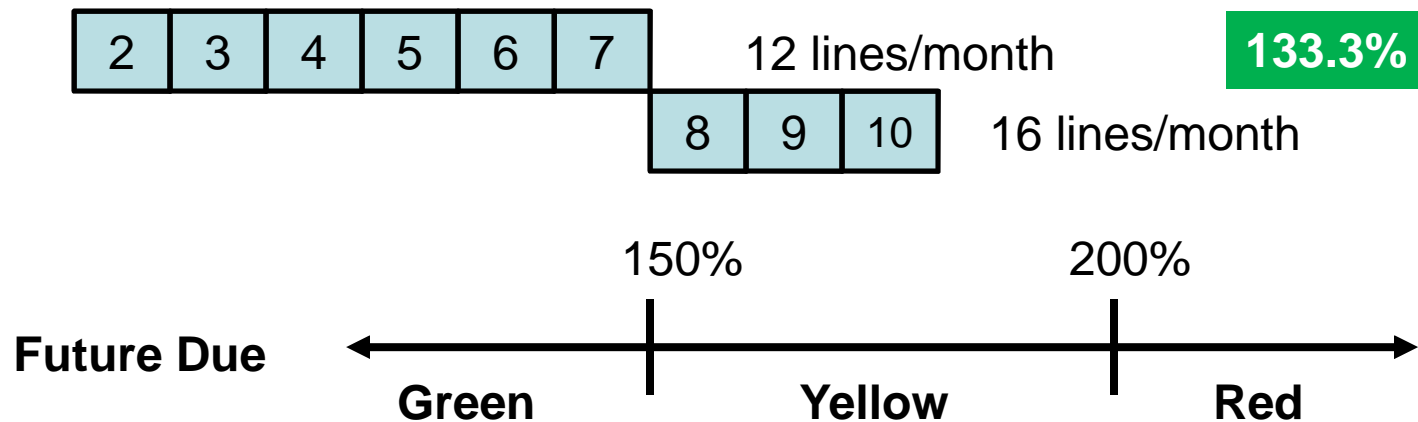
- The ratio of past due PO lines to the 6 month average PO lines received



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

Quality	Delivery	Open
Current 6 Month 98.6%	Current 6 Month 92.5%	Past Due 8.3%
Change 6 Month 1.8%	Change 6 Month -2.7%	Future Due 133.3%

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