

# Global Supplier Quality Performance Monitoring Scorecard

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*Abstract - Monitoring the performance of suppliers in any industry ensures the continuous improvement of the relationship between a supplier-customer through the identification of gaps between the current performance and the customer expectations. In the Medical Device industry, Quality Performance is not only a business improvement activity, but the expectation of regulatory agencies across the world. With globalization, the need to have a global scorecard has become more evident.*

*The goal of this design project was to create a new supplier quality performance tool, which utilized the defined Quality Key Performance Indicators and weights each one based on risk, in order to score and rank each supplier with the final goal of identifying which monitoring process will be utilized to assess and improve the supplier quality and meet regulatory compliance expectations. A DMAIC approach was utilized to execute the project. The designed tool demonstrated to be effective in ranking the suppliers and identifying high risk suppliers with poor quality performance to focus on.*

## Introduction

Medical Device manufacturing is

a regulated industry which needs to comply to regulations determined by established regulatory agencies across the world. One of the largest and costliest portions of these requirements is supplier monitoring [1]. Historically, the industry has mostly complied with this by auditing suppliers on an established schedule, depending on the risk of the supplier. In most cases, these types of audits are based on standards, which might not provide the company with the real story on the supplier's process controls and their capability to protect the customer from receiving nonconforming parts. The design project explores and develops a new supplier performance monitoring system that will take into consideration all the Quality Key Performance Indicators (KPI) to increase focus on top-offender or higher risk suppliers utilizing other methods to monitor them and improving their quality.

## Background

Monitoring the quality performance of a supplier is not only a regulatory requirement, but it also ensures that supply chain is not interrupted due to nonconforming parts or rejections and reduce risk to the patient or final user. Historically, Supplier Quality at the sites have monitored and trended issues for their suppliers, investigated, and documented corrective action, but in recent years, globalization has become a priority in the Organi-

zation and Sourcing has become a global organization. This shift has promoted that suppliers, especially the ones that provide products and services to various sites within the organization, have single point of contacts globally.

The supply chain is the single largest spend within the Operations Organization for the company, and the need to improve both the relationship and the quality of the suppliers has become more evident [2]. This year, a new team was created- Global Supplier Quality, with engineering and leadership resources across the board in one single organization which directly reports to Global Quality and not to the manufacturing sites. Global Supplier Quality has the mission of monitoring suppliers through the audit program and creating improvement projects at the suppliers which need to improve. Global Supplier Monitoring is performed through Supplier Audit, for which the frequency is a function of the Supplier Type and Risk, but currently there is no tool to score and monitor Supplier Quality Performance on a global scale since Quality KPIs are mostly monitored on a site level (table 1). The challenge lays on

Key Quality Performance Indicator (KPI)	Current Monitoring level	Future Monitoring Level
Nonconformance Investigations	Site level	Global level
CAPA investigations (Corrective Action/Preventive Action)	Site level	Global level
Escapes (Complaints or confirmed escapes)	Site level	Global level
Defects per million (DPM=parts rejected/parts received *1000000)	Site level/Global level	Global level
Supplier Audit Score	Global level	Global level

Table 1 - Quality Key Performance Indicators

how to effectively choose, improve, show the improvement, and monitor the suppliers that enter the improvement program.

## DEFINE

### Problem

Supplier Monitoring at a global scale is currently performed through the supplier audit program, but when audit scores are compared to the supplier's quality key performance indicators (KPI), it can be observed that audits scores do not correlate with the what the KPIs demonstrate (i.e suppliers that might show low quality in various KPIs, might have high audit scores). Because not all KPIs are monitored on a global level, the new Global Supplier Quality Improvement team do not have an effective way to monitor the performance of the suppliers on a global scale and determine which suppliers need increased monitoring, and improvements. In addition, there is not a tool to assess the supplier's improvement or decline in quality performance on a yearly basis, globally.

### Goal

Create a new supplier quality performance tool, which utilizes defined Quality KPI and weights each one based on risk, in order to score and rank each supplier with the final goal of identifying which monitoring process (either improvement project, audit, or no actions) will be utilized to assess and improve the supplier quality and regulatory compliance expectations.

## MEASURE

Eleven manufacturing sites from the same company were utilized in the measure phase, the total quantity of suppliers from these

sites add up to 423 suppliers. Data for each KPI was gathered for the 12-month rolling of the year 2019. Suppliers that provide products to more than one site, were combined in order to ensure that each supplier was a unique data point. Each site utilizes the same Quality Management System, triggers, documentation system to record each of the data points of the KPIs, therefore the data can be considered comparable.

### Nonconformance Investigations

Nonconformance Investigations (NCs) are records generated to contain, investigate, and correct any product / documentation / specification / change / control issue, etc. which fails to conform with the approved standards, design, or procedure. If the occurrence of the issue deemed to be caused by that supplier, then the nonconformance is attributed to that supplier. After the data was gathered and combined, a pareto was generated (figure 1). It was determined that 71/423 (16%) of suppliers make up 80% of the nonconformance records.

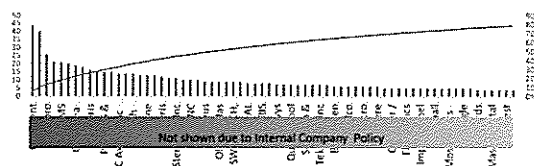


Figure 1 - Pareto of Quantity of NC by Supplier 2019

### Corrective Action/Preventive Action

Corrective Action/ Preventive Action (CAPA) records generated when nonconformances are observed to have a trend, deemed a systemic issue, or present a high patient risk. CAPAs are expected to include a root cause investigation and at a minimum, Corrective Actions to ensure that the probability of reoccurrence of

the issue is lowered or eradicated. If the occurrence of the issue deemed to be caused by that supplier, then the CAPA is attributed to that supplier. After the data was gathered and combined, a pareto was generated (figure 2). It was determined that 26/423 (6%) of suppliers make up 80% of the CAPA records.

### Escape Nonconformances

Escape Nonconformances are records which the product is confirmed to have escaped the company's control. They can either be recorded from customer complaints or through internal investigations where product escape is confirmed. If the occurrence of the issue deemed to be caused by that supplier, then the escape nonconformance is attributed to that supplier. After the data was gathered and combined, a pareto was generated (figure 3). It was determined that 30/423 (7%) of suppliers make up 80% of the Escape Nonconformance records.

### Rejected Parts

Rejected Parts are the actual quantity of received parts that were rejected at any point during incoming inspection or manufacturing and reported on a monthly basis. This data is recorded into each site's ERP system through return to vendor (RTV) or scrap. After the data was gathered and combined, a pareto was generated (figure 4). It was determined that 16/423 (4%) of suppliers make up 80% of the rejected parts.

### Received Parts

Received parts data for each supplier is recorded into the ERP system and reported on a monthly basis. After the data was

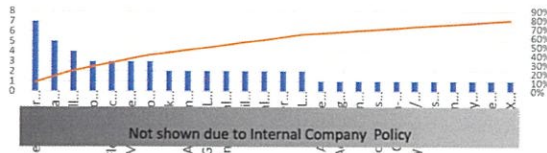


Figure 2 - Pareto of Quantity of CAPAs by Supplier 2019

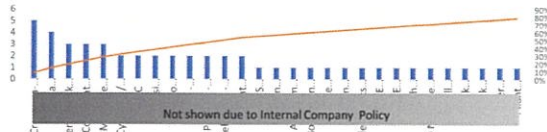


Figure 3 - Pareto of Escapes by Supplier 2019

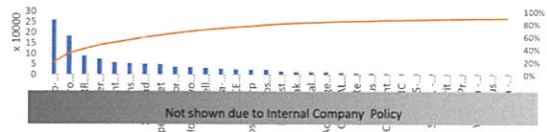


Figure 4 - Pareto of Rejected Parts by Supplier 2019

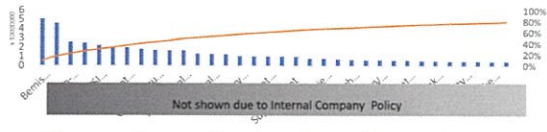


Figure 5 - Pareto of Received Parts by Supplier 2019

gathered and combined, a pareto was generated to determine which suppliers make up 80% of our received parts. This indicator is not considered to be a Quality KPI but it will be useful to show which are the company's top business suppliers by quantity. These suppliers might present higher risk if they are low quality due to the amount of parts supplied. After the data was gathered and combined, a pareto was generated (figure 5). It was determined that 34/423 (8%) of the suppliers make up 80% of the rejected parts.

### Audit Scores by Supplier Type and Risk

Each supplier is categorized by Supplier Type and risk. Each supplier fits into these categories depending on the product, component, manufacturing material, or service that they provide to the company. The risk of the supplier is based on the patient risk that part or service poses to the pa-

tient. When suppliers provide multiple types of parts or services with multiple risks, the worst case (highest risk) scenario is utilized to classify the supplier. Audit frequency and type (either on-site audit, documentation audit, or none) depend on the supplier type and risk. Audits are a standardized checklist based on the applicable standards and the scores are based on the amount of acceptable questions/total amount of questions for each checklist. An analysis of audit scores by supplier type and risk was performed in order to be able to see

where suppliers are currently in terms of audit. For this company, an audit score of >96% is considered "good standing" audit. The findings in each supplier are monitored for correction and closure. When data was gathered, it was found that 89/423 (21%) of suppliers have unacceptable audit scores, but in most cases the audit score of the supplier does not provide an indication of the quality of the parts/services being provided by that supplier (table 2).

Avg Audit Scores by Supplier Type and Risk 2019	Critical	Major	Minor
Component Supplier	97.7	95.4	99.1
Contract Manufacturer (CM)	97.7	97.5	-
Contractor	99.2	80.0	-
OEM Device Supplier (OEM)	97.8	95.8	97.0
Service Provider	98.8	96.2	100.0
Consultant	-	-	-
Manufacturing Material Supplier	99.0	-	-

Table 2 - Quality Key Performance Indicators

### Analyze Top-10 Offender Supplier for each KPI

Top 10 suppliers for each category were observed. For Quality KPIs (ie. NCs, CAPA, Escapes, Rejected Parts), this means the top offender, or the suppliers with the highest amount of records. For the business KPI (Received Parts), this means the suppliers that provided the most amount of parts. Lastly, for audit scores, these are the suppliers with the lowest audit scores. After all top suppliers were analyzed, it is observed that none of the top offender may correlate to the worst audit scores.

The following observations were noted:

- A total of 31 suppliers compose the top 10 offenders for all Quality KPIs.
- None of the 31 suppliers correlate with the Top 10 worst audit scores.
- The Supplier that is repeated the most (Supplier #4) has an audit score of 100% in 2019.
- Only 6/31 suppliers have less than 96% (minimum acceptable) in their audit scores.
- The average audit score for all top offender suppliers is 97.6%.
- The average audit score for the top offender suppliers for Audit Scores (worst audit scores) is 70.5%.

### Top Offender Supplier Audit Score by Year

Each Quality KPI's Top-10 supplier offenders were gathered (ie. NCs, CAPA, Escapes, Rejected Parts) (figure 6). For each of the 31 total suppliers identified, the last 5 years of audit scores were reviewed. When averaged by year, it was found that all averages were found to be >96% avg audit score by year. It can be concluded that, generically, audit scores do not provide solid indica-

Rank	Top Supplier- Qty of Parts	Top Qty NCs	Top Qty of CAPAs	Top Qty of Product Escapes	Top Qty Part Rejections	Worst Audit Scores
1	Supplier #1	Supplier #11	Supplier #20	Supplier #16	Supplier #3	Supplier #39
2	Supplier #2	Supplier #12	Supplier #21	Supplier #21	Supplier #4	Supplier #40
3	Supplier #3	Supplier #4	Supplier #22	Supplier #20	Supplier #31	Supplier #41
4	Supplier #4	Supplier #13	Supplier #19	Supplier #11	Supplier #32	Supplier #42
5	Supplier #5	Supplier #14	Supplier #23	Supplier #24	Supplier #33	Supplier #43
6	Supplier #6	Supplier #15	Supplier #24	Supplier #27	Supplier #34	Supplier #44
7	Supplier #7	Supplier #16	Supplier #4	Supplier #28	Supplier #35	Supplier #45
8	Supplier #8	Supplier #17	Supplier #25	Supplier #29	Supplier #36	Supplier #46
9	Supplier #9	Supplier #18	Supplier #26	Supplier #4	Supplier #37	Supplier #47
10	Supplier #10	Supplier #19	Supplier #2	Supplier #30	Supplier #38	Supplier #48

Table 3 - Top-10 Supplier Offenders for each KPI 2019

tion of the product/service quality of a supplier.

### Improve

After analyzing the data and comparing the worst scores (top offenders) for each KPI and being able to observe the lack of correlation between all the KPIs and the audit scores, the need for a tool to monitor the overall quality performance of a supplier is evident. The goal was to create a tool which takes into consideration the Supplier Type and Risk, Audit scores, Nonconformances, CAPAs, Escape Nonconforman-

### Tool Creation

- Data for all 423 suppliers was put together by supplier.
- For each KPI, the data point for the suppliers that were identified as creating 80% of the issues (from the pareto charts), were individually marked in red.
- A Weight Factor was chosen for each of the KPIs (table 4). To choose the weight factor, a team of leaders which included Supplier Controls team, and Supplier Quality team members were invited as a team to fill out a prioritization matrix based on Business Risk and Patient Risk to come up with

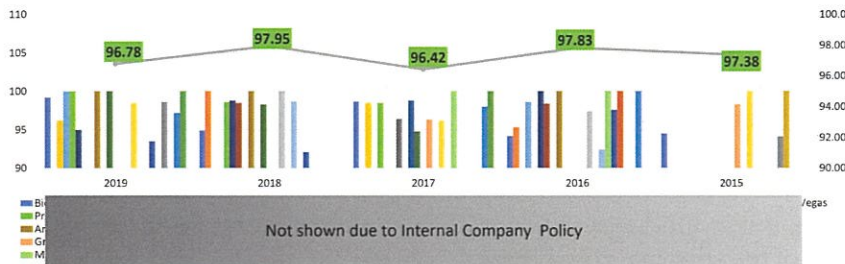


Figure 6 - Top Offender Supplier's Audit Score per Year 2015-2019

ces, Rejected Parts, and Parts Received. Once each of these KPIs have an indexed score, a total quality index score could be calculated [3]. The score is an indication of the overall quality performance of the supplier and the tool provides a decision-making matrix which instructs which action to take based on the supplier performance. Below, each of the steps taken to create the tool explained.

the weighted factors.

- Supplier Type and Risk: because these values are not variable, a weight factor was also determined to each (table 5). The value was also chosen with the same team based on risk and control of the product after the parts/products leave the supplier. Each supplier was given a value from 1-10 based on these elements.
- Each KPI required their scores

(before weight was applied) to be adjusted in order to ensure that the values between KPIs were comparable and that the score of the KPI was being compared against the range of values within that KPI. This would create an index within the KPI and ensure that the supplier with the highest value will always have the highest score. The adjusted score will provide a score between 0 and 10.

KPI	Weight
Supplier Type and Risk	20%
Supplier Audit Score	13%
NCs	13%
CAPA	13%
Escapes	15%
Qty parts Rejected	10%
Qty Parts Received	16%

Table 4 - KPI Weights

Supplier Type and Risk	Weight
CM Critical	10
CM Major	8
CM Minor	6
Component Supplier Critical	6
Component Supplier Major	5
Component Supplier Minor	4
Consultant Critical	7
Consultant Major	5
Consultant Minor	1
Contractor Critical	8
Contractor Major	6
Contractor Minor	4
Manufacturing Material Critical	6
Manufacturing Material Major	4
Manufacturing Material Minor	3
OEM Critical	10
OEM Major	8
OEM Minor	7
Service Provider Critical	9
Service Provider Major	7
Service Provider Minor	4

Table 5- Supplier Type and Risk Weight Score

$$f(n_x) = \frac{n_x - \min}{\max} * 10$$

Example: KPI= NCs, Supplier #4 had 26 NCs in 2019. The maximum number of any supplier has is 44 NCs in 2019.

$$Sup \#4 NC adj. score (26) = \frac{26 - 0}{44} * 10 = 5.9$$

- After all KPIs had their adjusted score, then each KPI was multiplied by their weight factor.



will be reviewed by leadership on a yearly basis (with 12-month rolling data), where the suppliers KPI for each site will be gathered and entered in order to evaluate the suppliers and plan the needed actions. This will help the Global Supplier Quality team assign resources each year to the suppliers in Red and Yellow for deep dive analysis and know which suppliers can continue to be monitored through the audit program (Green suppliers).

In addition, the scorecard will be published on a quarterly basis in

order to review any changes, improvements, or potential additional actions to be taken if a supplier shows to have an adverse trend.

Moving forward, data will be available to be trended throughout the years, which can lead to leadership decision on if the company should move away from a supplier and if other high-quality suppliers can be considered to expand business with.

#### Future Work

In the future, the tool can be utilized to:

- Standardize the type of Quality Improvement tool, training, or processes to be implemented in partnership with the supplier, depending on the score.
- Define the tools to reduce the number of audits in the audit program, based on the KPIs
- Create a Power BI view to review Supplier Scorecard at “real-time”.
- Create a portal for suppliers to review their own score and how that ranks against the pool of suppliers.

#### References

- [1] *Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*, ISO13485:2016, 2016. [Online]. Available: <https://www.iso.org/obp/ui/#iso:std:iso:13485:ed-3:v1:en>
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