

# ***Improving Change Management of Supplier Changes While Mitigating Supply Chain Risk and Impact on Manufacturing Line***

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**Abstract** — *Unattended Supplier Change Requests represent a problem for Company XY. The lack of action toward Supplier Changes Requests results in a build-up of open changes that may impact the company's supply chain and manufacturing line. There are multiple causes for this problem: the lack of prioritization tools, limited human resources vs. workload, lack of monitoring, and in some cases, the overall complexity of the change. Data showed some changes were not a priority, were not being worked on, were submitted prematurely, or were not applicable for different reasons. A Go/NoGo Tool was implemented to minimize the number of aging changes in the portal. Workload Assignment was redistributed, monthly monitoring of the change requests was implemented, and RACI (Responsible, Accountable, Collaboration, & Information) roles are being redefined. With these management tools in place, Company XY can expect to significantly reduce the balance of open change requests and disposition them on time.*

**Key Terms** — *Change Management Culture, Medical Devices Manufacturer, Supplier Change Requests, Supply Chain Management*

## **INTRODUCTION**

Company XY is a manufacturer of medical devices with an experience of over 70 years. Like many manufacturing industries, Company XY and its product quality depend on its relationship with external suppliers. As a crucial part of the supplier management process, Company XY relies on suppliers to produce products and/or services to achieve the desired quality standards for its products.

Company XY has put in place a change request portal where suppliers can notify the company of all changes done on the supplier side. These changes can impact the current validated processes used for

the materials supplied for manufacturing the finished device and, consequently, the product delivered to the patient. Therefore, suppliers must do their due diligence of notifying Company XY of any changes to the validated process or product procured.

In the last few years, there has been an increment in changes reported to the portal. Company XY has accrued a balance of unattended supplier changes that need attention and represent a risk to the finished device. All supplier change requests (SCR) are submitted to Company XY for evaluation before implementation. All changes need to be assessed and approved by Company XY, most requiring rigorous validation activities. If a supplier change is not addressed in a timely manner, there is a risk it will impact the supply chain and ultimately create a manufacturing line-down situation at Company XY. It is in the company's interest to improve the management of supplier changes while continuing to deliver the best quality, safety-conscious, uninterrupted supply of life-saving products to patients.

This project had the following objectives:

- **Goal 1:** Complete disposition of SCRs within a 180-day timeframe. The company goal is to close at least 75% of the SCRs in 180 days or less.
- **Goal 2:** Company XY needs to achieve a reduction of 35% or more of the open changes at the baseline of the start of FY23. Backlog Reduction: A 35% Reduction from FY23 Baseline.

## **LITERATURE REVIEW**

Companies worldwide, whether they produce medical devices, pharmaceuticals, retail products, or any other industry, need to create strong supplier/customer relationships. The quality and

success of a manufactured final product can be diversely affected by the product or service provided by any supplier. Any modification, addition, or removal of something from a given environment is considered a change. Supplier change reasons may include: Raw Material Availability, Continuous Improvement, Cost Savings Projects, Safety Measures, Compliance, Capacity Increase, Capital Management, Yield Improvements, and others. Therefore, it is of great benefit to all organizations worldwide to categorize supplier changes according to the risk and impact that a change may represent on the overall product [1].

In every relationship between a supplier and a purchasing organization, the frequency of changes and each organization's approach to performing changes and change management are critical to the successful delivery of services. Strategic, operational, and tactical suppliers should be regularly involved in a buying organization's change management activities. As previously mentioned, all suppliers can introduce changes that may dramatically impact the buying organization's services and, consequently, the product [1]. For that reason, supplier change management and implementation require robust planning by designing a good process of implementation side by side with the supplier, identifying suitable communication channels, process standardization through the adoption of the implementation, and showcasing the benefits to all stakeholders [2].

There are two basic approaches to the management of the supplier relationship. The Reactive approach is where the organization works on the supplier relationship only when something unpleasant occurs and tries to figure out how to improve the situation and the performance of unreliable suppliers. And the Strategic approach, where the relationship with the supplier begins even before any agreement is signed. This helps assure the organization's competitive advantage in the long run by implementing initiatives for long-term gain and considering inputs from stakeholders [3]. Working with reliable, high-quality suppliers can help a business grow. Unreliable suppliers can create

bottlenecks in the organization's workflow and negatively impact the customers' impression of the company [3]. Therefore, maintaining the integrity of the supply chain flows without suffering interruptions is critical to the success of all organizations. Currently, several techniques and strategies use tiering and risk classifications associated with the changes to maintain supply chains and consequently use these techniques to prioritize the risks [4].

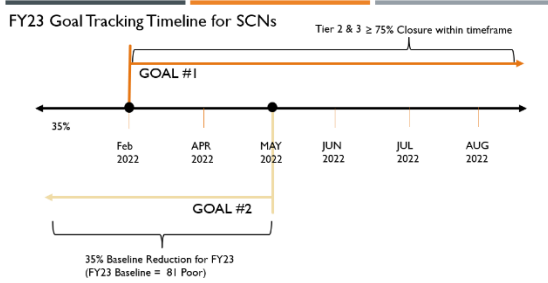
## **ANALYSIS**

### **Trending Behavior of Supplier Changes and their Management**

During Fiscal Year 2022 (FY22), Company XY noticed that supplier change requests were accumulating. More requests were being submitted to the Supplier Change Portal (SCN Portal) than requests dispositioned each month. So far, the culture of the organization has been lacking an effective supplier change management strategy, leaving many changes unattended and aging in the portal. Moving forward, Company XY intends to focus resources on both the legacy changes and the new changes for the Fiscal Year 2023 (FY23).

February 2022 was decided on as the starting point for measuring the closure of SCRs. Based on the assumption that requests that are open in the last quarter of FY23 will carry over to the next year. Therefore Goal 1 will apply to change requests submitted on February 2022 or after, while Goal 2 for the Legacy changes will be applicable to change requests that remained open prior to May 2022 (beginning of FY23). The timeline shown in Figure 1 will help visualize how each goal is interpreted.

Company XY uses a PowerBi tool software for measuring all data related to supplier changes in the SCN portal. By generating a data report, Company XY was able to define the baseline for FY23 at 81 Legacy records. As shown in Table 1, to achieve the 35% reduction, the company would need to disposition and close  $\geq 29$  Legacy records in the portal during FY23.



**Figure 1**  
**Goal Tracking Timeline**

**Table 1**  
**FY23 Baseline**

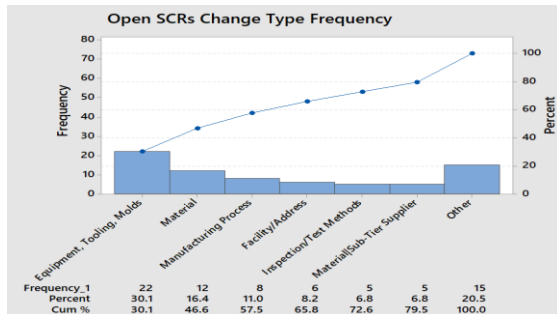
Category	Start of FY23 Baseline	Goal Reduction (35%)	Goal SCR Balance
Tier 2	74	≥ 26	<48
Tier 3	7	≥ 3	<4
<b>Tier 2 / Tier3</b>	<b>81</b>	<b>≥ 29</b>	<b>&lt;52</b>

### Tiering of Supplier Changes

In SCN Portal, the company currently uses a Tiering strategy to categorize each change based on its urgency and its impact on Supply Chain and Manufacturing Line. Goals #1 and #2 are directly impacting all changes in Tier 2 and Tier 3.

### Categorization of Supplier Changes

The change type can vary extensively. A Pareto Analysis was performed for the currently open records in the SCN Portal displayed in Figure 2. Per Figure 2, the most common change types are related to Equipment, Tooling, & Molds, Material Availability, changes in Supplier Facility/Address, and changes in Manufacturing Process. Together, these represent ~58% of all open in the portal.



**Figure 2**  
**Open SCRs Change Type Frequency**

## RESULTS & DISCUSSION

### Data Analysis

Several interviews took place with stakeholders and cross-functional teams to add their input regarding the change management teams. A Kaizen was organized with the Supplier Quality team to brainstorm and identify areas of opportunity while focusing on the goals. The data gathered shows that change request submissions for this year are likely to increase. SCR Submissions from the year 2016 to year 2022 are compiled in Table 2. The monthly average for this year (based on the year-to-date data) is second to the year 2019, with 25.5 changes per month submitted.

**Table 2**  
**SCR Submissions (2016-2022)**

Year	Month												Year Total	Monthly Avg/Year
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec		
2016	9	13	25	13	18	23	13	12	22	23	14	13	198	16.50
2017	14	23	28	8	26	25	17	13	29	25	19	4	231	19.25
2018	16	17	13	13	22	12	19	12	19	25	21	26	215	17.92
2019	26	21	32	52	32	52	28	34	18	22	38	20	375	31.25
2020	34	20	26	28	25	30	30	11	26	17	13	12	272	22.67
2021	23	29	34	14	12	22	11	10	39	29	19	22	264	22.00
2022	27	24	24	31	43	37	20	19	19	11	tbd	tbd	255	25.50

The data for Baseline Reduction referring to Goal 2 was collected on a monthly basis and is shown in Table 3. The data in Table 3 compiled data for the first and second quarters of FY23. As the data shows, the goal for the backlog reduction has surpassed the 35% reduction and is currently reporting a Year-to-Date 44.4% reduction at the end of September 2022.

**Table 3**  
**Baseline Reduction Status for FY23**

Tier	Start of FY23	Q1 FY23						Q2 FY23					
		MAY		JUNE		JULY		AUGUST		SEPTEMBER		OCTOBER	
		EDM	%	EDM	%	EDM	%	EDM	%	EDM	%	EDM	%
Tier 2	74	64		61		54		45		40		tbd	tbd
Tier 3	7	7		7		7		7		5		tbd	tbd
<b>Tier 2 &amp; Tier3</b>	<b>81</b>	71	12%	68	16%	62	23%	52	35.8%	45	44.4%	tbd	tbd

Monthly monitoring of the aging of all currently open changes is shown in Table 4 below. The Leading Indicator data shown in Table 4 records the compliance of the current changes against Goal 1, the current balance of open changes, and their

distribution per Operating Unit. From the table, we can see that 6 of the 37 open changes for FY23 are already >180 days, which translates to 83.7%.

**Table 4**  
Leading Indicator for FY23 (Goal 1)

Company XY	Total Qty	Tier 2	Tier 3
DBT	19	18 / 83.3% (15)	1 / 100% (1)
Neuro	18	18 / 83.3% (15)	0 / N/A
CRM	0	0 / N/A	0 / N/A
<b>Total</b>	<b>37 / 83.7% (31)</b>	<b>36 / 83.3% (30)</b>	<b>1 / 100% (1)</b>

The Monthly Closure of changes that are being reported to leadership is shown in Table 5. The company has been able to close a total of 59 changes in compliance with Goal 1. The Closure Metric shown in Table 5 is reported to leaders monthly.

**Table 5**  
SCR Closure Metric for FY23 (Goal 1)

Closure Metrics	Tier	YTD FY23	Q1 FY23			Q2 FY23		
			MAY	JUN	JUL	AUG	SEP	OCT
DBT	Tier 2	27 / 100% (27)	3 / 100% (3)	3 / 100% (3)	2 / 100% (2)	14 / 100% (14)	5 / 100% (5)	TBD
	Tier 3	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	TBD
NEURO	Tier 2	12 / 100% (12)	1 / 100% (1)	4 / 100% (4)	4 / 100% (4)	1 / 100% (1)	2 / 100% (2)	TBD
	Tier 3	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	TBD
CRM	Tier 2	20 / 100% (20)	0 / 0% (0)	0 / 0% (0)	11 / 100% (11)	7 / 100% (7)	2 / 100% (2)	TBD
	Tier 3	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	TBD
JUNCO SITE	Tier 2	59 / 100% (59)	4 / 100% (4)	7 / 100% (7)	17 / 100% (17)	22 / 100% (22)	9 / 100% (9)	TBD
	Tier 3	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	TBD

### Prioritization and Monitoring of Changes

Due to the current SQE team only having four resources available and dedicated to managing the supplier, the need arose to filter and determine what changes should be prioritized moving forward. Hence, the need to establish a Go/No-Go Tool was identified. The Go/No-Go Tool should help in the initial assessment of Supplier Change Requests (SCR) submitted by suppliers. The creation of the Go/NoGo Tool, shown in Figure 3, for the initial assessment of the change requests submitted in the portal will be key to the successful management of changes moving forward.



**Figure 3**  
Go/NoGo Assessment Tool

### Resources

Resource allocation is defined based on commodity and is shown in Table 6. Company XY currently has four SQEs that are leading, executing, and monitoring the change requests. The SCR Allocation table is an effort that will help make sure no SCR is left unattended. The workload allocation was also defined based on the difficulty and volume of activities that a given change may require.

**Table 6**  
SCR Resource Allocation Guideline

Commodity	SQE	SQE	SQE	SQE
	Resource 1	Resource 2	Resource 3	Resource 4
Molded and Plastics	X	X	X	
Chemicals & Off the Shelf	X			
Electronics and Metals			X	
Packaging & MIMs		X		
Indirect Services				X
China Related				X
Neuro Related	X			X
Cost Reduction			X	
NPI/Hypercare		X		

### Change Management Culture

During the Kaizen and discussion with the cross-functional teams, one of the topics was Special Builds. A 14% of the SCRs submitted require a special build to be performed on the assembly line, either for Endotoxin, Bioburden, Microbiology, or other testing. In many of those cases the project had to compete with priorities on the manufacturing line, manufacturing resource constraints, and deal with the additional cost of performing these builds. As part of this project, Company XY and its leaders are working on strategies to change the culture behind the changes and how they are being managed. A RACI (Responsible, Accountable, Collaborator, & Informed) tool is in discussion as a means to

maintain involvement, from an early stage, from all key players in the project.

## CONCLUSION

The objective of this paper was to identify ways to help Company XY with the management of Supplier Changes and their timely disposition within the SCN Portal. By prioritizing all supplier change requests diligently, the company can mitigate any supply chain risks and impacts on the manufacturing line, the finished device, and patient safety. As part of the deliverables of this project, a Go/NoGo Tool and a Resource Allocation Guideline were implemented. Although a systematic control was not possible to implement, monthly monitoring of the Baseline Reduction for FY23, SCR Closure Metric for FY23, and Leading Indicator for FY23 were implemented. Both Goals are achievable with these tools in place, and Company XY can expect to significantly reduce and disposition the remaining SCRs in a timely manner.

Special Builds for Bioburden testing, which are done at the finished device level, are taking too long and adding much stress to the project timeline. As an alternative for this deliverable, a meeting will be held to contemplate testing at the component level. Another recommendation, based on what was observed in this report, is to increase the Baseline Reduction of Goal 2, which is currently at 35%. Halfway through Q2 for FY23, the Company has reduced by 44.4%. However, the volume of changes is increasing every year, and a more aggressive backlog reduction is needed to ensure the success of Supplier Change Management next year. Hence, a new goal of 75% Backlog Reduction is recommended.

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