



Felipe Quiñones Zayas

Advisor: Dr. Héctor J. Cruzado, PhD, PE  
Master in Engineering Management Program

## 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.

## 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.

## Background

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]. 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]. 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].

## Problem

Company XY has accumulated a backlog of open Supplier Changes in the SCR Portal which are adding up to the incoming changes for FY23. The balance of unattended SCRs represent a risk to the supply chain and manufacturing line.

## 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.

## Methodology

The trending behavior for this Fiscal Year 2022 (FY22) was evaluated using available data from the SCN 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. 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.

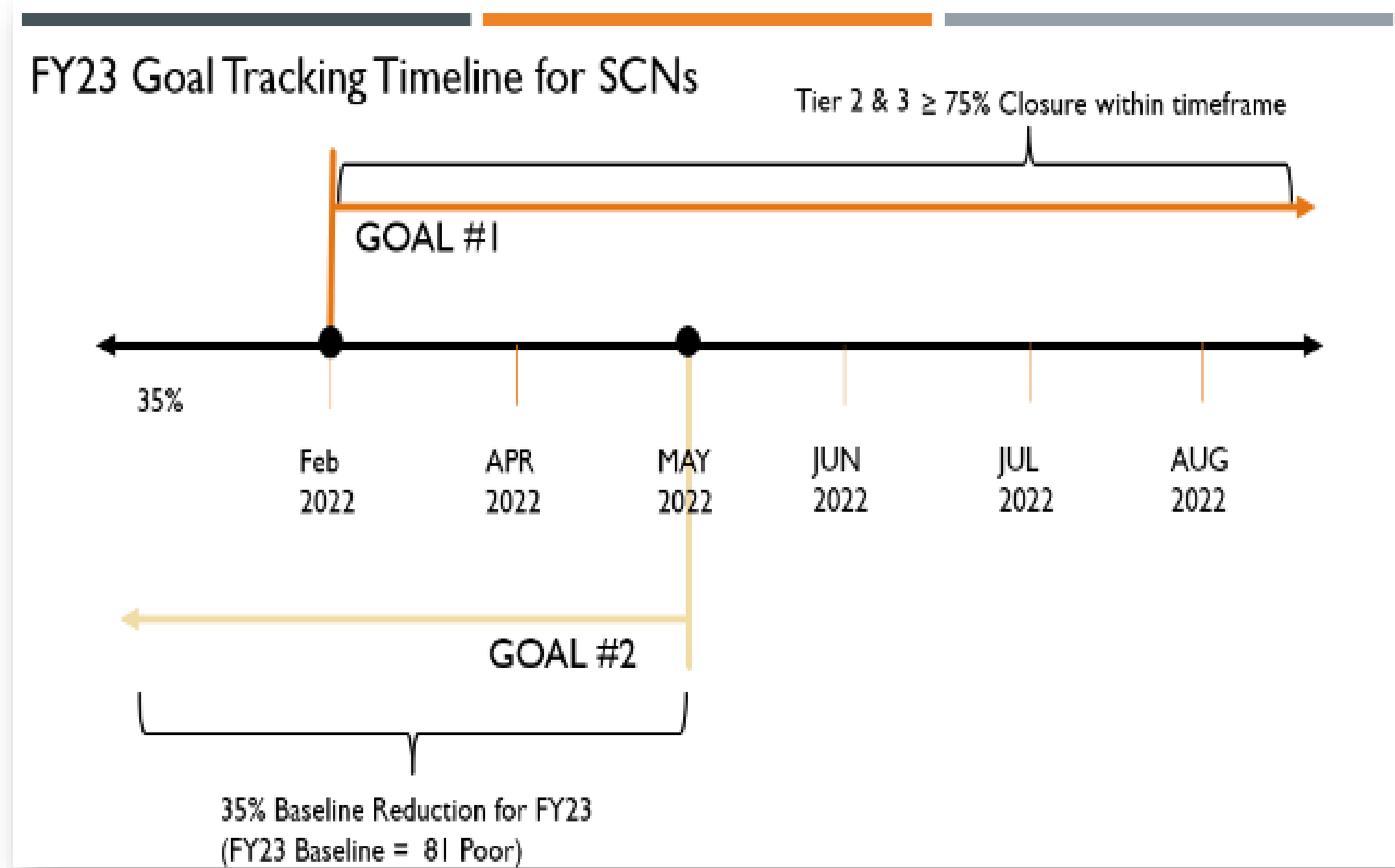


Figure 1  
Goal Tracking Timeline

Table 1  
FY23 Baseline

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

An Analysis was performed for the currently open records in the SCN Portal, 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. These changes are often complex and require specific expertise. Data also showed that change request submissions for this year are likely to increase as shown in Table 2. SCR Submissions from the year 2016 to year 2022 are compiled in Table 2.

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

## Results and Discussion

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. The Monthly Closure Metric for Goal 1 is shown in Table 4, and the Year-to-Date for the closure metric is 98.4%.

Table 3  
Baseline Reduction Status for FY23

Base Line Reduction (35%)	Tier	Start of FY23	Q1 FY23						Q2 FY23					
			MAY		JUNE		JULY		AUGUST		SEPTEMBER		OCTOBER	
			EOM	%	EOM	%	EOM	%	EOM	%	EOM	%	EOM	%
Tier 2	74	64	86.5%	61	82.4%	54	73.0%	45	60.8%	40	54.1%	tbd	tbd	
Tier 3	7	7	100%	7	100%	7	100%	7	100%	5	71.4%	tbd	tbd	
<b>Tier 2 &amp; Tier 3</b>	<b>81</b>	<b>71</b>	<b>12%</b>	<b>68</b>	<b>16%</b>	<b>62</b>	<b>23%</b>	<b>52</b>	<b>35.8%</b>	<b>45</b>	<b>44.4%</b>	<b>tbd</b>	<b>tbd</b>	

Table 4  
SCR Closure Metric for FY23

Closure Metrics	Tier	YTD FY23	Q1 FY23				Q2 FY23			
			MAY	JUN	JUL	AUG	SEP	OCT		
DBT	Tier 2	28 / 100% (28)	3 / 100% (3)	3 / 100% (3)	2 / 100% (2)	14 / 100% (14)	5 / 100% (5)	2 / 100% (2)		
	Tier 3	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)		
NEURO	Tier 2	19 / 93.75% (15)	1 / 100% (1)	4 / 100% (4)	4 / 100% (4)	1 / 100% (1)	2 / 100% (2)	4 / 75% (3)		
	Tier 3	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)		
CRM	Tier 2	20 / 100% (20)	0 / 0% (0)	0 / 0% (0)	11 / 100% (11)	7 / 100% (7)	2 / 100% (2)	0 / 0% (0)		
	Tier 3	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)		
JUNCO S SITE	Tier 2	64 / 98.4% (63)	4 / 100% (4)	7 / 100% (7)	17 / 100% (17)	22 / 100% (22)	9 / 100% (9)	6 / 83.3% (5)		
	Tier 3	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)	0 / 0% (0)		

Due to limited resources, the need arose to filter and determine what changes should be prioritized moving forward. Resource allocation was defined based on commodity and is shown in Table 5. Hence, the need to establish a Go/No-Go Tool was identified. The creation of the Go/No-Go Tool, shown in Figure 2, for the initial assessment of the change requests submitted in the portal will be key to the successful management of changes moving forward.

Table 5  
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		

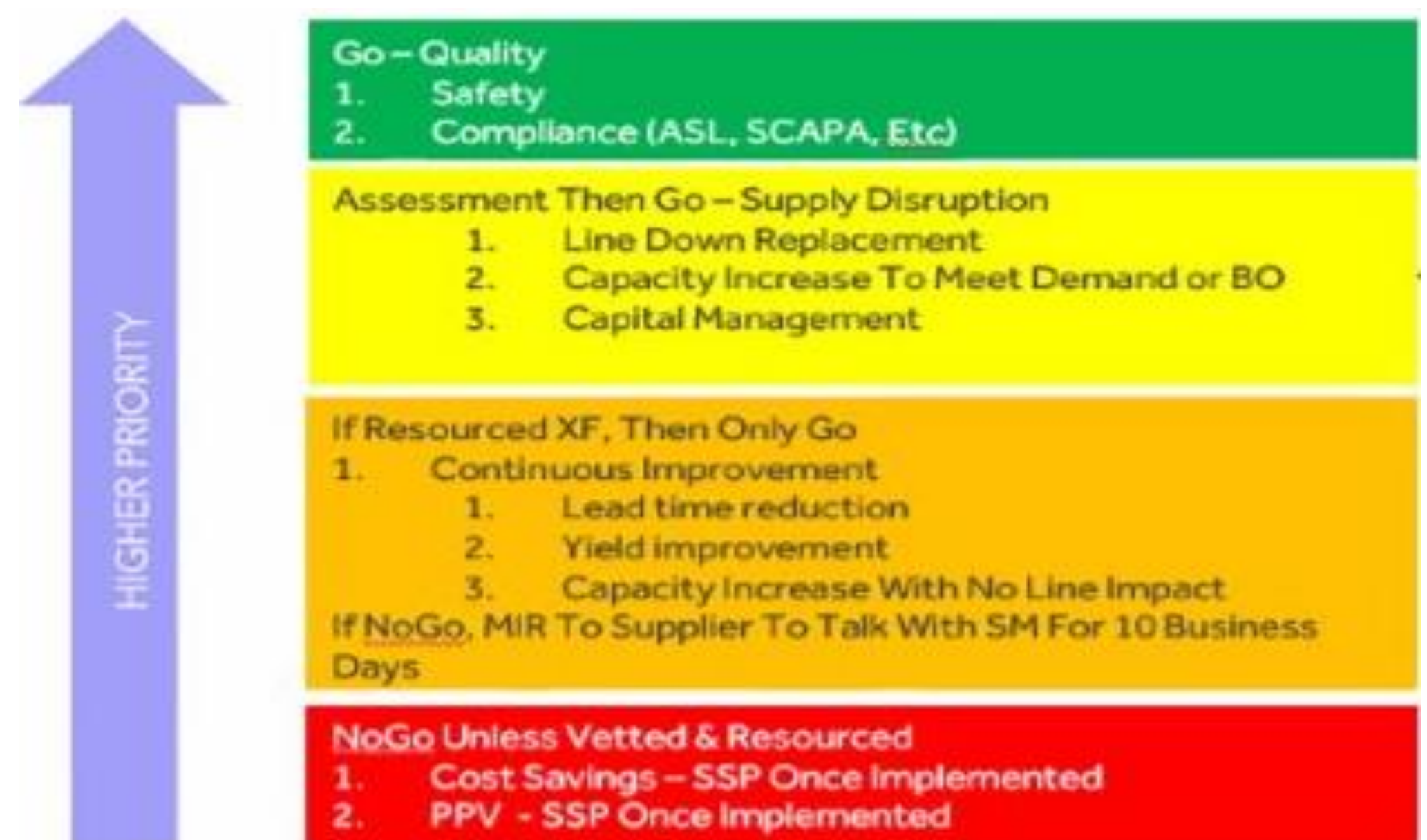


Figure 2  
Go/NoGo Assessment Tool

## Conclusions

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. We conclude that with the new tools in place, both Goals are achievable, and Company XY can expect to significantly reduce and disposition the remaining SCRs in a timely manner. Furthermore, as part of this project, Company XY and its leaders will continue to working on strategies to change the culture behind the changes and how they are being managed. For example, 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 each project. Leaders will also contemplate the implementation of a "Pause Button" as an alternative for SCRs that hit a roadblock during their execution. These SCRs are usually changes that although not currently resourced, Company XY prefers not to lose track of.

## Future Work

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.

## References

- [1] Scarborough, M. (2013, March). Engaging Suppliers in Change Management. Global Knowledge by Skillssoft. Available at: <https://www.globalknowledge.com/ca-en/resources/resource-library/articles/engaging-suppliers-in-change-management/>
- [2] Rybak-Pazdur, R. (April 2021). Change Management in Procurement Requires a Robust Plan. Capgemini Inc. Available at: <https://www.capgemini.com/blog/improve-supplier-relationship-management/change-management-in-procurement-requires-a-robust-plan/>
- [3] Murphy, K. (2022). 10 Strategies for Improving Supplier Relationship Management (SRM). Planergy Inc. Available: <https://planergy.com/blog/improve-supplier-relationship-management/>
- [4] Faisal, M. (2009). Prioritization of Risks in Supply Chains. In: Wu, T., Blackhurst, J. (eds) Managing Supply Chain Risk and Vulnerability. Springer, London. Available: [https://doi.org/10.1007/978-1-84882-634-2\\_4](https://doi.org/10.1007/978-1-84882-634-2_4)