

Improving Quality Performance of Third Party Warehouse Supplier

Soft System Methodology

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Introduction

Medtronic International Ltd. is a multinational medical device manufacturer, focusing on less-invasive medical devices such as the products in cardiovascular, endoscopy, neurovascular, etc. As such the storage and distribution of the medical devices require quality services from a trusted warehouse supplier. DHL Global Forwarding is the third party (3PL) warehouse partner for Medtronic International Ltd. in Malaysia.

Recent supplier audit on DHL Global Forwarding conducted by Medtronic International Ltd. showed that there was a lack of robust management and control of the third party supplier by Medtronic International Ltd. Several non-conformities raised in the Supplier Audit. Most importantly, the warehouse was very dirty and messy in some areas. At the day of the audit there was significant amount of dust on the machines and on some of the shelves containing active products. In addition, the document control system in the DHL Global Forwarding was absent, and there was no issuance that their Standard Operating Procedures taking into account all applicable requirements from Medtronic International Ltd.

Medtronic International Ltd. has a set of in-house warehousing requirements to the third party (3PL) warehouse partner in the world, which includes the security, environment, cleaning, pest control and storage requirements.

Soft systems methodology (SSM) was used to help my boss to think more objectively about improving such business of the DHL Global Forwarding to meet the in-house warehousing requirements from the Medtronic International Ltd. SSM helps to define the system in a set of parts, which related to each other, pursuing them for purposeful activities. CATWOE has been defined in order to facilitate the understanding the issue area and the impact from the solution (Bergvall-Kåreborn, 2004). The activities help to compare and monitor agreed performance criteria. If the activity is failed to meet the criteria, necessary action shall be taken. Root cause analysis has been conducted based on several quality tools, such as the Is/ Is Not Analysis, Ishikawa, etc (Doggett, 2005).

The report concludes by suggesting solution to correct and prevent the issue happened again.

Research Rationale

Referencing the issue from DHL Global Forwarding, normal solution plan is hard to identify the root cause and implement the solution to prevent future issues. Therefore, it is good to design the solution based on the SSM.

Design and Objectives

In order to solve the quality issue from the DHL Global Forwarding, investigation of the issues have been conducted, which involves quality tools, such as the Is/ Is Not Analysis to determine the scope of the issue; and Ishikawa to identify potential root causes, and the 5 whys tool to determine the root cause(s). After investigation, potential causes have been determined. Solutions shall be proposed, and the

performance criteria have been setup in order to verify the effectiveness of the solutions. The objectives of the solutions are to eliminate or prevent the root causes.

Design and Implementation of Primary Data Collection

As mentioned above, Is/ Is Not Analysis to determine the scope of the issue. In addition, Medtronic International Ltd. identifies and reviews all Standard Operating Procedures pertaining to management of this supplier, and identifies gaps between requirements and how the program was executed by Medtronic International Ltd. Ishikawa shall be conducted to identify potential root causes, and the 5 whys tool shall be used to determine the root cause(s) (Testa, 2006).

Presentation and Interpretation of Primary Data Collected

CATWOE has been defined in order to facilitate the understanding the issue area and the impact from the solution.

CATWOE	Description
Customers	Medtronic International Ltd.
Actors	Staffs from Medtronic International Ltd. Staffs from DHL Global Forwarding
Transformation	To solve and improve the quality issues identified during the recent supplier audit on DHL Global Forwarding conducted by Medtronic International Ltd.
Weltanschauung	<ul style="list-style-type: none"> - The impact of improving the quality issues from the DHL Global Forwarding shall increase customer satisfaction (Medtronic International Ltd.) - Protect the products from potential adverse effects
Owner	Medtronic International Ltd.
Environment	<ul style="list-style-type: none"> - Patients from the Medtronic International Ltd. - Regulations from the Ministry of Health - Financial Constraints from the DHL Global Forwarding

Customers are Medtronic International Ltd. because the changes to improve the quality issues from DHL Global Forwarding affecting the Medtronic International Ltd.

Actors are the staffs from both companies, Medtronic International Ltd. and the DHL Global Forwarding, because they are implementation the change.

The transformation is the change of the system in the DHL Global Forwarding from the supplier audit conducted by Medtronic International Ltd.

Weltanschauung is the justification regarding the transformation. If no change happened, there shall be the business impact for DHL Global Forwarding to meet customer satisfaction (Medtronic International Ltd.).

The owner of the CATWOE analysis is Medtronic International Ltd.

There are environment constraints regarding the change, such as the Regulations from the Ministry of Health.

Is/ Is Not Analysis has been conducted to determine the scope of the issue. From the analysis, it concluded that the issue is only related to the Medtronic International Ltd. internal requirements towards DHL Global Forwarding, no issues were found from external customers.

Description	<u>IS</u> (Observation):	<u>IS NOT</u> (Observation):	Conclusions
What...?			
<i>What is the issue?</i>	Several non-conformities raised in the Supplier Audit and Assessment to DHL Global Forwarding. They included: <ul style="list-style-type: none"> - The warehouse is very dirty and messy in some areas - Product flow as defined in signage is not respected - FEFO is not respected - Lack of document control system in place in DHL Global Forwarding 	The issue is not related to: <ul style="list-style-type: none"> - External customer complaints towards DHL Global Forwarding 	The issues are related only to the Medtronic International Ltd. internal requirements towards DHL GLOBAL FORWARDING, no issues were found from external customers
<i>What is the process affected?</i>	<ul style="list-style-type: none"> - Supplier Management - Warehouse Management 	<ul style="list-style-type: none"> - Design Controls - Product Approvals 	The only affected process is supplier management related to warehouse management in DHL GLOBAL

Description	IS (Observation):	IS NOT (Observation):	Conclusions
			FORWARDING.
Who...?			
<i>Who are complaining or affected?</i>	<ul style="list-style-type: none"> - Operations - Quality Assurance - DHL GLOBAL FORWARDING 	<ul style="list-style-type: none"> - Regulatory Affairs - Finance - Sales - Customer 	The affected departments are the ones that are involved in the Supplier Management.
Where...?			
<i>Where is the issue seen?</i>	The issue is seen on DHL GLOBAL FORWARDING warehouse.	The issue is not observed in the MEDTRONIC INTERNATIONAL LTD. office	The only affected location is DHL GLOBAL FORWARDING warehouse.
When...?			
<i>When in the process flow is the problem occurring?</i>	This is an issue with regards to overall supplier and warehouse management where non conformity observed can affect product quality throughout the distribution chain within the DHL Global Forwarding process control/flow	Post and pre DHL Global Forwarding process control/flow	The issues were found in the last two internal audits. It showed that the root causes have not been corrected.
How Much...?			
<i>Is the problem increasing or decreasing? Is there a trend?</i>	<p>Issues have been found during the supplier audits.</p> <p>This is an issue where no improvements have been observed since the audit conducted.</p>	None	This is NOT an isolated case, which issues are reoccurring.

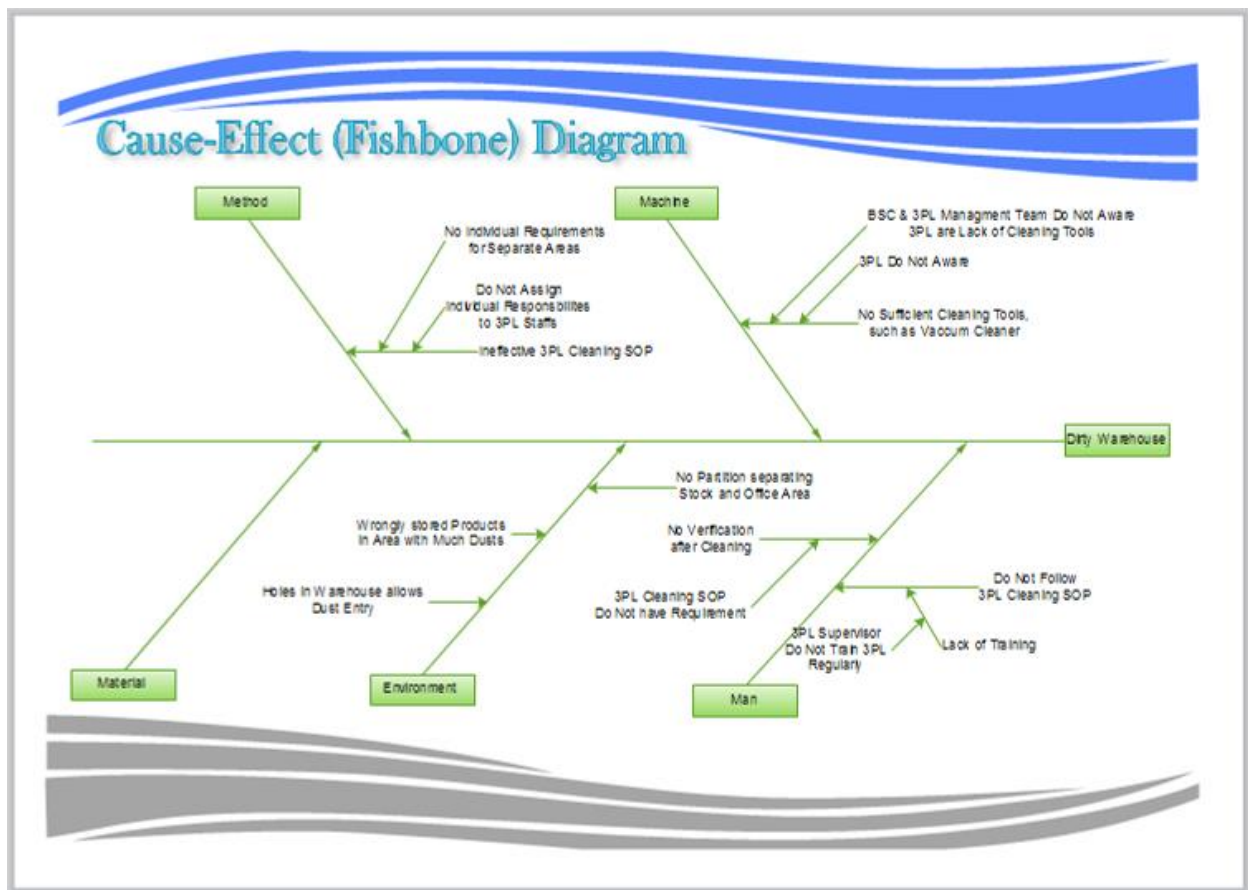
The issue was on the process of supplier management related to warehouse management in DHL GLOBAL FORWARDING, and the location of the issues only happened in DHL GLOBAL FORWARDING warehouse.

This is NOT an isolated case, which issues are reoccurring. The issues were found in the last two internal audits, which showed that the root causes have not been corrected.

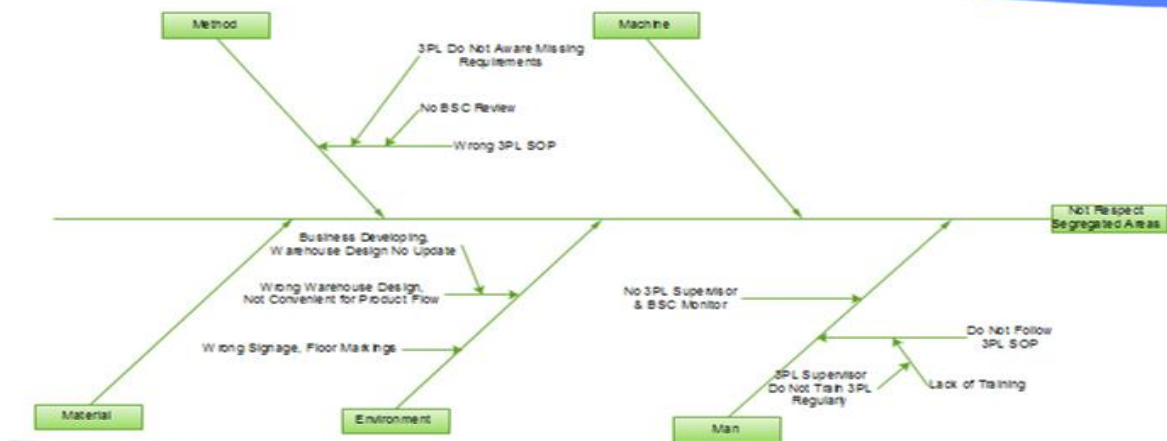
SOPs and WIs pertained to Supplier Management has been identified. The issue is a lack of robust management and control in the DHL Global Forwarding warehouse, which is the existing supplier. Therefore, the investigation only focuses on monitoring of the third party logistics.

All SOPs and WIs pertained to Supplier Management have been reviewed. The requirements in the SOPs and WIs have been compared with the program executed by MEDTRONIC INTERNATIONAL LTD.. It concluded that MEDTRONIC INTERNATIONAL LTD. fulfills most requirements pertaining to supplier management. The above discussion showed that the gaps are minor.

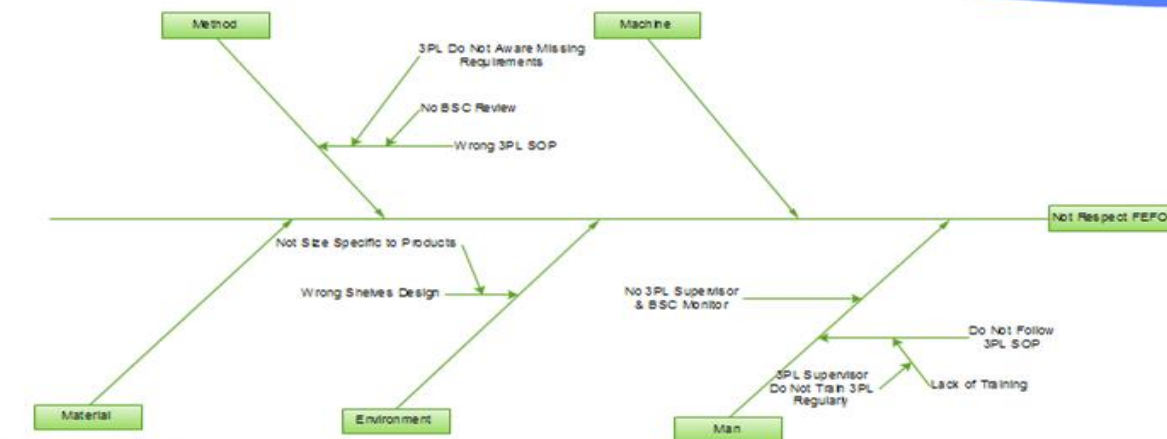
Ishikawa has been conducted to identify potential root causes, and 5 whys tool was used to determine the root cause(s).



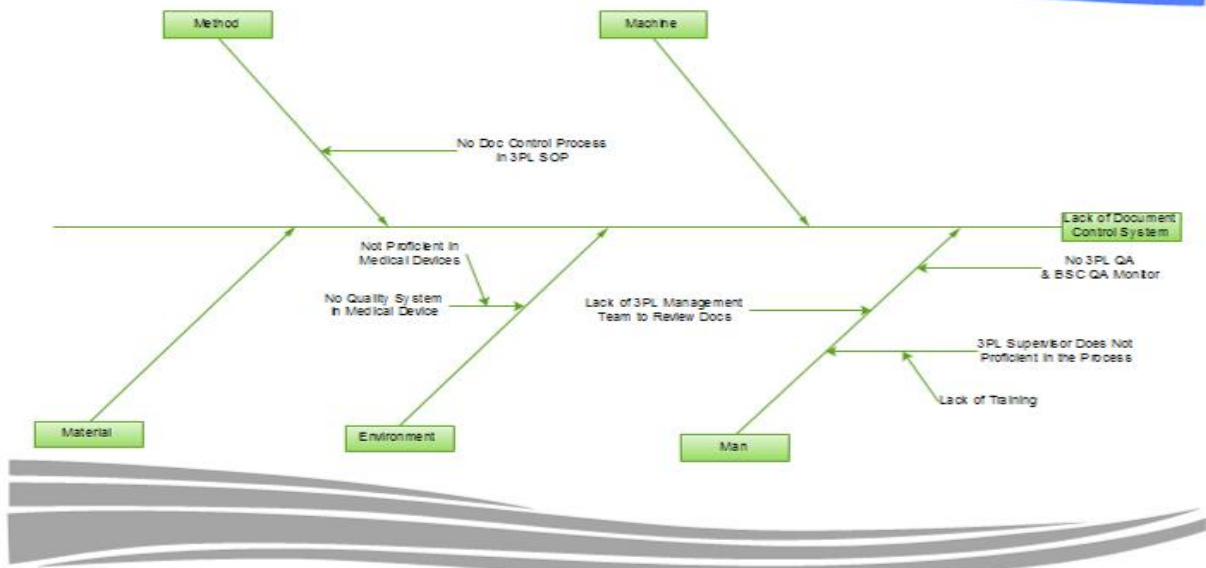
Cause-Effect (Fishbone) Diagram



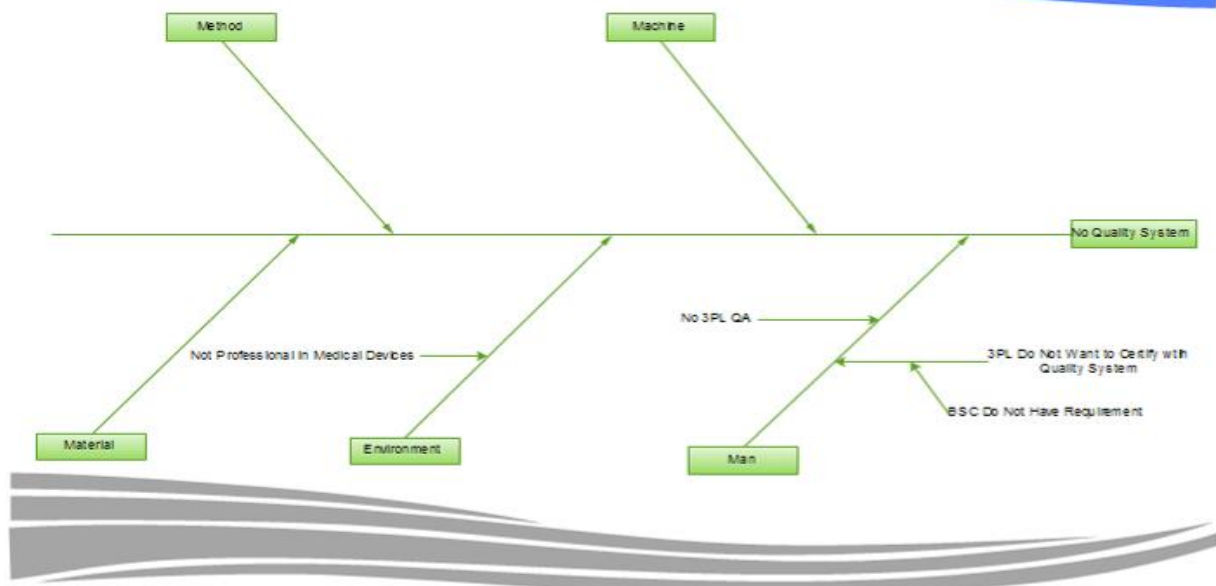
Cause-Effect (Fishbone) Diagram



Cause-Effect (Fishbone) Diagram



Cause-Effect (Fishbone) Diagram



5 whys tool was used to determine the root causes from the potential root causes identified in Ishikawa.

A.1. Dirty Warehouse

1. Why was the warehouse very dirty and messy in some areas?

Wrong warehouse design, such as holes at the doors, no partition separating stock and office area, lets dusts enter into the warehouse.

2. Why there was wrong warehouse design?

As business and environment change, the original set up of the warehouse is not sufficient to prevent dusts. 3PL did not aware such change, and do not make any update on the warehouse design, including the 3PL cleaning SOP.

3. Why 3PL do not aware the warehouse is not sufficient to prevent dusts?

3PL and MEDTRONIC INTERNATIONAL LTD. do not perform verification after cleaning every day.

4. Why 3PL do not perform verification after cleaning every day?

3PL SOP does not specify the requirement on the Cleaning SOP.

A.2. Dirty Warehouse

1. Why was the warehouse very dirty and messy in some areas?

The 3PL Cleaning SOP is not effective.

2. Why 3PL Cleaning SOP is not effective?

3PL Cleaning SOP does not determine the individual requirements for separate areas and the appropriate cleaning tools such as vacuum cleaner.

3. Why 3PL Cleaning SOP does not determine the individual requirements for separate areas and the appropriate cleaning tools?

3PL Supervisor do not aware that there is a need to determine the individual requirements for separate areas, sufficient cleaning tools, individual responsibilities of 3PL staffs.

B. 1. Not Respect Segregated Areas

1. Why 3PL staffs do not respect segregated areas?

3PL do not follow 3PL SOP.

2. Why 3PL do not follow 3PL SOP?

Wrong warehouse design such as wrong signage and floor markings make 3PL staffs confused. The warehouse design is not convenient for product flow.

3. Why wrong warehouse design?

As business development, the warehouse design has not been updated to suit the increasing need.

4. Why no update on warehouse design?

3PL Supervisor and MEDTRONIC INTERNATIONAL LTD. do not monitor the warehouse performance and aware the change.

C.1. Not Respect FEFO

1. Why 3PL staffs do not respect FEFO?

3PL do not follow 3PL SOP.

2. Why 3PL do not follow 3PL SOP?

The shelves design is wrong, which is not convenient to respect FEFO.

3. Why the shelves design is wrong?

The design of shelves is general to all products, which does not specific to product.

4. Why the shelves design is wrong?

3PL Supervisor and MEDTRONIC INTERNATIONAL LTD. do not monitor the shelves design is correct or not.

D.1. Lack of Document Control System

1. Why 3PL is lack of document control system?

3PL supervisor does not proficient in the process.

2. Why 3PL supervisor does not proficient in the process?

There is lack of training provided to 3PL Supervisor from 3PL.

3. Why there is lack of training from 3PL?

3PL do not have the quality system in medical device, because they are not proficient in medical device industry.

F.1. No Quality System

1. Why 3PL does not have Quality System?

3PL HK is not professional in medical devices industry. Therefore, they do not want to certify with quality system.

2. Why 3PL do not want to certify with quality system?

MEDTRONIC INTERNATIONAL LTD. supplier management program does not require 3PL to have quality system.

Results indicate that the lack of robust management and control in the DHL Global Forwarding warehouses are as below:

1. Man – Inadequate Training, i.e. DHL Global Forwarding SOP exists in DHL Global Forwarding warehouse, but DHL Global Forwarding Supervisor and MEDTRONIC INTERNATIONAL LTD. do not provide training regularly.

2. Man – Other Man, i.e. DHL Global Forwarding Supervisor and MEDTRONIC INTERNATIONAL LTD. do not monitor the warehouse performance, shelves design, review of DHL Global Forwarding SOP and aware the change.

3. Method - Existing Procedures Inadequate, i.e. the current DHL Global Forwarding SOP and Cleaning SOP are not adequate to cover the MEDTRONIC INTERNATIONAL LTD. requirements. For instance, Cleaning SOP does not specify the individual requirements for separate areas, sufficient cleaning tools, individual responsibilities of DHL Global Forwarding staffs, etc.

4. Other - Not Defined, i.e. DHL Global Forwarding do not have the quality system in medical device.

Critical Review of Related Academic Article

The basic concept of SSM is to define the human activities into parts (Peter D. C. Bennetts, 1997). The origin of the SSM was from the Biology, and the biologists would like to study the organism from the whole entity.

The other main concept of the SSM is the hierarchy (Checkland, 1994). An issue can be viewed from different levels of the system. SSM setup the system into parts, and each other can be related with each other. Communication between the parts is critically important. Only effective communication between parts can help to ensure the activities in the organization achieving the purposes.

In order to monitor the relevant activities, the SSM suggested to have agreed performance criteria (Presley, 2000). In case the activities failed to meet the performance criteria, necessary actions shall be taken to address the issue.

Root definition is important in the SSM, which is the basis for the organization to solve the “soft” problem (Mingers, 1992). Root definition can be completed by drawing the rich picture, or other root cause analysis tools. However, it is not necessary to draw the rich picture. As long as the root definition can be conducted, the SSM can be applied. The setup of the root definition helps to show the unstructured concern area.

SSM has been applied in many aspects, including the logistics industry (Li Zhoua, 2007). The paper shows the logistics practices of battery recycling in China. Based on the SSM, the paper aims to identify the weaknesses of the existing battery recycling system in China, and provide the better solution in this industry.

Theory Application

The basic concept of SSM is to define the human activities into parts (Peter D. C. Bennetts, 1997). The origin of the SSM was from the Biology, and the biologists would like to study the organism from the whole entity. The issue was happened from the supplier audit by the Medtronic International Ltd. shall be defined as “soft” problem, and can be separated into different parts.

The other main concept of the SSM is the hierarchy (Checkland, 1994). An issue can be viewed from different levels of the system. SSM setup the system into parts, and each other can be related with each other. Subjecting to this issue, the activities have been classified into different hierarchies, such as the Quality System, Dirty Warehouse, etc.

In order to monitor the relevant activities, the SSM suggested to have agreed performance criteria (Presley, 2000). In case the activities failed to meet the performance criteria, necessary actions shall be taken to address the issue. After investigation, agreed performance criteria have been setup in order to measure the effectiveness of the implemented solutions.

Root definition is important in the SSM, which is the basis for the organization to solve the “soft” problem (Mingers, 1992). Root definition can be completed by drawing the rich picture, or other root cause analysis tools. However, it is not necessary to draw the rich picture. In order to solve the quality issue from the DHL Global Forwarding, investigation of the issues have been conducted, which involves quality tools, such as the Is/ Is Not Analysis to determine the scope of the issue; and Ishikawa to identify potential root causes, and the 5 whys tool to determine the root cause(s). As mentioned above, Is/ Is Not Analysis to determine the scope of the issue. In addition, Medtronic International Ltd. identify and review all Standard Operating Procedures pertaining to management of this supplier, and identify gaps between requirements and how the program was executed by Medtronic International Ltd.. Ishikawa shall be conducted to identify potential root causes, and the 5 whys tool shall be used to determine the root cause(s).

Data Analysis Details

In order to solve the root cause, several solutions have been proposed. 3PL shall appoint QA representative to set up the quality system in 3PL warehouse. In addition, 3PL revises the existing SOPs in 3PL warehouse to align the requirements from applicable Medtronic International Ltd.’s SOPs and include requirements to monitor the shelves design, review of 3PL SOP and aware the change.

In order to help the 3PL to identify the issues in warehouse, 3PL develops non-conformity WIs to monitor the warehouse performance. In addition, the Medtronic International Ltd. develops check sheet to monitor the performance of 3PL warehouse.

For 3 months post Solution Implementation, if no issues are identified during this review period, then the issue shall be deemed effective.

Discussion and Conclusion

From the above discussion, the soft system methodology is sufficient to address the quality issues happened in the warehouse management of medical devices. The basic concept of SSM is to define the human activities into parts (Peter D. C. Bennetts, 1997). Recent supplier audit on DHL Global Forwarding conducted by Medtronic International Ltd. showed that there was a lack of robust management and control of the third party supplier by Medtronic International Ltd. Several non-conformities raised in the Supplier Audit. Most importantly, the warehouse was very dirty and messy in some areas. At the day of the audit there was significant amount of dust on the machines and on some of the shelves containing active products. Windows at the back of the warehouse were not covered allowing direct sunlight on machines and contain a hole allowing the dust to get in. In addition, the document control system in the DHL Global Forwarding was absent, and there was no issuance that their Standard Operating Procedures taking into account all applicable requirements from Medtronic International Ltd. The issue shall be defined as “soft” problem, and can be separated into different parts.

Root definition is important in the SSM, which is the basis for the organization to solve the “soft” problem (Mingers, 1992). Root definition usually completed by drawing the rich picture. In this case, rich picture have not been drawn. Instead, quality tools, such as the Is/ Is Not Analysis, Ishikawa and 5 whys tool have been used to determine the root cause(s). The report showed that Is/ Is Not Analysis successfully determined the scope of the issue. Ishikawa helped to identify the potential root causes of the issues, while the 5 whys tool helped to determine the exact root causes. Therefore, this study proved that other tools instead of rich picture can help to address the issues by SSM. It is suggested to select the tools based on the nature and complexity of the issues.

Although root causes have been identified, time is a limitation for this study. With the tight timeframes, quality tools can only help to identify the possible root causes. However, if the more time is allowed, many root causes might be identified. Therefore, time is a limitation for this project, and the root causes might not sufficiently address the issues. Further investigation shall be taken to identify the issues.

After investigation, potential causes have been determined. In order to solve the root causes, solutions have been proposed. The solutions help to eliminate or prevent the root causes. The performance criteria have been setup in order to verify the effectiveness of the solutions. The objectives of the verification are to determine whether DHL Global Forwarding can fulfill the in-house warehousing requirements from the Medtronic International Ltd. to the third party (3PL) warehouse partner in the world, which includes the security, environment, cleaning, pest control and storage requirements.

The report helps to verify that the SSM can successfully solve the quality issues in the third party warehouse for medical devices. However, the report did not show the strategy determination from the SSM.

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