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Abstract

Nowadays, regulatory agencies make manufacturers responsible for supplier-related non-conformance and compliance. An effective audit program based on the Quality Management Systems (QMS) requirements along with proper documentation is important to monitor suppliers and maintain compliance. The main challenge that affects organizations to assure ongoing compliance is the poor visibility into the Supplier Monitoring process. Therefore, this paper develops a method to maintain up to date the suppliers audit schedule, documentation and information. The principal step during this methodology is the creation of a Supplier Monitoring tool utilizing Microsoft Excel as a technology-based solution for monitoring suppliers regularly and accurately. Results obtained provide support that the developed methodology is useful to accomplish the purpose of this research. Organizations need to recognize the importance to have an effective Supplier Monitoring process in place facilitated by the appropriate technology and driven by the right people to ensure that supplier-related activities are always compliant.

Introduction

Usually, companies deal with hundreds of suppliers and managing the products/services procured from them can be complex and difficult. For this reason, there is a need of data handling which requires systematic approaches. However, even with systems in place, companies continue having quality and compliance issues. Most companies manage their supplier documentation and information by e-mails, phone calls, personal visits to the supplier location, among others. This approach is very risky since most of the supplier documentation and information is entirely handled by a person, making it rarely visible to the entire Staff Management until the situation turns into a very complicated problem to address. Consequently, a method to maintain up to date the suppliers audit schedule, documentation, and information is needed to assure ongoing quality products and compliance.



Background

Supplier Quality Management (SQM) is particularly essential for regulated companies. Regulators expect supplier audits to be conducted as part of a broader Quality Management System (QMS) in order to monitor quality and reveal potential and/or existing issues[5]. SQM is the series of procedures and processes that describes the organizational structure and responsibilities to ensure suppliers are able to deliver goods or services that will satisfy customer's and organization's requirements. SQM framework is composed by three main processes: Supplier Selection, Supplier Monitoring, and Supplier Development[2]. Figure 1 shows the SQM framework and the relationship between the processes[2]. This paper is focusing only in the Supplier Monitoring process. The Supplier Monitoring (SM) process is the continued analysis and evaluation of suppliers as per pre-approved requirements established in the Supplier Qualification (SQ) process. "Despite the importance of SQM to manufacturers, investment in SQM technology and automation has been lacking"[4]. In today's manufacturing industries and the findings by LNS Research surveys, highlight a significant need for automation tools to achieve end-to-end supply chain visibility[4].

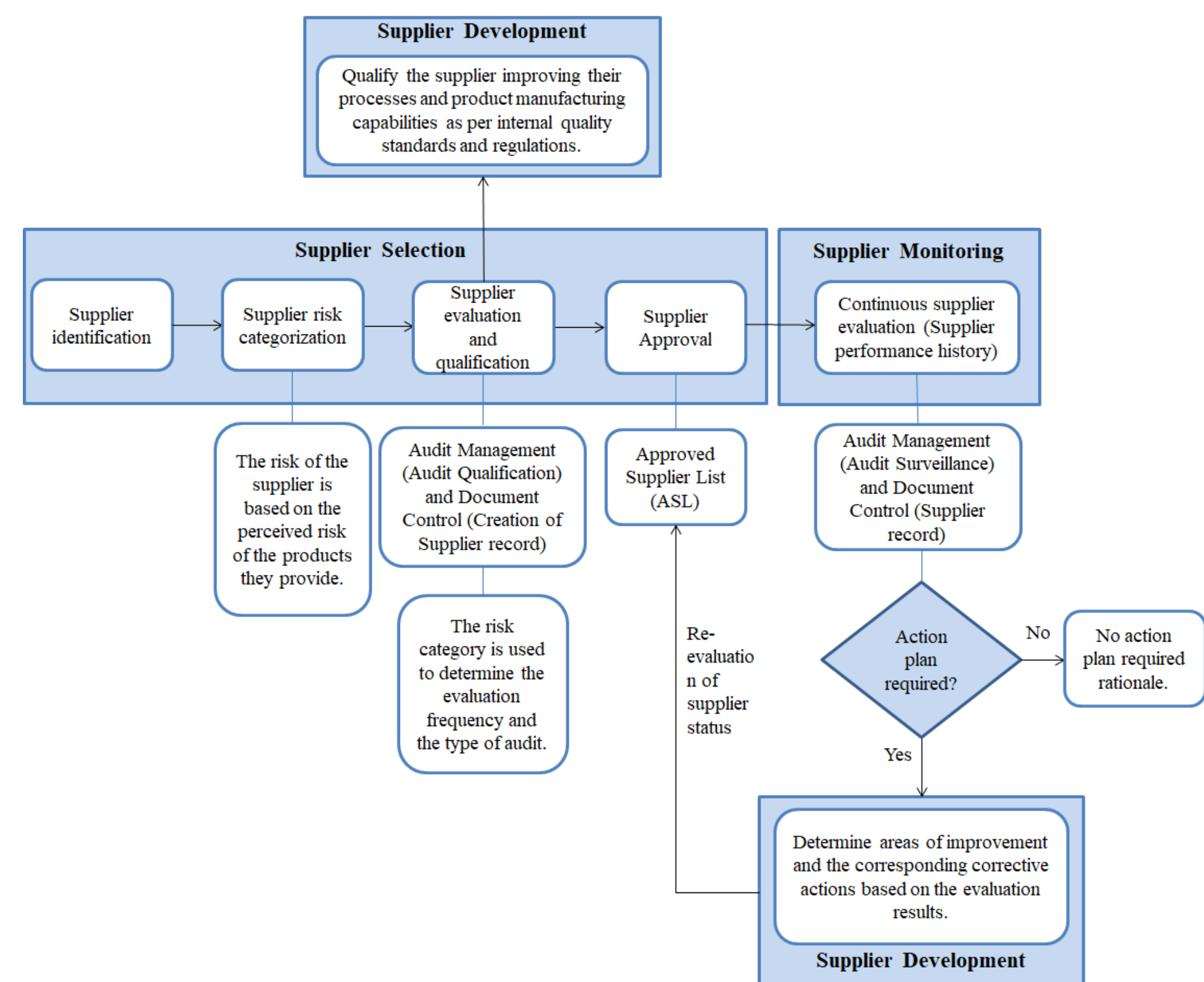


Figure 1: Supplier Quality Management (SQM) Framework [2]

Problem

A method to maintain up to date the suppliers audit schedule, documentation and information is needed for the purpose of assuring continued supplier's conformance to Quality Management System (QMS) requirements and organization's internal requirements. Therefore, it is essential to define the input variables of the Supplier Monitoring process, create a Supplier Monitoring tool, establish a method to assign tasks to the Supplier Management staff, develop a method to notify pending and overdue tasks to ensure they are tracked and completed, and control the access to edit information in the Supplier Monitoring tool.

Methodology

The following Table describe the methodology in which the research is developed to accomplish the objectives.

Table 1: Methodology Steps and Techniques

Methodology	Techniques	Expectations
Step 1: Defining input variables of the Supplier Monitoring process	<ul style="list-style-type: none"> Using the Audit Management process based on the QMS approach to define the variables. Using the risk of the supplier to determine the audit type and the frequency in which audits will occur [8]. Creating a supplier audit schedule to perform periodic audits to monitor suppliers [5]. 	1. The creation of the supplier audit schedule using the input variables defined as shown in Figure 2.
Step 2: Creating a Supplier Monitoring tool	<ul style="list-style-type: none"> Using Microsoft Excel to handle the supplier audit schedule. Using Macros or one of the great varieties of features that Excel has for itself. 	<ol style="list-style-type: none"> Have a mechanism in place to periodically collect data of suppliers. Automatizing task in Excel to avoid manual errors and ensure accuracy of the data.
Step 3: Assigning tasks to the Supplier Management staff	<ul style="list-style-type: none"> Defining the role and responsibilities for the Supplier Quality Manager. Defining the role and responsibilities for the Team members. Using the Pivot Table feature in Microsoft Excel to create reports. 	<ol style="list-style-type: none"> Roles and responsibilities of the Supplier Management staff defined to manage and maintain the tool and documentation. The Pivot Table feature in Excel can be used to organize, and analyze the data in the supplier audit schedule.
Step 4: A method to notify pending and overdue tasks	<ul style="list-style-type: none"> Using Conditional Formatting feature in Excel to allow the staff identifying trends. 	1. Conditional Formatting feature in Excel can be used to highlight pending and overdue tasks to ensure they are tracked and completed by the user [12].
Step 5: Controlling the access to the Supplier Monitoring tool	<ul style="list-style-type: none"> Using the Protect Sheet and Protect Workbook features in Excel to control the tool. Using the Data Validation feature in Excel to ensure accuracy of the data. 	<ol style="list-style-type: none"> A password could be created to prevent others from opening the entire Excel file and to protect the structure of the Excel file [14]. The Data Validation feature could be used to restrict entries in a cell [13].

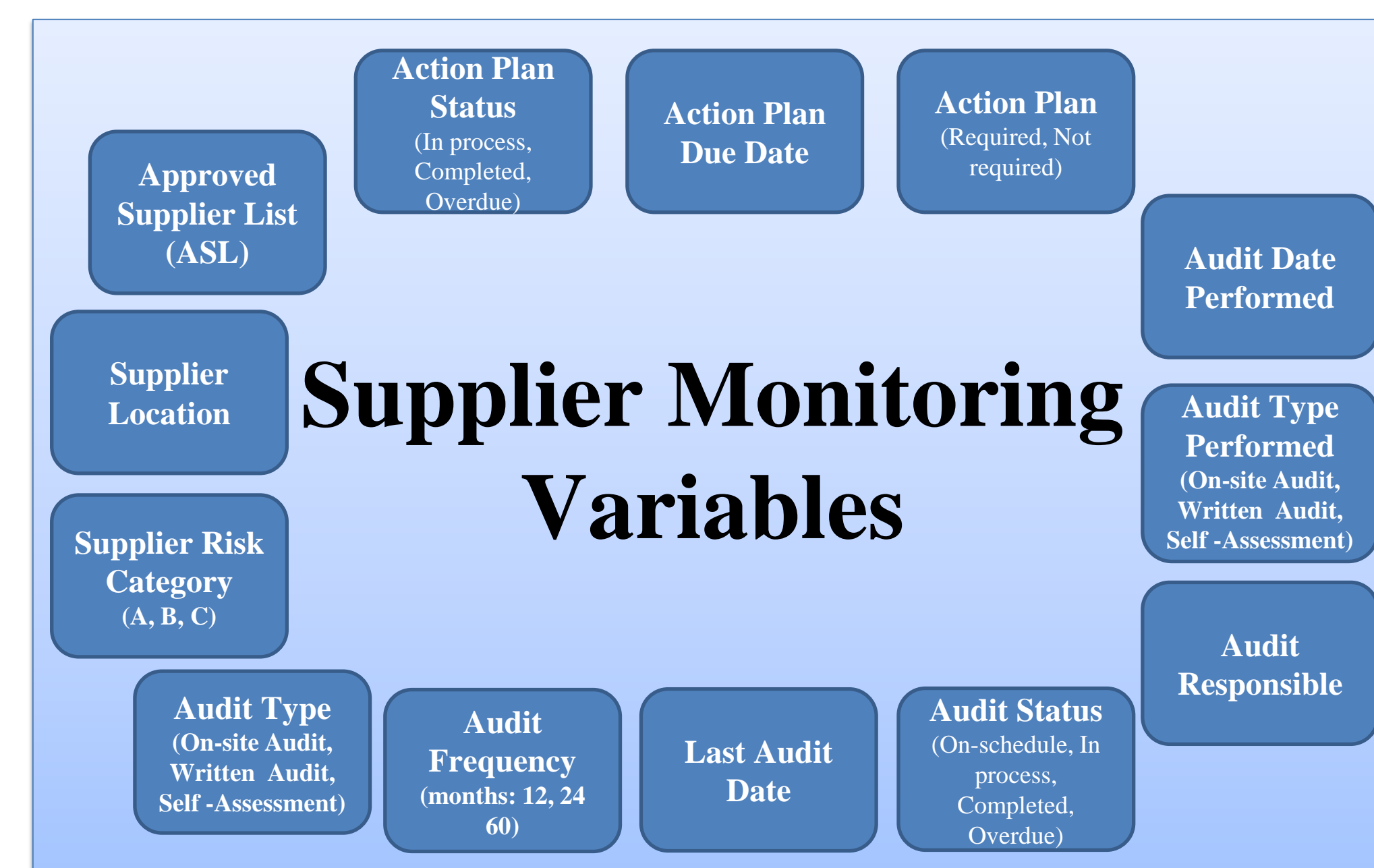


Figure 2: Supplier Monitoring Variables

- The main results expected from this methodology are the following:
 - To have better visibility of the audit status of each supplier.
 - To establish a plan to perform supplier audit activities.
 - To catch up with the overdue supplier audit activities progressively until there are up to date (in compliance).
 - To maintain up to date (in compliance) all the supplier audit activities in the audit schedule along with the corresponding information and documentation as per QMS and organizations' internal requirements.

Results and Discussion

The following Table describe the results and discussion from the developed methodology to evaluate if the objectives of this research were accomplished.

Table 2: Results from the Methodology

Methodology	Results
Step 1: Defining input variables of the Supplier Monitoring process	1. A supplier audit schedule was created using the variables defined according to QMS requirements and organization's internal requirements.
Step 2: Creating a Supplier Monitoring tool	<ol style="list-style-type: none"> Microsoft Excel was used as a tool to handle the supplier audit schedule to have a centralized and standard mechanism in place to periodically collect data of suppliers. A Macro in Excel was created to add automatically to the supplier audit schedule a supplier that is added to the ASL.
Step 3: Assigning tasks to the Supplier Management staff	<ol style="list-style-type: none"> Roles and responsibilities of the Supplier Management staff were defined to have a standard structure of managing and maintaining the tool and documentation. For example, the Pivot Table feature in Excel was used to organize and analyze the amount of audits assigned each month.
Step 4: A method to notify pending and overdue tasks	1. For example, the Conditional Formatting feature was used to turn green automatically an audit that remain "On-schedule" to let the user know that it is a pending task to be done.
Step 5: Controlling the access to the Supplier Monitoring tool	<ol style="list-style-type: none"> Protect Sheet and Protect Workbook features in Excel were used to protect the integrity of the data and limit the use of the tool and data entry to the authorized staff only. For example, in the Audit Type column, the Data Validation feature was used to restrict entries of data in the cells to choose only "On-site audit", "Written audit" or "Self-Assessment" as options when creating the drop down list.

- Before the development of the methodology presented, the audit status of each supplier was not known for the lack of a centralized mechanism to place the data.
- Following step by step the methodology, it was possible to know the audit status of each supplier and a plan was established.
- The suppliers audit schedule was divided by months and the corresponding personnel was assigned to perform the "Overdue" and "On-schedule" tasks established each month. The results obtained from the first four months (January to April) are presented in Figure 3.

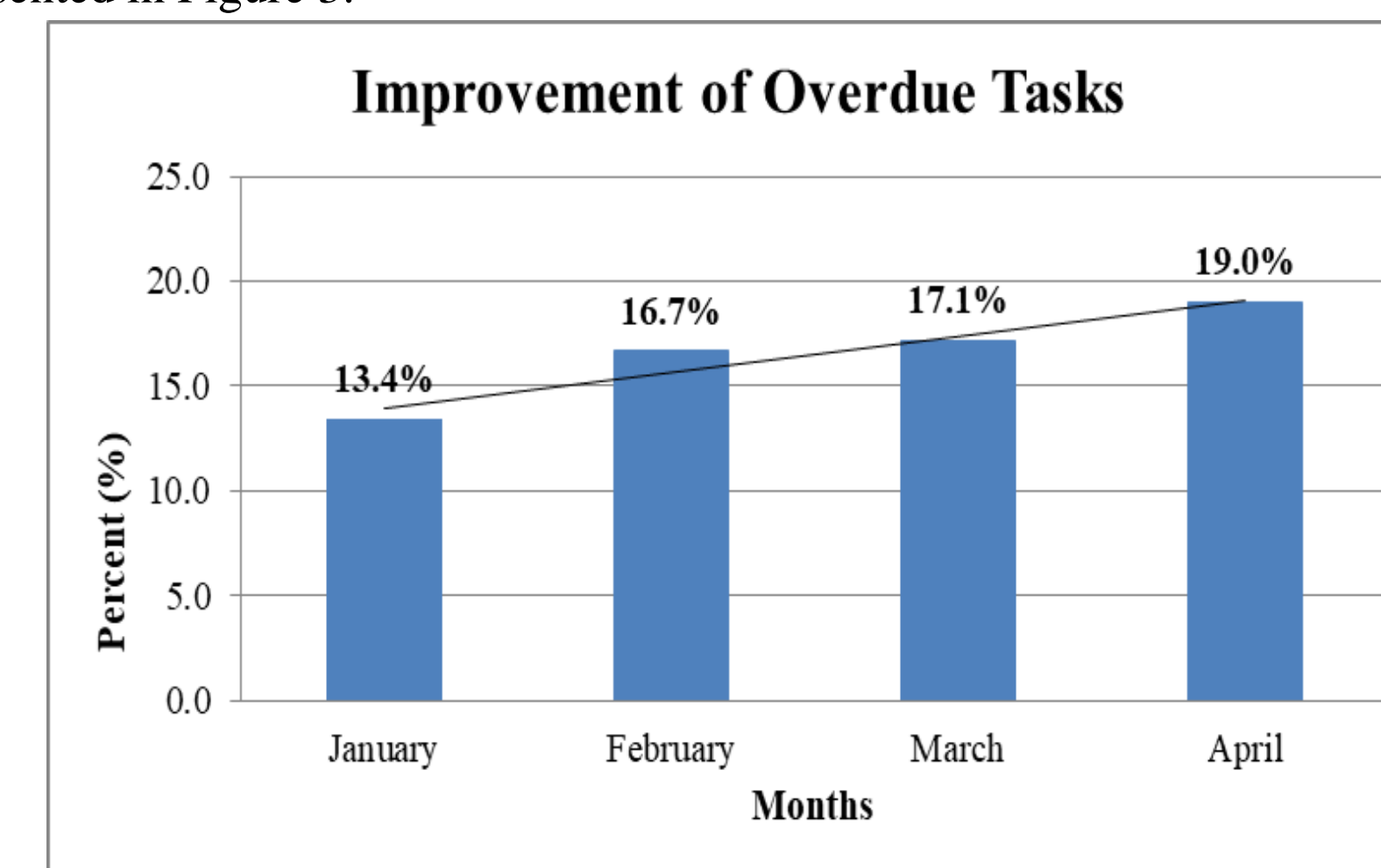


Figure 3: Improvement of Overdue Tasks

This Figure shows that each month the Overdue tasks were improved by performing the corresponding audits and supplier activities using the methodology and the Supplier Monitoring tool. This means that the staff is catching up with the audit activities progressively and maintaining up to date the supplier audit schedule, information and documentation.

- During these four months the Overall Overdue Tasks was reduced a 44% and the suppliers with the corresponding documentation required increased a 36% since some of the missing or incomplete Audit Action Plans were completed as shown in Figure 4.

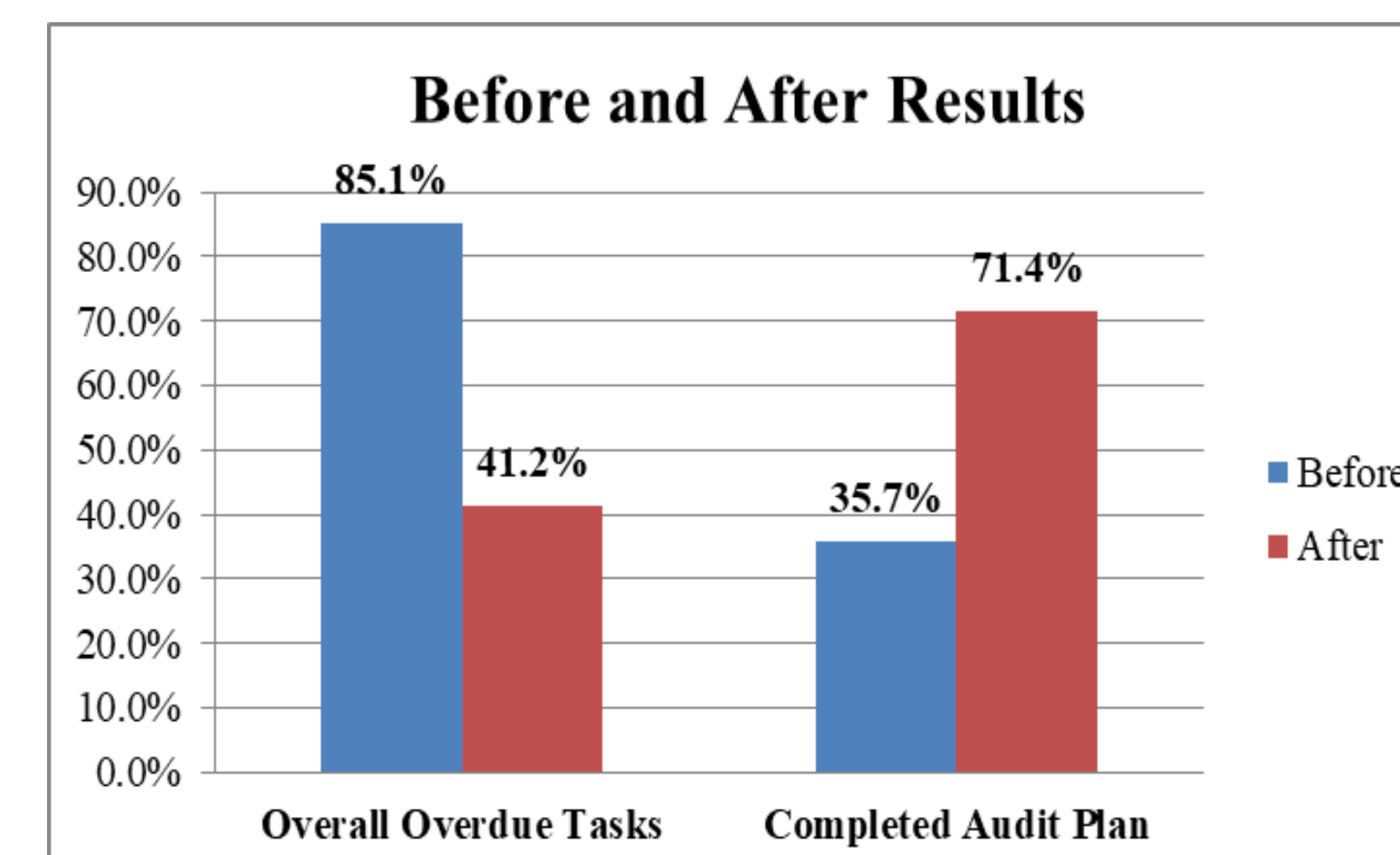


Figure 4: Before and after results of using the developed methodology

Conclusions

An **effective supplier audit program** is important to ensure that suppliers sustain compliance to applicable regulatory requirements. Consequently, the **efficiency of the staff is improved** by focusing on value-added/proactive activities to take actions before situations become major problems. The **results obtained** from this research provide support that the use of the **developed methodology is useful** to maintain up to date the supplier audit schedule, documentation and information. **Having the right information** on suppliers becomes imperative to have an effective supplier audit program. Organizations need to recognize that it is **essential** to have an **effective SM process and technology** in place to ensure that supplier-related activities are always **compliant**. **By utilizing Microsoft Excel as a technology-based solution** for monitoring suppliers, organizations can achieve a standardized and automated approach to collect and manage data regularly and accurately, identify trends, track audit tasks for completion, and make in-depth reporting and analysis. **With the methodology** developed, organizations will have the right SM process in place facilitated by the **appropriate tool** and driven by the **right people**. The principal step needed to maintain up to date the supplier information is the **Supplier Monitoring tool** that serves as a centralized mechanism that provides better visibility into the SM process.



Future Work

- It is recommended to perform statistical analysis in order to measure the impact of the variables into the SM process.
- The methodology can be further enhanced by developing a software that could link all the processes of the SQM system (Figure 1).
- Furthermore, it will be ideal to link the SQM system with other systems within the organization. For example, the SM process could be linked with the CAPA system.
- Further research can be performed in the SQ process particularly in the Supplier Risk Categorization step to provide more insight and techniques on how to appropriately select the risk of each supplier among organizations.



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