Developing a Method to Maintain Up To Date the Supplier Audit Schedule, Information and Documentation

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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.

Key Terms — "Audit Program", "Compliance", "Quality Management", "Supplier Monitoring".

PROBLEM STATEMENT

A supplier audit is the most important element to monitor and maintain supplier compliance. Regulatory agencies have become more vigilant in monitoring drug and device manufacturers by making them responsible for supplier-related nonconformance and compliance. Manufacturers should implement an effective supplier audit program based on the Quality Management Systems (QMS) approach as explained on the Food

and Drugs Administration (FDA)'s Guidance for Industry along with proper documentation. In addition, audit records of approved suppliers should be maintained by the manufacturer. The complexity of supplier management will depend on the size and scope of the company. Usually, companies deal with hundreds of suppliers. Therefore, managing the products/services procured from them can be complex and difficult. For this reason, there is a need in terms of data handling and therefore requires systematic approaches. However, even with systems in place, companies continue having quality and compliance issues. Most of the 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 complicated problem to address. very Consequently, a method to maintain up to date the suppliers audit schedule, documentation information is needed for the purpose of assuring continued supplier's conformance to Quality Management System (QMS) requirements and organization's internal requirements. Most of the manufacturing companies use products/services from suppliers that could potentially affect the product quality. Therefore, it is necessary to have a supplier audit program to conduct effective supplier audits to assure the product quality and compliance according to regulatory guidelines and internal requirements. Moreover, it is essential to have an effective Supplier Monitoring (SM) process to assure ongoing quality products and compliance.

Research Objectives

The objectives of this research are:

- To define the input variables of the Supplier Monitoring process.
- To create a Supplier Monitoring tool.
- To establish a method to assign tasks to the Supplier Management staff.
- To develop a method to notify pending and overdue tasks to ensure they are tracked and completed.
- To control the access to edit information in the Supplier Monitoring tool.

Research Contributions

The main contributions of this research will be,

to:

- Provide a user friendly tool with a defined Supplier Monitoring method that displays supplier status fields for each supplier.
- Reduce the risk of been out of compliance by maintaining up to date all the documentation and records related to each of the organization's suppliers.
- Provide better visibility into Supplier Monitoring process for staff management assuring compliance.
- Provide better visibility into Supplier Monitoring process for staff management assuring compliance.
- Improve the Supplier Management staff efficiency by focusing on valueadded/proactive activities such as analyzing and identifying trends in the supplier evaluation data. In other words, allowing the staff to have a clear understanding in where to focus next.

LITERATURE REVIEW

The production output of manufacturing and services companies is greatly dependent on their supplier's performances (Waller 2004) [1]. "As a consequence, suppliers and supply chains became increasingly critical for the success of companies (Handfield et al. 2002) [2]. Supply chain is a system of a synchronized flow of materials and information from suppliers to their customers [1].

Supply chain management is the active management of supply chain activities to maximize value and achieve a sustainable customer competitive advantage [3]. Therefore, it is very important that companies manage their supply chains efficiently. "Metricstream (2012) identifies visibility and traceability, delayed poor identification of errors, inflexible and delayed reporting, non-conformance, and non-compliance of products to standards as the main supplier quality management challenges in manufacturing industry" [1]. In addition, "recent LNS Research surveys found that supply chain visibility is a top challenge across industries and is a leading roadblock to achieving quality objectives" [4]. Supplier Ouality Management (SOM) particularly essential for regulated companies. The FDA and other regulatory agencies state that the company is ultimately responsible for the quality of purchased material. Regulators expect supplier audits to be conducted as part of a broader QMS in order to monitor quality and reveal potential and/or existing issues [5]. "A QMS is a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization. (i. e. areas that can impact the organization's ability to meet customer requirements)" [6]. "International Organization for Standardization (ISO) 9001 is an example of a QMS" [6]. "A process based QMS enables the organizations to identify, measure, control and improve the various core business processes that will ultimately lead to improved business performance" [6]. Therefore, 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 organization's requirements. SQM framework is composed by three main processes: Supplier Selection, Supplier Monitoring, and Supplier Development as shown in Figure 1 [2]. This paper is focusing only in the Supplier Monitoring process. Supplier monitoring is a relative young research area with a growing scientific interest and it is

expected to continue growing [2]. "Supplier monitoring is an independent but interrelated process, which follows the Supplier Selection process (Kleinsorge, Schary, and Tanner 1992; Ittner et al. 1999). Supplier Monitoring process is the continuous analysis and evaluation of supplier and supply chain information with regard to the compliance of defined minimum requirements (Hervani, Helms, and Sarkis 2005; Koplin 2006; Ragazzi, Crescentini, and Castelli 2012)" [2]. Failure to continuous analyzing and evaluating suppliers can affect the business with costly mistakes. "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 clear and significant need for automation tools to achieve end-to-end supply chain visibility [4].

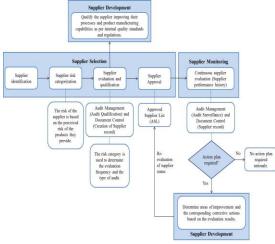


Figure 1
Supplier Quality Management (SQM) Framework [2]

METHODOLOGY

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

Defining Input Variables of 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 Selection (SS) process, specifically in the Supplier Qualification (SQ) process. The purpose of a supplier qualification is to provide evidence that the supplier is able to deliver consistent quality of product in compliance with regulatory and internal requirements [7]. To ensure ongoing reliability, suppliers should be monitored in a regular basis [7]. The risk of the supplier is based on the perceived risk of the products/services they provide and is used to determine the audit type and the frequency in which audits will occur. "The level of risk addresses the supplier situation individually and provides measurable controls around the supplier" [8]. Based on the risk assessment, manufacturers determine the criteria for selection, evaluation and monitoring each supplier. Example of risk categories and related supplier audit types and their frequencies based on risk level are shown in Table 1. The frequency could change upon previous audit findings and the quality trends of products/services received from the supplier [8]. If an audit reveals no problems, then audit intervals could be deferred. If problems are identified, audits may need to be conducted more often [8].

Table 1 Supplier Risk Categories and Associated Audit Type and Frequency [8]

Frequency [8]			
Risk Category	Applicable To:	Audit Type	Audit Frequency
Category A (High or Significant risk)	Suppliers that have a critical impact on the quality or availability of the product or Suppliers that have a direct impact on the product, but alternatives are available.	On-site audit	Annual
Category B (Moderate risk)	Suppliers that have an indirect impact on the product.	On-site Audit or Written audit	24 months
Category C (Low risk)	Suppliers that have no product impact.	Self- Assessment / Audit not applicable	As required based on Supplier Management staff decision.

In addition, as part of the SQ process, there are processes such as Audit Management and Document Control. Audit management consists on

formal designed steps to complete all of the individual audits needed to ensure that requirements established are fulfilled. Figure 2 shows the Supplier Audit Management process to conduct an On-site audit.

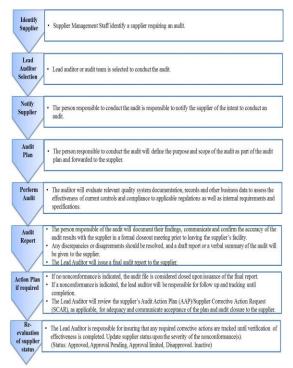


Figure 2
Supplier Audit Management Process

There are two types of On-site audits, a Oualification audit and Surveillance/ Routine audit. A Qualification audit is performed during the SQ process as an initial audit to determine the acceptability of a proposed supplier in order to regarding determine basic information supplier's systems and processes. After a supplier is qualified, the supplier is placed in the Approved Supplier List (ASL). The ASL is a tool used to ensure that buyers place orders to those suppliers that meet the company's established criteria. On the other hand, a supplier must be monitored on an ongoing basis to remain on an ASL to assure reliability [4]. Therefore, ongoing Surveillance/Routine audit is performed in the SM process with the purpose to continuous analyzing and evaluating suppliers, including covering changes since the last audit. That is, the Surveillance audit is a product and process focused audit that helps to maintain previously qualified suppliers in good standing. Moreover, Written audits may also be used when the supplier refuses to allow an On-site audit or when the Supplier Management staff decides to defer the audit when the supplier's performance is in good standing for a determined period of time. In this paper, Document Control refers to the storage of the documentation generated per the audit process. "Manufacturers should implement a rigorous and proactive supplier audit program, along with proper documentation" [7]. Companies should maintain a permanent storage of audit records for each approved supplier. "FDA has authority to review and copy all records required by the regulations" [7]. Consequently, manufacturers must ensure that supplier audits have been conducted and the results documented. including any actions taken as a result of the audit [7]. "This will ensure product quality, patient safety and reduce citations from regulatory agencies" [7]. During the SS process, the variables are defined to evaluate a supplier. To evaluate the supplier on an ongoing basis, a supplier audit schedule is created to perform periodic audits to address both preapproved audit verification steps as well as potentially problematic areas observed during previous audits [5]. Therefore, the SM process variables should include, but not limited to the following:



Figure 3
Supplier Monitoring Variables

Creating a Supplier Monitoring Tool

As manufacturing companies procure new goods/ services, tracking suppliers can become more complex and difficult [4]. Monitoring suppliers relies on supplier audits and documentation. Therefore, the supplier audit process is an ongoing monitoring process [7]. To have an effective monitoring process, it is necessary to have a tool that carries out all the variables that the SM process entails. Automation tools can help manufacturers reduce inefficiencies that relate to generating accurate and timely audit responses, reports, and trends [4]. This means that manufacturers will be able to adequately store, monitor and control existing and new supplier information, including audit statuses and recent data derived from a supplier audit to ensure continuity of supply, compliance, and product quality [4]. Consequently, the automation tool will serve as the basis for further action maintaining accurate and up to date records and information of suppliers.

From decades, there is a continuous need for businesses to store, analyze, manipulate, track and report authentic data in a fast and simple way. It is very common that companies use Microsoft Excel to gather data and prepare detailed reports. Therefore, Microsoft Excel is an essential valued tool for business and technological environments. However, most companies manually store and edit their data in Excel spreadsheets. This methodology takes a lot of time and is highly risky since there is a great possibility that manual errors will occur. This problem can be solved by automatizing tasks in Excel. One of the more powerful functions of Excel is the ability to very easily create automated tasks and custom logic within Macros [9]. However, this function is barely used, usually for lack of knowledge. "Macros provide an ideal way to save time on predictable, repetitive tasks as well as standardize document formats, many times without having to write a single line of code" [9]. Macros are recorded in the Visual Basic for Applications (VBA) programming language and can do the following list of functions, but not limited to [9]:

- Apply style and formatting.
- Manipulate data and text.
- Communicate with data sources (database, text files, etc.).
- Create entirely new documents.
- Any combination, in any order, of any of the above.

The main purpose of using VBA in Excel is to automatize repetitive tasks. The SM process is full of repetitive tasks. For example, every time a supplier is approved, the ASL needs to be updated to add the new approved supplier. Since the ASL is an input variable for the SM process, the supplier audit schedule needs to be updated as well. Using VBA to write clear commands for Excel to follow, the supplier audit schedule could be updated automatically once the authorized person places the supplier information in the ASL. new Nevertheless, sometimes a problem can be solved using one of the great varieties of features that Excel has for itself without using VBA, in which, most of the time, the user is not aware of all of them. According to Matt Allington, "Excel is a powerful tool with solid dashboard capabilities built in, which include PowerPivot, Pivot Tables, Slicers and Conditional Formatting. The modern versions have a powerful suite of capabilities, and are flexible, cheap and agile enough to present data almost any way that one could want to see it" [10]. Companies just need to know how take advantage of everything Excel has to offer and take the work in Excel to the next level.

Establishing a Method to assign Tasks to the Supplier Management Staff

After defining the variables to be monitored and establishing a Supplier Monitoring tool, it is very important to determine how this tool will be manage for the success of it. After defining tasks in the audit schedule, it is time to start assigning people to work on them. Depending on the size and scope of the company will be the complexity of the

SQM process. That is, depending on how big is the company will be the variety of duties and responsibilities. Usually, the SQM is administrated by the Supplier Quality Manager with the purpose of managing all supplier-related activities. For the purpose of this paper, the Supplier Quality Manager is responsible of establishing the frequency of the staff meetings, the level of authority, the responsibilities of its members, and the communication to the required staff. The team members will be responsible for maintaining the supplier audit schedule, the generation of the supplier audit documents, the review and approval of Audit Reports (AR) and Audit Action Plans (AAP), tracking outstanding audits for completion, and will be responsible for the permanent storage of the audit records. The team members are composed by Supplier Quality Engineers with the ability to act as an Auditor and/or Lead Auditor. The differences between both of them are:

- Auditor- Is any team member who has been trained to perform audits. The auditor is responsible for conducting quality audits, generating written records of the results; requesting corrective and preventive actions, as required; providing supplier recommendations and written results of the audit. She/he is also responsible for tracking and documenting with objective evidence the supplier's actions implementation and generating the audit closure documentation.
- Lead Auditor Is any team member who has been trained to perform audits and has completed an audit technique training or equivalent professional experience. When a member does not have the corresponding audit technique training to perform an On-site audit, this member must be accompanied by a Lead Auditor all the time. In the case that the member completes the audit technique training, it is recommended that the Auditor performs at least one audit with a Lead Auditor as part of the on job training.

Every time a member joins or leaves the team, the Supplier Quality Manager or designee is responsible to take the necessary action to maintain up to date the supplier audit schedule. Auditing involves planning, procedures, risk, management, among others. Therefore, weekly meetings will be established with the purpose of updating the supplier audit schedule and of storing the corresponding documentation in the supplier record. The Supplier Quality Manager or designee will be responsible of running the weekly meetings and updating the supplier audit schedule with the information provided by each team member. Communicating throughout meetings and written documents will help accurately maintaining the corresponding data in the supplier audit schedule along with the proper documentation in the supplier record. In addition, using the Pivot Table feature in Microsoft Excel will help organize, analyze and summarize data in the supplier audit schedule. This feature can be used if the data is too large and complex to analyze in its original format [11]. The Pivot Table helps to create reports in an efficient way without the need of spending a lot of time creating reports manually [11]. For example, most companies have a large list of suppliers. Therefore, when assigning tasks to the team members, the Pivot Table can summarize the workload that each member has.

Developing a Method to notify Pending and Overdue Tasks

Conditional Formatting is one of the useful features that Microsoft Excel has. This feature helps users to automatically format data in Excel spreadsheets. "Conditional formats can apply basic font and cell formatting such as number format, font color and other font attributes, cell borders and cell fill color. In addition, there is a range of graphical conditional formats that helps with visualizing data by using icon sets, color scales, or data bars" [12]. Therefore, Conditional Formatting helps users to quickly focus on important aspects of a spreadsheet, to highlight errors and/or to identify important patterns in data [12]. Regarding the

Supplier Monitoring tool, this feature can be used to highlight pending and overdue tasks to ensure they are tracked and completed by the user. As shown in Figure 3, the Audit Status is defined as On-schedule, In process, Completed and Overdue. Therefore, Conditional formatting can be applied to assign a specific color to each of the Audit Status to help the user identify easier the pending and overdue audits. For example, every time that an Audit is "Overdue", Excel automatically will turn red the task with the combination of the DATEDIF function to count the months that the audit is open. Consequently, the audit schedule can serve as basic further actions focusing valueadded/proactive activities such as analyzing and identifying trends in the supplier evaluation data.

Controlling the Access to edit Information in the Supplier Monitoring Tool

After establishing a Supplier Monitoring tool, it is very important to standardize the use of this tool. In Excel, the Data Validation feature helps to control what can be entered in a worksheet. This feature is used to create a drop down list of items in a cell, restrict entries and create custom rules for what can be entered [13]. For example, the Audit Status column can be restricted to only choosing "On-schedule", "In process", "Completed" or "Overdue" as options when creating the drop down list. That is, the user will not be able to enter another option. Since the Supplier Monitoring tool is shared with a group of people, it is important to protect the data that is in the Excel workbook (entire Excel file). Spreadsheets often contain essential data that should not be modified or removed by the recipient [14]. Excel has built-in features to protect spreadsheets to make sure that Excel workbooks maintain data integrity. There are three key techniques [14]:

- Password protect entire workbooks to prevent them from being opened by unauthorized users.
- Protect individual sheets and the workbook structure, to prevent the insertion or deletion of sheets in the workbook.

 Protect cells, to specifically allow or disallow changes to key cells or formulas in your Excel spreadsheets.

To control the access to the Supplier Monitoring tool, a password could be created to prevent others from opening the entire Excel file that is used to monitor the suppliers. In addition, to be preventive, the structure of the Excel file could be protected to ensure that no sheets are deleted, added, or re-arranged inside of the file [14]. The Supplier Monitoring tool has crucial data that will be used in making decisions. Therefore, it is essential to maintain control of the data and ensure that it is edited by the authorized staff only. Using these types of targeted protections will help to protect the structure of the Supplier Monitoring tool and will puts limits on how the user can edit the information inside of it.

RESULTS AND DISCUSSION

The following sections describe the results and discussion from the developed methodology that determine if the objectives of this research were accomplished.

Input variables of the Supplier Monitoring Process

"A well-run, comprehensive supplier audit program is perhaps one of if not the most important way to monitor and maintain supplier compliance" [5]. As mentioned before, a supplier audit schedule is created to perform periodic audits to evaluate the supplier on an ongoing basis. That is, the result of this section was a supplier audit schedule using the variables defined according to QMS requirements and organization's internal requirements with the purpose of establishing what companies need to monitor over time.

The Supplier Monitoring Tool

One of the results of this section was the use of Microsoft Excel as a tool to handle the supplier audit schedule with the purpose to have a centralized and standard mechanism in place to periodically collect data of suppliers. Another result of this section was the use of Macros in Excel to automate tasks to ensure accurate supplier data for analysis in real time. For example, a Macro was created to add automatically to the supplier audit schedule a supplier that is added to the ASL. "Since most large organizations have many strategic suppliers and lots of data, it is almost impossible to obtain, organize and review data from assessments effectively on a large scale without automation or software" [15].

Method to assign Tasks to the Supplier Management Staff

One of the results of this section was a method that defines roles and responsibilities of the Supplier Management staff to have a standard structure of managing the tool with the purpose to maintain up to date the data of suppliers in the supplier audit schedule and the generation and storage of the suppliers audit documentation. Monitoring supplier performance proactively can ensure that personnel and resources are assigned to address the problem quickly [15]. Another result of this section was the use of the Pivot Table feature in Microsoft Excel to create reports, analyze and summarize data in the supplier audit schedule. Having a tool that can take the assessment data and can output it in a report or other formats is helpful because team members can all access and review the information quickly and easily [15]. For example, the Pivot Table feature was used to organize and analyze the amount of audits assigned each month.

Method to notify Pending and Overdue Tasks

The result of this section was the use of the Conditional Formatting feature in Excel to identify trends ensuring that tasks are tracked and completed by the authorized team member. "In order to be effective, the supplier audit schedule must be structured in such a way that it produces information and data that can actually be used to make a decision [15]. For example, every time that an Audit was "On-schedule", Excel automatically

turned green the task to let the user know that it is a pending task to be done. This was done with the combination of the DATEDIF function to count the months that the audit is open and the Conditional Formatting feature to turn the task green when the audit remained "On-schedule". If the information of the supplier audit schedule is vague or ambiguous, then the Supplier Management staff cannot make any official decisions based on this information and the effort was effectively wasted [15]. "Ideally, the format that the data is in should lend itself to comparison and analysis" [15]. By identifying trends, the Supplier Management staff can make projections about where the supplier data will be in the future and can take action accordingly [15].

Controlling the Access to edit Information in the Supplier Monitoring Tool

The overall result of this section was a method that defines how to standardize and control the supplier data in the Supplier Monitoring tool. The Data Validation feature in Excel was used to create control/ restricted entries of data in a cell. For example, the Audit Type column was restricted to choose only "On-site audit", "Written audit" or "Self-Assessment" as options when creating the drop down list. In addition, features in Excel such as Protect Sheet and Protect Workbook were used to protect the integrity of the data and limit the use of the tool and data entry to the authorized staff only. It is essential to have these controls in place to ensure the data accuracy to take the right actions, and maintain up to date the supplier audit schedule, information and documentation.

Summary

Before the development of the methodology presented, the audit status of each supplier was not known because there was no centralized mechanism to place this information. Therefore, it was very difficult for the Supplier Management staff to maintain up to date the supplier audit schedule, information and documentation leading to compliance issues. A summary of the main results

obtained after the development of the methodology presented is shown in Table 2.

 $\label{eq:Table 2} Table \ 2$ Before and After the Development of the Methodology

Before	After	
Undefined variables (requirements) to monitor.	Variables (requirements) defined to be monitored.	
No Supplier Monitor tool in place.	Supplier Monitoring tool in place.	
No roles and responsibilities established to manage the tool.	Roles and responsibilities were established to manage the tool.	
No structure of the tool defined to ensure tasks are tracked and completed.	The structure of the tool was defined to ensure tasks are tracked and completed.	
No controls in place to manage the tool.	Controls were established to manage the tool.	

Following step by step this methodology, all the corresponding information (data) was placed in the Supplier Monitoring tool. Therefore, it was possible to know the audit status of each supplier. The supplier audit schedule had an 85% of Overall Overdue Tasks and only 36% of suppliers had the corresponding documentation required since the AAP of some suppliers was not developed or completed. Knowing the audit status of each supplier, a plan was established with the purpose of making up for the Overdue tasks (audits or incomplete AAP) and to continue monitoring the suppliers ensuring ongoing compliance. 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 4. This Figure shows that while the Overdue tasks are being performed month by month using the methodology and the Supplier Monitoring tool, there is an improvement each month of the Overdue tasks. This means that the staff is catching up with the audit activities progressively and maintaining up to date the supplier audit schedule, information documentation. Consequently, 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 5.

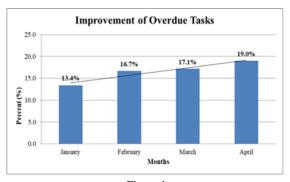


Figure 4
Each month the Overdue Tasks were improved by performing the Corresponding Audit and Suppliers
Activities to Place Suppliers in Compliance according to QMS Requirements and Internal Requirements

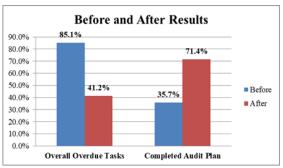


Figure 5
The Overall Results before and after the Use of the Developed Methodology

CONCLUSION

The following sections describe the evaluation of this research.

Most Important Findings

Considering the current regulatory climate, implementing an effective supplier audit program based on the QMS becomes a fundamental requirement for organizations. An effective supplier audit program will ensure that suppliers sustain compliance to applicable regulatory requirements and the quality of product or service procured from suppliers. In today's very competitive environment supplier information is the critical starting point. Having the right information on suppliers becomes imperative to have an effective supplier audit program. This information should always be live,

up to date and instantly retrievable. For this reason, a method to maintain up to date the suppliers audit schedule, documentation and information has been developed. With this methodology, 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. 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. 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. Organizations need to recognize that it is essential to have a well augmented SM process and technology in place to ensure that supplierrelated activities are always compliant.

Research Limitations

Features of Excel like Macros, Conditional Formatting, and Data Validation were used to automatize and standardize tasks in the Supplier Monitoring tool. Protect Sheet and Protect Workbook features were used to control and protect the integrity of the data. The Pivot Table feature was used to analyze and summarize data and create reports. All of these features are available in Excel and any of them require advance programming knowledge to use them. However, the Supplier Monitoring tool can be further enhanced by incorporating advance Excel features that requires programming like VBA. This will help to automate more audit tasks taking the tool to a next level and assuring compliance. Another limitation of the research is that the Supplier Monitoring tool does not have the capability to store the documentation generated by the audit process. This means that the tool helps the user to generate the required audit documentation until completion of the audit but does not assure that the documentation will be permanently stored in the supplier record. The permanent storage of the supplier documentation is also important to ensure compliance according to regulatory guidelines.

Future Research Recommendations

The purpose of this research was to develop a method to maintain up to date the supplier audit schedule, documentation and information. The developed methodologies serve as a key function in the SM process and can be used by organizations as a strategy to assure continued compliance of suppliers. It is recommended to perform statistical analysis in order to measure the impact of the variables into the SM process. In addition, the methodology can be further enhanced developing a software that could link all the processes of the SQM system (Figure 1). Maintaining and controlling supplier quality information across the entire SQM system is complex and error prone when this information is kept in separate systems. Furthermore, it will be ideal to link the SQM system with other systems within the organization. For example, during the Audit Management process (Figure 2) there is the possibility that a Supplier Corrective Action Request (SCAR), also known as Corrective Action/Preventive Action (CAPA), is generated as part of an On-site audit report when serious nonconformance are found. Therefore, the SM process could be linked with the CAPA system established in the organization as part of the QMS. In addition, 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. This is important because the risk established for a supplier is used to determine the Audit Type and Frequency which are input variables of the SM process. Furthermore, there is cost associated to the On-site audits which organizations want to keep to a minimum.

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