DEVELOPING AN EFFECTIVE SUPPLIER SCORECARD PROCESS TO MEASURE SUPPLIER PERFORMANCE FOR MEDICAL DEVICE COMPANIES

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ABSTRACT

Supplier performance scorecards have been introduced and used throughout organizations for decades, but they often vary with different weight measurements and performance metrics. Suppliers play an important role within organizations, and the collaboration that each organization has with its suppliers can promote cost savings, improved quality, and overall business relationship development. In recent years, Food and Drug Administration (FDA) regulations and International Organization for Standardization (ISO) standards for the medical device industry have placed an increased emphasis on purchasing controls, including supplier performance monitoring.

The FDA and ISO standards provide general minimum requirements organizations need to control, monitor, and measure. However, these organizations must determine how. There currently is no defined standard process for creating a supplier performance scorecard for organizations that are transitioning into this type of monitoring. Therefore, this study outlines a process for creating a supplier scorecard process to help medical device organizations properly monitor supplier performance while ensuring compliance with FDA/ISO regulations.

CHAPTER 1

INTRODUCTION

Background

Supplier Scorecards have become an important aspect of supplier performance management. At this point in time, many companies have already implemented supplier scorecards, or they want to use them to measure supplier performance. However, it can be difficult for medical device manufacturing companies that are satisfied with their scorecard process but still run into some common problems (Biedron, 2018). This is because organizations often focus on the components of the scorecards and the logistics it takes for implementation without taking into consideration the effectiveness of the scorecard. There are a few reasons why some supplier scorecard processes have failed in the past and for some of the challenges that organizations have faced (Busch, 2009). Some of these challenges occur when organizations are in the process of transitioning into a scorecard process, and, as a common practice, begin by borrowing metrics from other companies that are not appropriately relevant to the organization's business objectives and priorities. While it may be beneficial for an organization to learn from scorecards of other organizations in similar industries, this method typically fails when the organization cannot gather the raw data to complete those metric calculations.

Other issues with key performance indicators that organizations face occur when easily measured key performance indicators are chosen rather than key performance indicators that are important to the organization. This situation results when organizations

develop a list of meaningful metrics and key performance indicators are chosen, but there is not enough raw data available to measure them. This may cause an organization to adjust their metrics and key performance indicators to deploy different and less meaningful ones. In addition, some organizations track too many key performance indicators or choose indicators that are confusing or have no meaning to suppliers. Having too many key indicators can cause the supplier scorecard to be convoluted and not provide an effective way to measure overall supplier performance.

Supplier Scorecards also fail when the metrics are not actionable, meaning that the metrics do not help expose the root cause of performance issues. This makes it difficult for the supplier to make corrective actions that drive improvements, which defeats the purpose of the supplier scorecard. In addition, some scorecards fail when there are no follow-ups or corrective actions after the scorecards are issued. Some examples of the post-scorecard actions or follow-ups include supplier recognitions, awards, disengagements, or corrective action follow-ups. These post-scorecard actions show the supplier that there are positive or negative consequences resulting from their performance ratings.

Within the past decade, supplier scorecards have become an important supplement that can help medical device organizations maintain compliance with industry regulations and standards. Standards now require supplier performance monitoring, but do not specify how it must be monitored. Examples of these are standards and regulations set out by the Food and Drug Administration (FDA) and the International Organization for Standardization (ISO) for medical devices. Maintaining compliance

with these regulations and standards helps ensure that organizations can manufacture medical devices safely and effectively according to industry requirements.

The ISO has developed an international standard for medical devices that is called Medical Device—Quality Management Systems—Requirements for Regulatory Purposes (ISO 13485:2016). This standard outlines the requirements for medical device organizations and their quality management systems. ISO 13485:2016 is based upon ISO 9001:2015, which is the international standard for Quality Management Systems—Requirements. The relationship of ISO 13485:2016 with ISO 9001:2015 is that ISO 9001:2015 is a core quality management system standard that can provide organizational benefits such as improved internal communication and a better understanding and control of the organization's processes. Although a company may be in compliance with ISO 9001:2015, it does not guarantee that the organization is in compliance with ISO 13485:2016 and vice versa.

Within ISO 13485:2016, purchasing controls for the organization are covered, stating that each organization is required to have an established criterion for the evaluation and selection of suppliers. This established criterion should be based on:

- The supplier's ability to provide product/services that meet the organization's requirements;
- Supplier performance;
- Effect of the purchased product/service on the quality of the Medical Device; and
- Criteria for evaluation/selection will be proportionate to the risk associated with the medical device's fit, form, function.

After the initial supplier selection and evaluation process requirements, ISO 13485:2016 outlines requirements for measurement, analysis and improvement. Within this section of the standard the following areas are outlined:

- Complaint handling.
- Auditing, requirements for monitoring and measurement of processes and products.
- Control of nonconforming product.
- Data analysis.
- Improvements.

The requirements outlined in this standard are all applicable to outsourced products, which includes suppliers. Therefore, it is important for organizations to have a process for monitoring their suppliers' performances and capabilities to meet their requirements for purchased components, products, or services. The records and results of the initial supplier evaluation, selection, monitoring, and re-evaluation of each supplier's performance and any necessary actions arising from this process should be maintained by the medical device organization. The requirements of ISO 13485:2016 can also be used by suppliers or other external parties who provide products for medical device organizations—such as raw materials, components, maintenance services, and sterilization services. Purchasing verification activities and requirements along with notifications of changes in purchased products are also a requirement to meet ISO 13485:2016 now. This is a significant change from the previous revisions of ISO 13485:2003 and EN ISO 13485:2012, as there is now an increased focus on supplier sourcing, selection, and monitoring.

Although ISO 13485:2016 is the standard that is internationally agreed upon and defines the general requirements for quality systems for medical device companies, it is not a set requirement for medical device companies. However, the standard does define ways to address quality management system concepts, specifically for medical device companies; and when these medical device companies are able to meet the requirements for this ISO certification, the likelihood that a medical device company can meet customer and regulatory requirements is improved.

In parallel with the ISO standard, the FDA Code of Federal Regulations for Quality System Regulation for Medical Devices (21 CFR 820) also exists but, in contrast, is the law and requirement for all medical device companies manufacturing and selling products within the United States (U.S.). Although 21 CFR 820 still only broadly outlines the requirements for compliance, the FDA has increased its focus on supplier management within the past several years. This allows for flexibility within different medical device organizations to determine how they can best implement supplier management programs that meet the requirements.

According to 21 CFR 820.50 for Purchasing Controls, each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as follows:

- Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements—including quality requirements—that must be met by suppliers, contractors, and consultants. Each manufacturer shall:
    - Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including

quality requirements. The evaluation shall be documented.

- Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
- Establish and maintain records of acceptable suppliers, contractors, and consultants.

Based on the requirements outlined by 21 CFR 820.50, supplier selection and evaluation must be documented. Then, based on the evaluation, the type of control to be exercised with the supplier must be properly maintained. Suppliers play an important role in medical device companies and are typically managed by supplier management or supplier development programs. Because of the critical role that suppliers play in the design and manufacture of medical devices and their direct effect on medical device quality management systems, it becomes pertinent to appropriately monitor and measure supplier performance for critical suppliers. Supplier quality management programs have begun to sprout up among many different organizations. The ultimate end-goal of a supplier management and development program is to build an organization's relationship with its suppliers, where both parties can share a vision and commitment to continuous improvement in a mutually beneficial buyer-supplier relationship. These supplier quality management programs are designed not only to manage suppliers, but they also are to promote the development and improvement of suppliers by creating a strategic way to increase quality, reliability, and efficiency. Supplier Quality Management and Development programs often consist of the five lifecycle steps, shown as a general overview in Figure 1:

1. Supplier Selection

2. Supplier Evaluation
3. Supplier Performance Monitoring
4. Supplier Assessment
5. Supplier Quality Development

Figure 1. General supplier quality management process with emphasis on supplier performance monitoring. Adapted from "Measuring the Performance of Suppliers," by P.M. Simpson, J.A. Siguaw, and S.C. White, *Journal of Supply Chain Management* (p. 29-41), 2002; and from "Supplier Quality Development: A review of literature and industry practices," by Noshad and Awasthi, *International Journal of Production Research* (p. 466-487), 2015.

This thesis focused solely on the Supplier Performance Monitoring phase (as shown in Figure 1). This phase of supplier quality management and development programs was important because it ensured that even after suppliers had been selected and evaluated initially, they were able to maintain their overall performance to meet the organization's requirements and expectations.

Statement of The Problem

Supplier performance management is a complicated process that attempts at effectively integrating the interests of multiple working groups and companies into consistently delivering a safe and reliable product. This provides the space for inconsistencies to occur.

The focal point of the research for this thesis was on the many different components involved in supplier performance monitoring, and—due to the complexity of different medical device organizations—the many different factors involved. These factors included supplier types, key performance indicator options, raw data availability, and management pressure for delivery commitments. Some problems that might arise due to these complexities were seen in various supplier performance measurement or monitoring programs when the measurements chosen were too difficult to calculate or explain and when there were too many measurements or factors used. This made the overall calculation and measurement hard to calculate, understand, or explain—leading to a convoluted supplier performance measuring program that did not add value to the business relationship or overall supplier development process.

Supplier Performance Measurements

In addition, many large organizations have upper level management acknowledge the benefits that can result from monitoring supplier performance, which leads them to identifying the requirement for a supplier performance measurement program. Supplier performance measurement programs often lean toward the use of supplier scorecards as a form of documentation for supplier performance. Upper level management then reviews criteria that are believed to be critical for effectively measuring supplier performance and the key performance indicators that they would like to see reported for review on a monthly or quarterly basis. These decisions are often made by upper level management without knowing if the organization has the tracking programs or resources that could easily pull the key performance indicators that are being requested.

Lack of Raw Data

At times, the raw data is not readily available to even measure or calculate the chosen key performance indicators. This leaves those downstream in the organization with the task of attempting to gather raw data for the measurements and calculations when that information is not readily available or reliable—leading to scorecards with information that might not add value to the purpose of the supplier scorecard.

Supplier Numbers

Another issue identified is when there is a large number of suppliers, and it is necessary to determine which suppliers require scorecards based on their risk, cost, and value to the organization (buyer). These are important factors when determining which suppliers to evaluate to this extent. An example of a supplier type that may not require

supplier scorecards can be in cases where low-risk suppliers have low-cost products, seldom receive orders, and have little buyer-supplier interaction (such as distributors). Distributors of off-the-shelf products typically don't have many quality issues, for they don't manage manufacturing processes or have control of manufacturing processes. Therefore, visibility with these suppliers often have little to no value to an organization where a supplier scorecard is created, for their ratings almost always reflect full marks. This means that there must be a process in place to determine the criticality level of the supplier in relation to the medical device organization, and, based on the supplier criticality, it can determine if the creation of a supplier scorecard is required.

Purpose of the Study

The purpose of this study was to provide recommendations for an effective supplier performance monitoring scorecard process that could be used within the medical device industry where there was an emphasis on quality, while still incorporating other valuable aspects of delivery, and business partnership and continuity. This was intended to define a detailed process for medical device organizations to develop a supplier scorecard, where the components of the supplier scorecard could be customized in a step-by-step process to create a finalized supplier scorecard. The final scorecard should be able to assist with identifying critical criteria that would be valuable for each individual medical device organization. It could help medical device organizations that would like to adapt a supplier scorecard method for supplier performance measurement that would be easily quantifiable and understood by both the buyer and the supplier.

This thesis focused on the creation process of building and implementing an effective supplier performance monitoring and measurement scorecard that could comply with ISO standards and FDA regulations in relation to supplier performance monitoring. The scorecard to be created would be an overall summary supplier scorecard that would provide a comprehensive overview of the supplier's performance with regard to the organization's business priorities. A valuable overall performance rating would then help the buyer and supplier identify and understand areas of weakness and underperformance at the supplier level along with what actions that could be taken to continually drive the supplier's improvements. These improvements would eventually result in process improvements, technology updates, increased industry competitiveness, potential annual cost savings, and an overall stronger buyer-supplier relationship.

Theoretical Bases for The Study

The theoretical basis for this study was based on using a Balanced Business Scorecard and applying it to external suppliers to create a supplier scorecard. The supplier scorecard would be based on the four most common supplier key performance indicator categories, along with an optional additional category for service. These main focus categories are: Quality, Cost, Delivery, and Service. The theoretical basis for this study would also be based on the requirements listed in the international standard for Medical devices—Quality Management Systems—Requirements for Regulatory Purposes (ISO 13485:2016) and the FDA's Code of Federal Regulations for Quality System Regulation for Medical Devices (21 CFR 820). These standards and regulations formed the basis for this study and were important because they provided the bare

minimum requirements for compliance with medical device industry standards and regulations. This study would help provide a method for documenting the supplier maintenance and performance monitoring process for meeting those requirements.

Limitations of the Study

Although there were many different inputs within the supplier's management process lifecycle that feed into the supplier's performance monitoring phase, this study was limited to the monitoring and measurement of supplier performance. This study only attempted to guide medical devices companies that did not already have a set supplier performance monitoring process in place and were looking to find an effective way for documenting their basic supplier performance monitoring activities. In addition, the organizations for which this study would be best applicable were those organizations that already had defined processes in place for the initial supplier selection and supplier evaluation phases of the supplier quality management lifecycle. This was because organizations typically chose to monitor suppliers differently, based on the supplier's criticality or risk categorization.

Necessary Risk-based Approach

Prior to attempting to implement a supplier performance monitoring process using a supplier scorecard documentation method, medical device organizations should already have a risk-based approach in place to appropriately classify the risk of their suppliers and categorize them on their approved supplier list (ASL). This would occur during the initial supplier selection and supplier evaluation phase of the supplier management lifecycle. The organization's risk classification or categorization of their suppliers might

then act as an input to determine which suppliers they would choose to require a supplier scorecard as a form of supplier performance monitoring documentation. This study was limited to these types of organizations, because organizations with the initial supplier selection and supplier evaluation phases of the supplier quality management lifecycle already in place indicated that they were mature enough to begin implementing a supplier performance monitoring process. This was also an indicator that the medical device organizations in scope had the initial supplier processes in place, allowing them the means and capability to gather the raw data required for choosing key performance indicators and calculations. There were also many different organizations with exemplary supplier performance monitoring programs and supplier scorecards, where unfortunately this study was limited due to business confidentiality agreements. Therefore, the research involved in this study was confined to information and supplier scorecard examples from businesses that had information readily available for the public.

This study was also only limited to guiding organizations on the different types of key performance indicator options that could be chosen for each key performance indicator category (Quality, Cost, Delivery, and Service). The scorecard process proposed would not incorporate all possible key performance indicator calculations, and the calculations provided would only be general examples and potential options that attempted to account for business variability, such as raw data management systems and data collection methods within different organizations. This study would also be limited to (1) helping organizations choose an overall rating system for these key performance

indicator measurements and (2) providing a general layout for documenting a supplier scorecard that could be altered, based on the organization's business priorities and needs.

Definition of Terms

Component: Any raw material, substance, piece, part, software, firmware, labeling or assembly that is intended to be included as part of the finished, packaged, and labeled device.

Corrective Action Reports (CARs): A corrective Action Report issued to suppliers when defects or issues are identified.

Corrective and Preventative Action (CAPA): A corrective action and preventive action system used to identify the root cause of an existing or potential nonconformity, defect, or other undesirable situation to correct and prevent occurrence or recurrence.

Design Validation: This validation establishes through objective evidence that device specifications conform to user needs and intended use(s).

Device Master Record (DMR): This is a compilation of records containing the procedures and specifications for a finished device.

Direct Suppliers: Suppliers that provide materials that are used in the production of a final product—such as raw materials, packaging, components and parts that affect the value of the finished product.

Field Action: Any recall, market withdrawal, stock recovery, safety alert, correction, product removal, or field action.

Gage Repeatability and Reproducibility (GR&R or GRR): A statistical measure for analyzing how much variation exists in a gauge, measurement, or test equipment.

Indirect Suppliers: Suppliers that provide goods and services ranging from standardized items—that may include lab equipment, office supplies, one-time purchases, maintenance and repair operations, and calibration services—to consulting services and information technology.

ISO 13485: The International Organization for Standardization (ISO) standard for Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes. This standard outlines requirements for a quality management system for the design and manufacture of medical devices.

Key Performance Indicators (KPIs): Criteria used to measure the supplier's performance.

Lot or Batch: One or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Manufacturer: This refers to any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

Nonconforming Product: The nonfulfillment of a specified requirement. A product or material that does not meet specified requirements, such as:

1. Material built to an incorrect configuration.
2. Material built with non-validated process parameters or material processes outside of approved parameters.

3. Material built with unapproved components, counterfeit components, or components not meeting specifications.

OEM Supplier: A supplier that manufactures medical finished devices used and/or sold by Medtronic, in which the supplier holds legal title, design, manufacturing, and regulatory responsibility.

Purchase Price Variance (PPV): The difference between actual price paid to purchase an item and its standard price, multiplied by the number of units purchased.

Product: Components, manufacturing materials, in- process devices, finished devices, and returned devices.

Quality: This refers to the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

Quality Audit: This refers to a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

Quality Policy: The overall intentions and direction of an organization with respect to quality as established by management with executive responsibility.

Quality System: This includes the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Rework: Action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

Specification: Any requirement with which a product, process, service, or other activity must conform.

Supplier: A provider of products or services to an organization (customer).

Supplier Owned Quality: A term used to describe the various levels of maturity in our Suppliers Quality Management system for conducting inspections, monitoring and acting on performance trends, and ensuring stable and predictable Product performance.

Validation: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. Process validation means establishing by objective evidence that a process consistently produces a result or product, meeting its predetermined specifications.

Verification: The means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

CHAPTER 2

LITERATURE REVIEW

Many articles, books, and references were reviewed in order to: (1) learn and understand what the requirements were for supplier performance monitoring within medical device organizations and (2) see what types of current supplier performance monitoring programs were currently being used throughout different organizations, how they were being used, and which were best practices.

The FDA website (http://www.fda.gov/) and the ISO Standard website (https://www.iso.org/standard/59752.html) were both reviewed and referenced throughout this paper in order to understand the requirements for purchasing controls and supplier performance monitoring. These standards and regulations provided a foundation for this study because they drove medical device organizations to define a process for supplier performance monitoring and a method for documenting the activities. Creating a supplier scorecard for measuring supplier performance could help them maintain compliance with regulatory requirements.

Dror (2008) provided great insight into the advantages of using the balanced scorecard with two levels of feedback, which enabled controlling and updating the long-term programs to continually make improvements. Information provided in this article also assisted in outlining the limitations or disadvantages that come with using the balanced scorecard. These included simultaneous and complex feedback from the

financial perspective to the customer and the processes, along with time lag between the cause and effect.

Another book that was beneficial in the development of this thesis was *The Balanced Scorecard: Translating Strategy into Action*, by Kaplan and Norton (1996). This book focused on information regarding the importance of an organization's vision and strategy the balanced scorecard covers and translating them into a coherent set of performance measures. This book covered: (1) theoretical foundations of the standard balanced scorecard, (2) steps organizations must take in order to build their own scorecards, and (3) how those scorecards can be used in order to drive changes and process improvements—which is the basis of this thesis. The measures and measurement criteria that this book uses were referenced throughout the Methodology section of this thesis.

Le Dain, Calvi, and Cheriti (2011) provided an additional source that gave great insight into the overall product lifecycle and how the supplier played an important role throughout the entire product's lifecycle. This article showed informative results with a method for measuring supplier performance in collaboration with new product development. Le Dain et al. (2011) also covered the important difference between the supplier selection (before) process and supplier performance (during and after) criteria. In addition, this article covered supplier capability related to: (1) what was measured during the supplier selection process and (2) the evaluation that came with the supplier's results when they are able to meet the appropriately defined criteria and achieve customer specifications and performance objectives.

In "The Effects of SRM Capability on Supply Management Performance," Lintukangas and Kahkonen (2010) discussed supply management basics and how it was divided into two primary components: efficiency and effectiveness. In this article, efficiency addressed the input-output perspective, based on optimizing volume and capability. The effectiveness side addressed performance based on planned outcomes, which were determined by inventory, quality, supplier development, logistics, delivery reliability, and price. The focus of this article was to determine if supplier relationship management capability had a positive relationship with supply management performance monitoring. This article concluded that the greater the supplier relationship management capability, the more positive effects were reflected in the measured performance. This meant firms that were more thoroughly monitoring and measuring their supplier performance showed more positive results. These positive results included supplier relationship opportunities that had opened doors to an increased ability to develop diversified performance measures (not just based on financial and supply-based measures). Lintukangas and Kahkonen (2010) confirmed the importance of monitoring supplier performance and how an increase in supplier relationship management had a positive correlation with supplier performance and helped increase supplier capabilities. By measuring and monitoring supplier performance, areas of weakness by the supplier could be identified, and continuous process improvements, communication, delivery, etc. were driven.

In *A Review of Sustainable Supply Chain Management Practices in Canada*, Morali and Searcy (2013) provided a general overview of supply chain management

activities. There were many different supplier standards and performance monitoring areas covered. For example, three key themes were focused on for supplier standards, which were: codes of business conduct, product/process-related certifications, and management systems and initiatives. The article stated that only 33% of the companies examined reported on a supplier management monitoring system. The sources showed that the method of monitoring used for those 33% varied greatly and included methods such as CSR audits, social impact assessments, site inspections, etc. The information provided by this article helped contribute to the thesis since it helped identify possible sources where supplier performance measurement data sources can come from, and the various methods to measure them.

In "A Multi-Criteria Group Decision Making Model for Supplier Rating," Muralidharan, Anantharaman, and Deshmukh (2002) identified different mathematical programming models for assessing suppliers. The different models covered for evaluating supplier performance were Linear Programming (LP), Mixed-Integer Programming (MIP), Goal Programming (GP), and Multi-Objective Programming (MOP). These models were more important for evaluating suppliers prior to committing to business with them, based on quality and delivery. This was important because it explained how suppliers could be broken into different groups, based on their initial evaluation of suppliers. This could be a risk-based approach that could help organizations quantitively assess their suppliers. Especially for large organizations with many different suppliers, it provided a way to determine the impact and criticality of a supplier on the business. This later played a role in how they were rated in supplier performance monitoring processes.

As shown by Noshad and Awasthi (2015), a focus on Supplier Quality Development provided information that assisted with the structure of supplier quality management and development. It was broken down into two main processes: Quality Measurement and Quality Development. Quality Measurement involved the following activities: supplier quality evaluation, supplier quality certification/qualification, supplier quality performance measurement, and measuring and tracking the cost of poor supplier quality. The criteria for supplier quality evaluation were also listed with different attributes and divided into four main criteria: Product Quality, Service Quality, Process Quality, and Organizational Quality. This paper was helpful in covering supplier quality performance measurement (SQPM) as an important step in supplier quality development. As a basis for this paper and the supplier scorecard process, Noshad and Awasthi (2015) defined and outlined performance measurement as an important baseline for driving improvements with suppliers by measuring the quality, cost, delivery, health, safety, and environmental aspects of the supplier performance. This tied back to the purpose of this study because it helped outline necessary supplier performance monitoring criteria and its role in supplier quality development. The core of this paper was also based on the main components of the supplier scorecard end result.

In Quality Management and a Balanced Scorecard by Pimentel and Major (2014) assisted with the organization and basis of this thesis by providing supporting frameworks for a new management model that incorporated organizational change. Discussions by Pimentel and Major (2014) regarding Total Quality Management (TQM) highlighted how a balanced scorecard helped organizations successfully respond

to regulatory demands by measuring their performance (starting as a baseline) and then monitoring improvements or areas of weakness by using a balanced scorecard. The idea of a balanced scorecard was then applied to a supplier performance measurement rather than just an internal business performance measurement.

In "Measuring the Performance of Suppliers: An Analysis of Evaluation Processes," Simpson, Siguaw, and White (2002) covered how different organizations chose to routinely evaluate their suppliers and often had issues determining the design and content that would be used to evaluate supplier performance. Simpson et al. coded each line item listed (approximately 2,278 items) into 19 different categories, and the different categories evaluated the importance of each category (2002). The categories identified as the evaluation categories receiving the most attention were: Quality and Process Control, Continuous Improvement/R&D/Innovation, Facility Environment, Customer Relationship and Communication, Delivery, Inventory and Warehousing, Ordering, and Financial Condition and Size. This study outlined key considerations in the supplier evaluation process that could be applied to developing a well-rounded supplier performance scorecard based on quality, physical distribution, delivery, etc.

Solano, de Ovalles, Rojas, Padua, and Morales (2003) covered the BSC (Balanced Score Card) systematic model that translated the organization's vision and strategy into specific strategic objectives—monitored through a coherent set of performance indicators (criteria). By using the BSC, there could be a balance between the business objectives by using easily quantifiable measurements or indicators. This article then covered a process for creating a BSC aimed at the integration of systemic quality. This was applicable for

the overall purpose of the thesis, for the thesis was attempting to explore an effective way to create a balanced supplier scorecard to effectively measure supplier performance.

In "The Intersection of Power, Trust and Supplier Network Size: Implications for Supplier Performance," Terpend and Ashenbaum (2012) provided background on supplier network sizes and how buyer-supplier relationships were affected differently, based on supplier-network sizes. The different levels of supplier sample sizes were categorized into "single-supplier," "few-suppliers," and "multiple-suppliers" groupings. Next, the buyer (customer) relationship with these different supplier size categories were examined to see how the relationships differed in terms of power and trust—and then see how that information fed into the overall supplier relationship and performance. Expanding the size of a given organization's input (i.e., dual-sourcing suppliers, rather than relying on one sole-source supplier) could reduce the risks associated with having a sole-source supplier for the buyer. However, that reduced supply network could weaken the relationship between the individual buyer and supplier—If the supplier network had remained as a "single-supplier" relationship.

Supplier performance measurements are different for every organization, and thus the relationships between the buyer and supplier can vary greatly, based on the size of the "supplier network." By understanding how the size of the supplier network can impact the buyer and supplier relationship and overall supplier performance, it can help determine, based on size, what type of supplier quality metrics and supplier scorecard weights might be best for measuring a supplier's performance.

CHAPTER 3

METHODOLOGY

Design of the Investigation

The study for this thesis was formulated to investigate (1) what the medical device industry standards and requirements were for purchasing controls, supplier controls, and performance monitoring and (2) how organizations could effectively create a process to document these activities. The key performance indicators were an important aspect of performance monitoring that an organization could use as metrics to measure and effectively monitor supplier performance. It aimed to identify a process for identifying and creating key performance indicators that were valuable, quantifiable, easily understood, and aligned with business objectives.

The first phase of this study was to summarize the medical device industry standards and requirements. Summarizing the criteria outlined in the supplier controls and performance monitoring sections of the standards ensured that the scorecard process created would have at least the minimum requirements to be in compliance with the standards. These minimum requirements could then be taken into consideration during the scorecard creation process.

The second phase of this study was to review the four different supplier scorecards that were shown to be historically effective when implemented in both the medical device and aerospace industries. The four supplier scorecards chosen for review were from the following companies: Northrop Grunman, Boeing, Honeywell, and Abbott.

The key performance indicators and scorecard layout and process were individually reviewed for each of these companies. The aerospace industry was specifically reviewed because they had historically been identified for implementing successful supplier management programs that included supplier performance development practices beneficial for supplier performance monitoring (Noshad and Awasthi, 2015; Murphy, 2007). The review of each of the scorecards consisted of an overview and explanation of the different components of the scorecard. This included scorecard inputs, key performance indicators used, frequency of scorecard distribution, and overall scorecard rating scale. An analysis of each of the individual scorecards was reviewed for the identification of best practices.

The last phase of the scorecard review was a comparison of the analysis of each of the four scorecards and combined best practices. The scorecard process was outlined and defined using the best practices from each of the scorecard components identified. In addition, the process incorporated the minimum supplier control/purchasing control requirements outlined by the FDA and ISO Standards (as showed in Table 1).

Data Analysis Procedures

As previously mentioned, the purchasing control sections from ISO 13485:2016 and 21 CFR 820 have been identified. These were the basis for the minimum requirements for compliance that should be incorporated into the supplier performance monitoring process. Since the supplier scorecard was the method chosen for documenting and reflecting supplier performance, it was important to identify how the scorecard could effectively be used for a medical device organization to maintain compliance.

Table 1

Supplier Performance Regulations and Standards

Regulation	Clause/Section	Requirement
FDA 21 CFR 820	820.50 Purchasing Controls	a) Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall: 1. Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented. 2. Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results. 3. Establish and maintain records of acceptable suppliers, contractors, and consultants.
ISO 13485:2016	7.4.1 Purchasing Process	The organization shall document procedures to ensure that a purchased product conforms to specified purchasing information. The organization shall establish criteria for the evaluation and selection of suppliers, based on: a) The supplier's ability to provide product that meets the organization's requirements; b) The performance of the supplier; c) The effect of the purchased product on the quality of the medical device; and d) Whether it is proportionate to the risk associated with the medical device. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide input into the supplier re-evaluation process.

Table Continued

	Non-fulfillment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained.

Note. Adapted from "ISO Standard No. 13485:2016," by the International Organization for Standardization (ISO), 2016 (http://www.iso.org/); and from "21 Code of Federal Regulations Title 21" by The Food and Drug Administration (FDA), 2018.

Based on these two ISO and FDA industry standards and requirements, the following criteria were chosen to be required components to take into consideration during the supplier scorecard creation process:

- Risk: Determine extent of control to be exercised over the supplier-provided product, services, contractors, and consultants proportionate to the risk associated with the medical device and overall business impact.
- Quality: Supplier's ability to meet requirements of the product purchased.
- Performance Criteria: Organization to determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers—based on their ability to provide processes or products and services in accordance with requirements.
- Frequency: When the monitoring and measuring shall be performed and when the results from monitoring and measurement shall be analyzed and evaluated.
- Documentation: Requirement of organization to maintain records of the results of supplier monitoring and re-evaluation of supplier capability or performance.

The data obtained from the second phase of the study during the review of the four supplier scorecards was analyzed by first understanding challenges that many

organizations faced, using the supplier scorecard method for performance monitoring. These challenges were broken down into four different categories and summarized as follows:

1. Key Stakeholders:
    a) When internal key stakeholders are not involved in initial conversations during the scorecard creation process, their input into important and measurable key performance indicators is not considered. This creates gaps in the raw data available for calculating metrics.
    b) If internal key stakeholders are not involved in the process, then the metrics chosen may not align with an organization's business objectives. Without management support, the scorecard results may not drive supplier performance improvements or allow for resources to be provided by management to even drive those improvements.
2. KPI's/Metrics:
    a) Challenges often associated with key performance indicators and metrics occur when organizations choose metrics that are easily measured rather than what is important to the business goals and objectives.
    b) Organizations may even choose metrics that are important to the business goals and objectives, but the raw data required to calculate the metrics may be unattainable or require too much data manipulation to produce.
    c) Organizations may track too many KPIs, causing the scorecard to be hard to understand and easily convoluted.
    d) The key performance indicators, calculations, and number of suppliers requiring scorecards may be too much or too complicated to complete—thereby causing a lack of resources to produce the scorecards.
3. Communication/Alignment:
    a) Challenges are presented when the suppliers are not aware or unclear regarding the expectations. Therefore, it is important that the

expectations are communicated.

b) Organizations may also choose metrics that are confusing to suppliers. Therefore, it is important that there is a key that identifies the key performance indicator, the definition or purpose for measuring that key performance indicator, and the metric calculation used. This helps ensure that the scorecard is easily understood and is able to provide valuable performance monitoring information for both the organization and supplier.

c) Another communication challenge is when scorecard results are created by an organization, but they are not shared with the supplier within a defined frequency. If supplier performance is measured and monitored by the organization and not shared with the supplier, the supplier may not be aware or given the opportunity to improve.

4. Actionability

a) Actionability relates to any post supplier scorecard actions or follow-up after scorecards are distributed. A reason why some scorecard processes fail can be attributed to the lack of rewards or recognitions for good performance and no consequences or corrective actions required for bad performance. With no positive or negative post supplier scorecard actions, the supplier scorecard loses its purpose.

b) A challenge that may occur is when key performance indicators or metrics chosen to measure are complicated and do not help identify performance weaknesses or problems. If the scorecard metric chosen does not help identify problems or root causes at the supplier level, then it makes it difficult for the supplier to implement any corrective actions. This prevents the supplier from continuous improvement and defeats the overall purpose of the supplier performance scorecard.

These supplier performance scorecard challenges also provided a basis for reviewing and analyzing the supplier scorecard processes from the four organizations chosen for the thesis. The process for analyzing the four scorecards was to be defined by highlighting the different components of each scorecard process based on the common criteria above. Strengths and potential weaknesses would be identified where applicable.

Best practices were pulled from each scorecard after analyzing and identifying the strengths and weakness for each of the four scorecards. The creation of a supplier performance scorecard process was defined, using the acquired knowledge from each of the reviewed scorecard processes, along with understanding the purchasing control requirements.

CHAPTER 4

RESULTS AND DISCUSSIONS

The supplier performance scorecard process that was reviewed first came from Northrop Grunman. Northrop Grunman, a dominant aerospace company, was being reviewed because it had been known to have a well-defined supplier performance monitoring process. Northrop Grunman utilized two different types of scorecards to monitor supplier performance. The first were SAP scorecards, which were generated to specifically support procurement (as shown in Figures 2, 3, and 4). The second type of scorecard was the Supplier Assessment Management System (SAMS) assessment, which was generated specifically for subcontract suppliers (as shown in Figure 5). The SAP scorecards and SAMS assessments were generally completed on a quarterly basis but could also be completed monthly depending on the type of SAMS assessment.

Each supplier from Northrop Grunman was assigned a Supplier Quality Field Engineer (QFE), who managed the SAP scorecard to ensure accuracy of the quality profile while also inputting the process health/lean/six sigma rating. The SAP scorecard received input from Supplier Quality and Procurement team members, as well as Buyers, who were responsible for reviewing and correcting the delivery and customer satisfaction metric portions of the scorecard. The SAP scorecard was comprised of the following focus areas and key performance indicators:

1. Quality (50 Points):
    - Hardware Acceptance Rating: 1—(Quantity of pieces rejected/ quantity of pieces received) x 100 based on previous twelve months of supplier history.
    - Level 1 Corrective Action Reports: Have no impact on Quality Score.
    - Level 2 Corrective Action Reports: Three (3) months of closed CARs and all CARs with open Corrective Actions.
    - Level 3 Corrective Action Reports: Will result in zero points for the Quality Score.
2. Late Delivery (30 Points):
    - Material received more than seven days late, based on the negotiated purchase order date, within the last twelve months.
    - Team Assessment Elements.
3. Customer Satisfaction (10 Points):
    - Responsiveness: Provides real time delivery status updates and communicates changes and cost schedule impacts.
    - Oversight: Oversight Required in the Areas of Quality, Technical, and Delivery Requirements.
    - Management: Displays Technical and Management Expertise Required to Identify and Implement Innovative Solutions to Issues.
4. Process Health and Lean and Six Sigma (10 Points):
    - Process Health: Mature Quality Management System—Corrective Action Processes.
    - Lean and Six Sigma: Embraces Continuous Process Improvement with Tools such as Lean and Six Sigma (Northrop Grunman, 2016).

Hardware Acceptance Rating (70% wt)			Level 2 CARs (30% wt)			Supplier Quality Profile		
100	(70)		0	(30)		100	=	Blue
99	(47)	+	1	(20)	=	67 to 99	=	Green
97 – 98	(24)		2	(10)		35 to 66	=	Yellow
0 - 96	(0)		3	(0)		< 35	=	Red

Figure 2. Northrop SAP scorecard quality profile rating key. Adapted from "Northrop Grunman Supplier Scorecard Guidelines," by T.N. Lewis and G. Manuel, 2016. Copyright 2016 by Northrop Grunman.

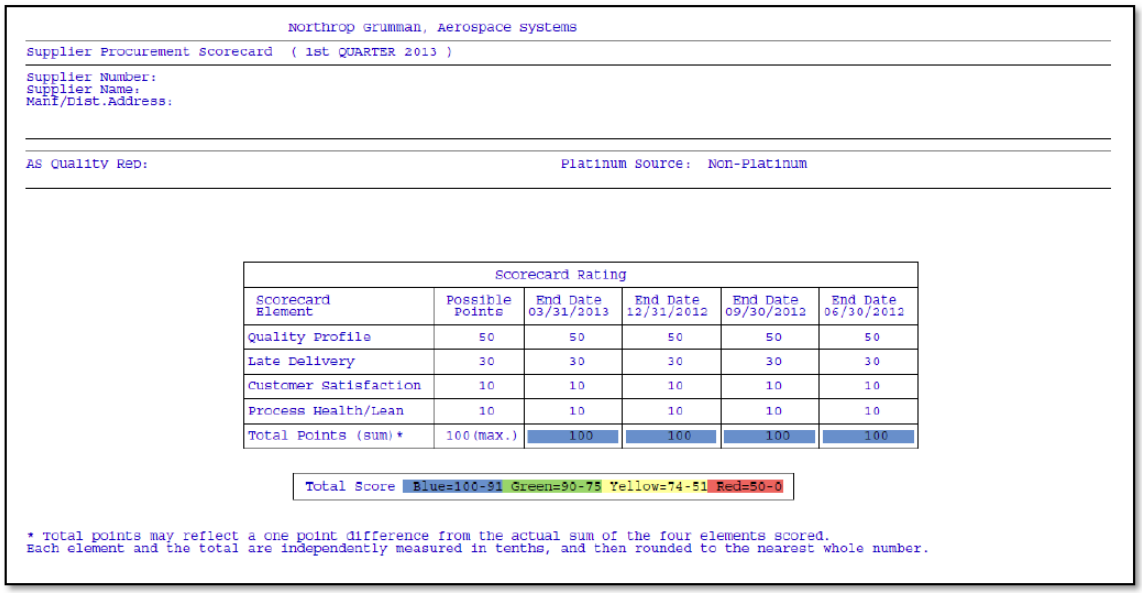
The overall performance rating score for the SAP scorecard was calculated by adding the quality score, late delivery score, customer satisfaction score, and process health score together for a total maximum of 100 points. The SAP scorecard broke down the overall rating by point value ranges and the following colors: red (unsatisfactory), yellow (marginal), green (satisfactory), or blue (excellent), as detailed in Figure 3.

Quality Profile Rating (See Figure 2)		Late Delivery (last 12 months) (PO Date > 7 days)		Customer Satisfaction	Process Health/Lean/ Six Sigma
Actual	Points	Actual	Points	Points	Points
100	50	0%	30	10	10
90	45	1%	27	9	9
80	40	2%	24	8	8
77	39	3%	21	7	7
70	35	4%	18	6	6
67	34	5%	15	5	5
57	29	6%	12	4	4
54	27	7%	9	3	3
47	24	8%	6	2	2
44	22	9%	3	1	1
34	17	> 9%	0	0	0
30	15				
20	10				
10	5				
0	0				

Supplier Scorecard Rating	
Blue	91-100
Green	75-90
Yellow	51-74
Red	0-50

Figure 3. Northrop SAP supplier scorecard key. Adapted from "Northrop Grunman Supplier Scorecard Guidelines," by T.N. Lewis and G. Manuel, 2016. Copyright 2016 by Northrop Grunman.

The SAP scorecard metrics were input manually into the SAP system, and the layout of the scorecard was generated and pulled from the SAP system. An example of the SAP scorecard template is provided in Figure 4.



Northrop Grumman, Aerospace Systems

Supplier Procurement Scorecard (1st QUARTER 2013)

Supplier Number:
Supplier Name:
Manf/Dist.Address:

AS Quality Rep: Platinum Source: Non-Platinum

Scorecard Rating					
Scorecard Element	Possible Points	End Date 03/31/2013	End Date 12/31/2012	End Date 09/30/2012	End Date 06/30/2012
Quality Profile	50	50	50	50	50
Late Delivery	30	30	30	30	30
Customer Satisfaction	10	10	10	10	10
Process Health/Lean	10	10	10	10	10
Total Points (sum)*	100(max.)	100	100	100	100

Total Score Blue=100-91 Green=90-75 Yellow=74-51 Red=50-0

* Total points may reflect a one point difference from the actual sum of the four elements scored.
Each element and the total are independently measured in tenths, and then rounded to the nearest whole number.

Figure 4. Northrop SAP supplier scorecard. Adapted from "Northrop Grunman Supplier Scorecard Guidelines," by T.N. Lewis and G. Manuel, 2016. Copyright 2016 by Northrop Grunman.

The second scorecard type that Northrop used was the SAMS scorecard. The scorecard acted as a supplement online database that could regularly assess the supplier's performance. The scorecard was completed by the Subcontract Management Team (SMT) that was comprised of different team members who were stakeholders that could provide accurate supplier performance details. The subcontract suppliers were split based on their impact on the organization (subcontract value/level of complexity of activities/program criticality). Based on these elements, it determined if a "quick"

assessment or "full" assessment was completed. The SAMS scorecard consisted of the following eight primary focus areas and key performance indicators:

1. Management
    - Management Responsiveness
    - Program Management
    - Risk and Opportunity (R/O) Management
    - Staffing
2. Technical
    - Product Performance
    - Systems Engineering
    - Software Engineering
    - Logistics and Sustainment
    - Part Material and Process
    - Service Level Performance
3. Schedule
    - Schedule
    - Schedule Performance Index
4. Cost (including: Financial Stability/Health)
    - Cost
    - Cost Performance Index
    - Financial Health

5. Proposal
    - Team Commitment
    - Proposal Strategy
    - Proposal Adequacy and Negotiation
6. Mission Assurance/ Quality
    - Quality
    - Process Effectiveness
7. Supply Chain Management (optional)
8. Customer Satisfaction (optional) (Northrop Grunman, 2016).

Each of the eight key performance indicators above is given a rating between one through four. The ratings were based on a color scale of red (1), yellow (2), green (3), or blue (4). Each of the four possible color ratings had detailed definitions for every key performance indicator with specific criteria for each color rating to act as a guide for categorizing the supplier's performance into red (1), yellow (2), green (3), or blue (4) ratings. To obtain the final overall supplier rating, the numbers associated with each color rating was then averaged for all eight key performance indicators.

NORTHROP GRUMMAN

Northrop Grumman Supplier Assessment Management System

SUPPLIER XYX

Program:	Program Name
Effective Date:	(Qtr) - (Year) (time period being evaluated
Average Score:	Automatically calculated in SAMS based on Average of all rated Sub - elements)

Assessment Subcontract Information:

Estimated Quarterly Expenditure	$xx.xxxM (format)	**Open Balance**	$xx.xxxM (format)
Funded Value	$xx.xxxM (format)	**EVMS**	Required/Not Required
CPI Value	0 - 1.00	**SPI Value**	0 - 1.00
Deliverables Received	# of Deliverables	**Deliverables Due for This Period**	# of Deliverables
Quality Deliverables Received	# of Deliverables	**On-Time Deliverables Received**	# of Deliverables
Acceptance Rate	0 - 100%	**Delivery Rate**	0 - 100%

Scorecard:

Color Grade	Category	Comments / Actions
	Management	
B	**Management Responsiveness**	Measured on the timeliness/completeness of problem identification and corrective action plans. supplier's history of resonable and cooperative behavior, and effective business relations
G	**Program Management**	Measured on the extent to which the suppler discharges it's responsibilitiy for integration and coordination of all activity needed to execute the subcontract purchase order, identifies and applies resources requred to meet schedule requirements; assigns reponsibility for tasks/actions required by the subcontract/purchase order, communicates appropriate information to affected program elements in a timely manner. integration and coordination of activites should reflect those required by the Integrated Master Plan Schedule

Figure 5. Northrop SAMS supplier scorecard example. Adapted from "Northrop Grunman Supplier Scorecard Guidelines," by T.N. Lewis and G. Manuel, 2016. Copyright 2016 by Northrop Grunman.

Table 2
Northrop Grunman Supplier Performance Rating Scale

Performance Level	Point Range	Definition
Blue	91 – 100	Excellent: Exceeds PO requirements; highly effective corrective actions. Scale: 4.00-3.76 total score.
Green	75 – 90	Satisfactory: Meets all PO requirements; satisfactory corrective actions. Scale: 3.75-2.76 total score.
Yellow	51 – 74	Marginal: Does not meet all PO requirements; recovery still possible; marginally effective corrective actions, not fully implemented. Scale: 2.75-2.0 total score.
Red	0 – 50	Unsatisfactory: Does not meet all PO requirements; recovery not likely; ineffective corrective actions. Scale: < 2.0 total score or any score containing 1 red in any subcategory

Note. Adapted from "Northrop Grunman Supplier Scorecard Guidelines," by T.N. Lewis and G. Manuel, 2016. Copyright 2016 by Northrop Grunman..

Some potential weaknesses that Northrop's supplier performance scorecard might be that the SAMS assessments were completed by individual Purchase Order (PO) number. This would mean that each vendor site could possibly or mostly likely have multiple assessments if it was only generated monthly or quarterly. One weakness or drawback of this method would be that it was common for quantities of material from a specific supplier to often be placed on multiple purchase orders, indicating that over one business quarter, there might be many scorecards for one supplier, resulting in an information overload. With this type of scenario, the scorecard could become too convoluted and would not provide a clear high level overall supplier rating. The reason that this method was not preferred was because gathering the information for each supplier for every purchase order could be an overkill for some companies—unless an automated system was already in place where the metrics were already readily available.

As previously mentioned, one of the reasons why some supplier scorecard processes fail was due to the amount of time and resources it would take to accurately obtain the metrics for the scorecards.

Northrop's supplier performance scorecard also could include a number of strengths. Although the SAMS assessments were completed by individual purchase order, this type of scorecard might also be valuable because it was granular by being able to look at each individual purchase order. Overall, for the amount of detail for each key performance indicator description, Northrop Grunman had a very clear and concise process for supplier performance monitoring scorecards. Since the supplier had two supplier scorecard types that catered to specific areas of the organization and defined why the chosen KPIs were measured, it could be stated that this method created value to the organization. Northrop's supplier performance program was advanced enough where they had broken down the SAMS scorecard into the quick and full assessment—based on the supplier subcontract value, level of complexity of activities, and program criticality. This was considered a strength because it allowed suppliers to be assessed based on their impact to the organization. By doing so, it ensured that internal resources were not being stretched to create detailed scorecards for suppliers that did not require that level of performance monitoring. In addition, from the information provided, the supplier scorecard rating had post scorecard actions or follow up. For example, a supplier with a good performance rating was the main criteria for Northrop's Platinum Source Certification program. This was their program for fostering supplier relationships by recognizing and rewarding suppliers.

Boeing was the next aerospace supplier performance monitoring process reviewed. Boeing used what was called the Boeing Enterprise Supplier Tool (BEST) that was created, based on the Enterprise Supplier Performance Measurement (ESPM) system. As of December 1, 2005, Boeing transitioned from using their Supplier Performance Measurement System to the Boeing Enterprise Supplier Tool (Boeing, 2005). The tool was online and an interactive website that was used to store all enterprise supplier data, which included supplier addresses, contact names, payment and diversity reports, corporate agreements and other data analytics. With this system, Boeing also introduced options to categorize suppliers into four distinct business model categories. These categories were production, development, support services, and shared services. The supplier's performance was measured with an overall supplier score or 'composite rating,' based on the following key performance indicators:

1. Quality
    a. Acceptance Percentage
    b. Received Quantity
    c. Rejected Quantity
2. Delivery
    a. Scheduled Quantity
    b. On-Time Quantity
    c. On-Time Percentage
3. General Performance Assessment
    a. Developmental

b. Production

c. Support Services

d. Shared Services

The online tool allowed suppliers to view the scorecard and individually click into each main key performance indicator in the online database to see a breakdown with more details. For example, the Quality section could be clicked on, and the details for part numbers and nonconformance documents would appear. The list of nonconformance document numbers could also be clicked on for an even further breakdown (see Figure 6 to view the nonconformance report details).

All of the data was updated monthly, and the supplier could access the report once having logged onto the BEST online tool system through the Boeing Supplier site. The overall supplier performance rating scale for Boeing fell under five different categories (as defined in Figure 7 and Table 3).

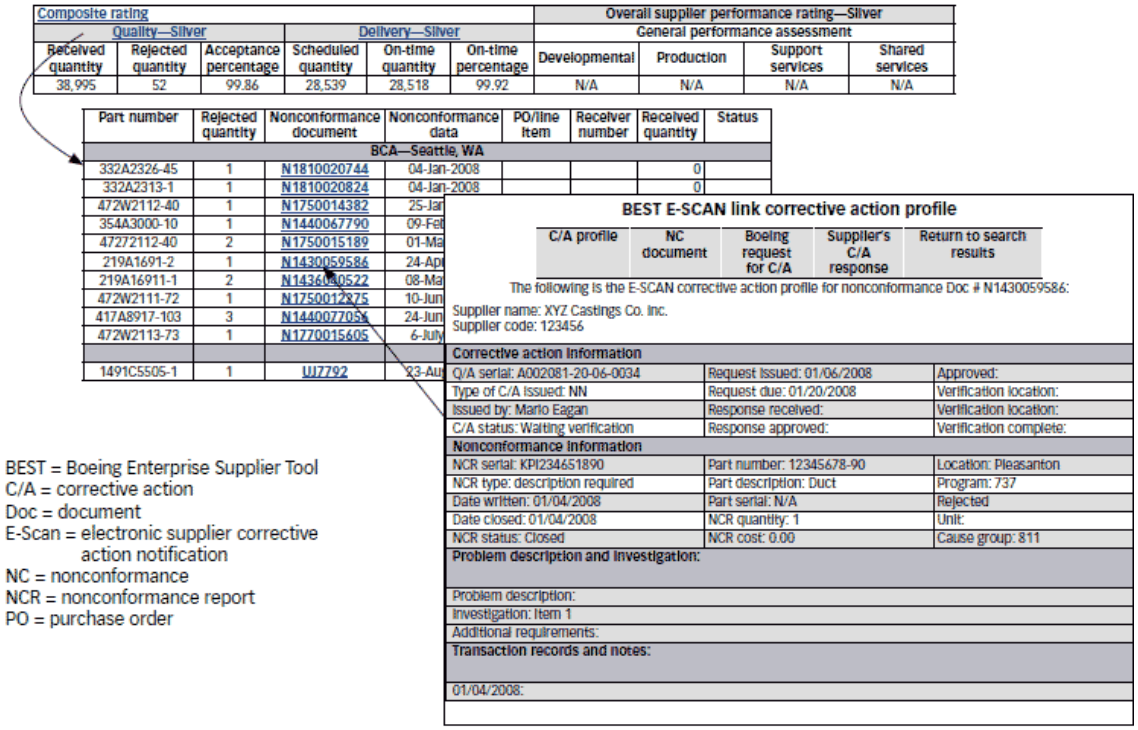


Figure 6. Boeing quality exception report example. Adapted from "Boeing's Supplier Performance Measurement Rating System" by Boeing, 2012.

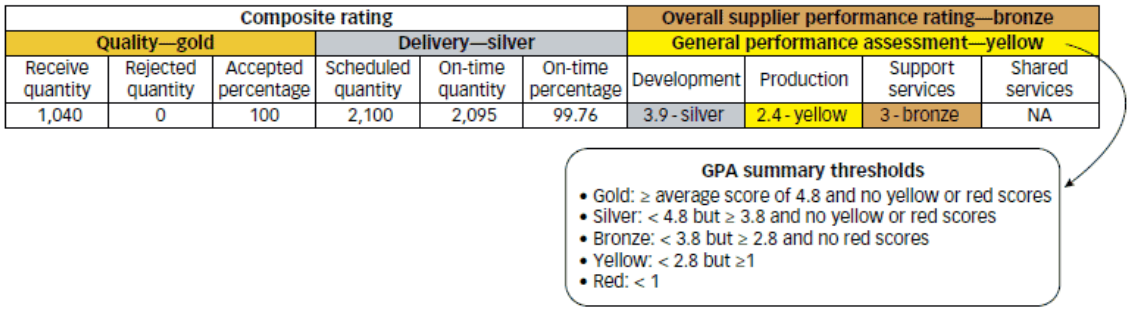


Figure 7. Boeing performance calculator example. Adapted from "Boeing's Supplier Performance Measurement Rating System" by Boeing, 2012.

Table 3

Boeing's Supplier Performance Rating Scale

Performance Level	GPA Threshold	Definition
Gold	4.8 – 5.0	Exceptional supplier performance, clearly exceeding expectations. Delivery and quality performance are 100% for 12-month period. GPA is 4.8 or above with no yellow or red ratings.
Silver	3.8 – 4.7	Very good supplier performance, meeting or exceeding expectations. Delivery performance is 98% and quality performance is 99.8% for 12-month period. GPA is less than 4.8 but greater than or equal to 3.8 with no yellow or red ratings.
Bronze	2.8 – 3.7	Satisfactory supplier performance, meeting expectations. Delivery performance is 96% and quality performance is 99.55% for 12-month period. GPA is less than 3.8 but greater than or equal to 2.8 with no yellow or red ratings.
Yellow	1.0 – 2.7	Improvement is needed in supplier performance to meet expectations. For 12-month period, delivery and quality performance are at 90% and 98%, respectively. GPA is less than 2.8 but is greater than or equal to 1.
Red	0 – 1.0	Unsatisfactory supplier performance, clearly failing to meet expectations. Delivery is less than 90% and quality is less than 98% for 12-month period. GPA is less than 1.

Note. Adapted from "Boeing's Supplier Performance Measurement Rating System" by Boeing, 2012.

Boeing's overall supplier performance scorecard was quite robust, for it was an online automated tool that could be directly accessed by the suppliers. This allowed the suppliers to log in online and review their performance rating at any given time. This was an added strength to the supplier performance scorecard, because it promoted data sharing that was readily available and acted as another line of communication to their suppliers. Boeing was also known for sharing their lean practices and improvement ideas with their suppliers, which helped drive improvements and competitiveness. Another

strength of the Boeing's supplier scorecard process was that the process contained post scorecard actions or consequences for when suppliers were falling below or above certain ratings. Boeing did this by stating that when a supplier had an overall supplier performance rating below their minimum requirement of a bronze rating, then the supplier might be subject to supplier funded source inspection. In contrast, suppliers that had achieved high performance standards were recognized and awarded. These recognition programs included The Boeing Performance Excellence Award and the Supplier of the Year. For the Boeing Performance Excellence Award, suppliers became eligible, based on their composite performance ratings for each month of the award performance period if they had either a gold or silver score, met Boeing's annual contract payment value minimum, and had a minimum of ten monthly deliveries or a General Performance Assessment Rating. The rewards for the Boeing Performance Excellence Award included a trophy suitable for lobby display and recognition in Boeing internal and external publicity—while also granting the supplier eligibility for the Boeing Supplier of the Year award. For the Supplier of the Year Award, the rewards included recognition at the Supplier of the Year ceremony and recognition in Boeing internal and external publicity. These were great examples of how a scorecard could be actionable, providing post scorecard actions for the supplier after the scorecard had been distributed.

Honeywell was the next supplier performance process that was reviewed. Honeywell Automation and Control Solutions (ACS) business unit was split into two separate sectors: Home and Building Technologies (HBT) and Safety and Productivity Solutions (SPS). Both Honeywell units split their supplier base by supplier criticality. Then, based on the supplier's criticality level, a performance scorecard would be created only for those suppliers that were identified to be critical to their supply chain. The

supplier scorecard was accessed via Honeywell's Supplier Portal website. The website was an interactive tool that allowed Honeywell to share information and communicate overall performance with their suppliers. The key performance indicators for the scorecard was split into the following focus areas:

1. Delivery
2. Lead Time
3. Quality
4. Productivity or Savings
5. Payment Terms

Each of the five focus areas above had a maximum total of 20 points so that the overall possible score for the supplier scorecard was 100 points. The scorecard was created and issued monthly and included both monthly data and year-to-date data. The five key performance indicators were defined and calculated by the criteria listed below:

1. Delivery Scoring (On Time to Request):
   OTTR was the percentage of parts that were delivered on time to the requested date on the Purchase Order. A shipment received on the requested date, or no more than five working days early, was "ON TIME."

   The calculation was: $\frac{Number\ of\ Units\ Received\ On-Time}{Total\ Number\ of\ Units\ Received} \times 100$

   20 Points: OTTR was 100% to 98%
   17 Points: OTTR was < 98% to 95%
   15 Points: OTTR was < 95% to 90%
   9 Points: OTTR was < 90% to 80%
   6 Points: OTTR was < 80% to 70%
   3 Points: OTTR was < 70% to 60%
   0 Points: OTTR was < 60%

2. Lead Time Scoring (LT):

Lead Time was defined as the agreed-to number of days the Supplier would require to deliver product to Honeywell's dock when a purchase order was received. The supplier's agreed-to lead time for each item was entered into Honeywell's Enterprise Resource Planning tool (i.e., Oracle or SAP) and could only be changed upon agreement between the Supplier and Honeywell. The lead time score was based on the average weighted (by spend dollars) lead time for all items received in that month. This score was not affected by the actual delivery dates.

The calculation was: $\frac{Sum\ of\ (Spend \times Lead\ Time)\ per\ Receipt}{Total\ Spend}$

20 Points: LT was 5 days or less
17 Points: LT was 6 to 10 days
9 Points: LT was 11 to 15 days
6 Points: LT was 16 to 20 days
3 Points: LT was 21 to 25 days
0 Points: LT was 26 days or more

3. Quality Scoring (Parts Per Million or PPM)
   Parts Per Million (PPM) measured product quality through the number of defective parts (non-conformance) per each million units.

   The calculation was: $\frac{Number\ of\ Units\ Rejected}{Total\ Number\ of\ Units\ Received} \times 1{,}000{,}000$

   20 Points: PPM was 0 to 100
   16 Points: PPM was 101 to 500
   12 Points: PPM was 501 to 1,000
   8 Points: PPM was 1,001 to 5,000
   4 Points: PPM was 5,001 to 10,000
   0 Points: PPM was greater than 10,000

4. Productivity Savings Scoring
   Cost Savings was measured by the year-over-year part price variance (PPV). A baseline price was established at the end of the previous year for each item. All deliveries in the New Year were compared to the baseline price. In order to receive points, the Commodity Manager had to have a Cost Savings goal (in dollars) entered into the Annual Operating Plan for the Supplier, and the savings due to part price variance would be totaled and compared against the goal.
   20 Points: 98 to 100% of AOP goal
   17 Points: 95 to 97% of AOP goal
   15 Points: 90 to 94% of AOP goal
   9 Points: 80 to 89% of AOP goal
   6 Points: 70 to 79% of AOP goal

3 Points: 60 to 69% of AOP goal
0 Points: Less than 60% of AOP goal

5. Payment Term Scoring
   Suppliers that met or exceeded Honeywell's expected Payment Terms would receive 20 points. The suppliers that failed to meet the expected Payment Terms would receive 0 points (Global Supplier Quality Requirements Manual, 2016; Honeywell, 2008).

Based on the key performance indicators and metric calculations above, the overall performance level of the supplier was then calculated by adding up all five-key performance indicator point totals. The combined total made up the overall supplier performance scorecard rating that was broken down into four levels (as shown in Table 4).

Table 4

Honeywell Supplier Performance Rating Scale

Performance Level	Point Range	Definition
1	71 – 100	Supplier is a preferred world class supplier that Honeywell rewards with New Product Development involvement and additional business
2	51 – 70	Supplier is performing at an acceptable level, where the Honeywell commodity management team should work with these suppliers to help them achieve Level 1 performance.
3	31 – 50	Supplier has a conditional level of performance, where the Honeywell commodity management team must work with these suppliers to get them to level 2 or develop alternative sources who can achieve level 2 or level 1 status.
4	0 – 30	Supplier is considered a restricted supplier. Honeywell will avoid using these suppliers in any new designs, and will seek to disengage with these suppliers in favor of alternate sources.

Note. Adapted from "Honeywell Global Supplier Quality Requirements Manual" by Honeywell, 2016.

Overall, one of the main weaknesses of Honeywell's scorecard was that the information provided did not list out associated colors for each performance level rating. Supplier scorecards were best conveyed when they were color coded, so suppliers could clearly view a scorecard and identify where they were meeting or not meeting expectations without having to assess each number. Although this might be a potential drawback of the Honeywell scorecard, there was some strength in this scorecard process as well. Honeywell's supplier scorecard process was well written and easy to understand, since there are only five key performance indicators. This provided a high-level overview of the supplier's performance. Another strength with the scorecard process was that it

stated that the scorecard program was meant to reward suppliers based on the data and assists with future sourcing.

The last supplier scorecard management process examined for this thesis was Abbott's. Abbott was a medical device company that divided its suppliers into three distinct supplier categories: Direct, Indirect, and Contract Manufacturers. The scorecards were only issued to suppliers that met three or more criteria from a list of certain business needs and thresholds. Each supplier scorecard differed, based on the specific supplier. In general, Abbott's supplier scorecards were based on the following three elements:

1. Objective measures
    - Quality
    - Delivery
2. Stakeholder surveys: A general survey questionnaire that covered the categories of service, process improvement, innovation and cost effectiveness. The survey was sent to specific Abbott employees who interacted regularly with the supplier throughout the reporting period. The surveys obtained feedback from various departments such as manufacturing, supply chain, quality, purchasing, research and development, regulatory, finance, engineering, materials planning, etc. The results of these stakeholder surveys were then reviewed during the business reviews between Abbott and the supplier that occurred based on business need, or typically held twice a year.
3. Goal performance: The goals section consisted of goals that were established collaboratively with the suppliers at the beginning of each year. The goals would reflect key performance indicators that were specific to projects and common business goals. It was required that a minimum of three joint goals would be identified at the beginning of the year during the business review with that supplier.

Abbott's supplier performance monitoring process also listed the following as potential key performance indicators:

1. Quality Performance

2. Delivery Performance
3. Social Responsibility Audit Status
4. Supplier Diversity Program
5. Abbott Experience
6. Price Leadership
7. Innovation
8. Flexibility
9. Customer Service
10. Technical Complexity
11. Contract Status
12. Invoice Accuracy
13. Electronic Invoicing
14. Payment Days
15. Financial Rating
16. Risk Analysis
17. Financial Solvency

Although these key performance indicators were listed as important measures, these criteria were not included in each supplier scorecard. Abbott does not have set goal weights for each key performance indicator or goal, as that was established during the first business review of the year with each supplier. The overall scoring or supplier performance rating was based on a total maximum of 100 points. An example of a Direct Material Supplier Scoring follows:

Table 5

Abbott Direct Material Supplier Scoring Example

KPIs and Goals	Available Points	Actual Score	Earned Points
Quality	30	100%	30
Delivery	30	90%	25
Goal 1	10	8	8
Goal 2	10	5	5
Goal 3	10	5	5
Survey (subjective KPI)	10	10	10
Overall Score	100		83

Note. Adapted from "Abbott Global Purchasing Services" by Abbott, n.d.

At the end of each year, the final scorecard results for the defined key performance indicators and goals were calculated using data that was compiled from all applicable affiliates and divisions, where the weight of each of the key performance indicators was predetermined during the first business review meeting of the year. The supplier performance rating scale had suppliers falling under four different categories, as shown in Table 6.

Table 6

Abbott Supplier Performance Rating Scale

Performance Level	Point Range	Definition
Superior	87 – 100	Suppliers performing hat highest levels and making a significant contribution to Abbott's success.
Acceptable	70 – 86	Suppliers are meeting Abbott's expectations, and delivering
Marginal	60 – 69	Supplier's performance is lacking in some key performance indicators. Some improvements can be made.
Unacceptable	0 – 60	Supplier's performance is not meeting Abbott's performance standards. Suppliers will develop an improvement plan to address documented deficiencies and improve their score.

Note. Adapted from "Abbott Global Purchasing Services" by Abbott, n.d.

Suppliers performing at an unacceptable level were required to develop an improvement plan to address documented deficiencies identified in the scorecard to improve their score. Suppliers that performed at a "superior" performance level were nominated for a Supplier Excellence Award, meaning that the supplier had been determined to consistently perform at the highest levels and made a significant contribution to Abbott's success. Both Abbott and the supplier signed the scorecards at the close of the business review meeting.

One aspect of the scorecard that was lacking might be that the scorecard did not detail any color-coding for the key performance indicators or final scores. Without the color coding on the scorecard, it did not convey clearly areas where they were meeting or not meeting expectations. A strong aspect of Abbott's scorecard process was that the communication and alignment aspect with their suppliers was agreed on prior to the start of every year. This ensured that the supplier was aligned with Abbott's business goals

and objectives, and that both the supplier and organization were striving and prioritizing the same key performance indicators. In addition, the supplier scorecard had post scorecard actions where there were follow-ups required for suppliers with an unacceptable score, and suppliers with a superior score were awarded. The supplier scorecard process also ensured that a survey would be sent to specific Abbott employees who interacted regularly with the supplier throughout the reporting period, such as manufacturing, supply chain, quality, purchasing, research and development, regulatory, finance, engineering, materials and planning department team members. These types of surveys could help contribute to the overall supplier score and was important because it provided a more subjective method of scoring the service afforded by suppliers. This was important specifically for examples where suppliers might have near perfect scores—based on quantifiable key performance indicators on the surface. However, working with suppliers included many other subjective aspects such as responsiveness, collaboration, partnership, and other aspects of service. This also included a service section that obtained input from multiple internal functions that worked with the supplier could help provide an overview of the actual service relationship with the supplier.

Once all four supplier scorecard processes had been reviewed, a comparison of the main components of the supplier scorecard was compiled, as shown in Table 7. This comparison included similar aspects between every scorecard, such as scorecard frequency, rating scale, overall performance level ratings, focus areas, and key performance indicators. These were also other important components of a scorecard that should be considered during the creation of the scorecard process that were identified as

similarities or strengths in each of the scorecards. The first part of the supplier scorecard process during the review of the scorecards was that the process would define the internal functions that would manage and have input into the scorecard. Therefore, it was important that key stakeholders were identified in the beginning of the scorecard creation process. The second important component of all the scorecards and the main portion of the scorecards were the key performance indicators. Each KPI in the scorecards had similar core components which consisted of the KPI name, definition, metric calculation, defined score ratings or ranges, and a total point value or weight that would eventually add up into the overall supplier performance level rating/score. In Abbott's supplier performance scorecard process, the process was defined by the organization; however, they were required to communicate with the supplier on a yearly basis to align with the key performance indicators chosen and ensure that the supplier understands the expectations for the year. This allowed for collaboration, shared business goals and objectives, and an overall stronger relationship with their suppliers. Another aspect of the scorecard processes identified was actionability. Actionability provided the scorecard with intention and purpose after the results of the supplier performance rating was communicated to the supplier. These included post-scorecard rewards or follow-ups for suppliers, based on their high or low overall performance rating. Based on these components of the scorecard, the outlined supplier scorecard process could be broken down into the following four steps:

1. Key stakeholder identification.
2. Key performance indicator creation.

3. Ranking and weighting.

4. Communication/actionability.

Table 7

Scorecard Comparison

Organization	Scorecard Frequency	Rating Scale	Overall Performance Level Ratings	Focus Areas	Key Performance Indicators
Northrop Grunman	Quarterly	0-100	Blue Green Yellow Red	Quality Late Delivery Team Assessment Elements Process Health and Lean Six Sigma Management Technical Schedule Cost Proposal Mission Assurance/Quality Supply Chain Management Customer Satisfaction	Management Responsiveness Program Management Risk and Opportunity (R/O) Management Staffing Product Performance Systems Engineering Software Engineering Logistics and Sustainment Part Material and Process Service Level Performance Schedule Schedule Performance Index Cost Cost Performance Index Financial Health Team Commitment Proposal Strategy Proposal Adequacy and Negotiation Quality Process Effectiveness

Table Continued

Boeing	Monthly	1.0-5.0	Gold Silver Bronze Yellow Red	Quality Delivery General Performance Assessment	Acceptance Percentage Received Quantity Rejected Quantity Scheduled Quantity On-Time Quantity On-Time Percentage Developmental Production Support Services Shared Services
Honeywell	Monthly	0-100	1-4 (1 being best)	Delivery Lead Time Quality Productivity Savings Payment Terms	On Time to Request Lead Time Cost Savings Defective Parts Payment Terms
Abbott	Bi-Yearly	0-100	Superior Acceptable Marginal Unacceptable	Quality Delivery Stakeholder Surveys Goal Performance	Quality Performance Delivery Performance Social Responsibility Audit Status Supplier Diversity Program Abbott Experience Price Leadership Innovation Flexibility Customer Service Technical Contract Status Invoice Accuracy Electronic Invoicing Payment Days Financial Rating Risk Analysis Financial Solvency

Note. Adapted from "Abbott Global Purchasing Services" by Abbott, n.d.; "Boeing's Supplier Performance Measurement Rating System" by Boeing, 2012.; "ACS Vendor Scorecard," by Honeywell, 2008.; "Northrop Grunman Supplier Scorecard Guidelines," by T.N. Lewis and G. Manuel, 2016.

CHAPTER 5

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Supplier relationship management capability had a positive relationship with supply management performance monitoring, meaning that the greater the supplier relationship management capability, the more positive effects were reflected on measuring performance. By monitoring and measuring supplier performance, opportunities could then open doors to increase the ability to develop diversified performance measures (not just based on financial and supply-based measures). It was reported that only 33% of companies that were examined reported on a supplier management monitoring system. These sources showed that the method of monitoring used for those 33% varied greatly and included methods such as: CSR audits, social impact assessments, and site inspections (Morali and Searcy, 2013).

Finding a way to effectively report supplier quality metrics was important, for it not only helped gauge how the Suppliers were performing, but it could also identify where performance was lacking for certain suppliers. Doing this could eventually help suppliers drive improvements in their own processes, which eventually would reflect on improvements in their metrics. The improvements that could be made throughout an organization through identifying the weaknesses between the supplier-to-customer relationship would not only help drive improvements with the supplier's internal processes but would also improve the Supplier and Customer relationship as a whole.

It was important for organizations to follow their own quality management system and take a risk-based approach to determining the extent of control to be exercised over the products or services provided by their suppliers in proportion with the risk associated with the medical device and overall business impact. This was a requirement per ISO 13485:2016. This could mean that not all suppliers on an organization's approved supplier list were required to be measured or monitored at the supplier scorecard level. This was typically done for larger organizations that might have hundreds of suppliers, where not all supplier performance results were beneficial for the organization, specifically if spend or product or service risk was low. Therefore, many companies had restricted performance measurement programs based on one or more of the following criteria: (1) suppliers that comprise the largest portion of total spending, (2) the critical nature of the product supplied, and (3) the critical nature of the supply relationship (Aberdeen Group, 2002).

In addition, after a risk-based approach was taken with managing suppliers—and determining which suppliers would require supplier scorecards—it was important to understand the supplier products and services provided. There could be separate scorecards for the different focus areas based on the supplier type as follows:

1. Direct Material.
2. External Manufacturer.
3. Indirect Material/Service Supplier.

Different supplier categories might have different key performance indicators. Therefore, it was important for the organization to distinguish these and ensure that the

supplier scorecard key performance indicators were appropriate. For example, direct material and external manufacturers might share the same scorecard key performance indicators because the key performance indicators often apply to both supplier types. In contrast, the direct material and external manufacturer scorecard might include 'lot acceptance rate' as a key performance indicator, but this metric would likely not applicable to an indirect material or service supplier type. Therefore, the key business stakeholders should work together with the suppliers to create scorecards that have appropriate key performance indicators that set mutual performance expectations and goals for both parties.

Based on FDA 21 CFR 820 and ISO 13485: 2016, the following five key takeaways need to be incorporated into the supplier scorecard process:

- Risk: Determine extent of control to be exercised over the supplier-provided product, services, contractors, and consultants proportionate to the risk associated with the medical device and overall business impact.
- Quality: Supplier's ability to meet requirements of the product purchased.
- Performance Criteria: Organization to determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.
- Frequency: Determining when the monitoring and measuring shall be performed and when the results from monitoring and measurement shall be analyzed and evaluated.
- Documentation: Requiring the organization to maintain records of the results of supplier monitoring and re-evaluation of supplier capability or performance

With those five key takeaways provided and after analyzing and reviewing the scorecards and extensive research, the following four-step process was identified for a recommended way to create a supplier performance scorecard process as follows:

1. Identify Key Stakeholders.
2. Create Key Performance Indicators.
3. Determine Ranking and Weighting.
4. Maintaining Communication/Actionability.

Identify Key Stakeholders

The first step in creating a performance measurement scorecard for suppliers would be to identify key stakeholders from different functions or departments of the organization that not only work with the supplier but could also influence the organizational decision-making process. Some examples of the key stakeholders chosen could be from the following functions: quality, production, planning, procurement, sourcing, and supplier relationship managers. It would be important to have a multifunctional team, for the members of that team would have the experience and knowledge regarding various business processes throughout the company. Having a multifunctional team providing perspectives and feedback across the different departments of the organization would ensure that the appropriate supplier performance attributes were identified and could be confirmed to have the appropriate systems or resources in place to measure or quantify those attributes. A multifunctional team would also be important because it would facilitate group discussion and consensus taking place prior to final decision-making. Many companies have key stakeholders choose supplier

performance metrics that might be important for meeting the businesses' objectives but are not realistically measured or lack the resources or system capabilities that allow for the measurement of those attributes. Therefore, it is important to have a multifunctional team of key stakeholders that can work together to identify key performance indicators that are valuable to meet business objectives but are still easily quantifiable and measured so that extensive resources are not required to manage the scorecards on a standard frequency.

Create Key Performance Indicators

The key performance indicators that are chosen must be aligned with business goals and objectives. One way to do that is to identify and understand the critical factors for success. This means that when these critical factors for success are achieved, it would be an indication that the business goals and objectives have been met. Critical factors for success can be discussed and aligned with key stakeholders. When choosing and creating key performance indicators, it would be important that the KPI's are clear and concise. One method for developing key performance indicators is outlined in Table 9, where each key performance indicator component is outlined. By filling out that information for each KPI, it would become clear regarding what the KPI is measuring, how to calculate or measure the KPI metric, why that KPI is being measured, and how to define the expected baseline or minimum acceptable score (International Atomic Energy Agency, 2016).

Table 9

Process to Determine Key Performance Indicators

Area	Area the KPI falls into (i.e. cost, service, quality, etc.)
Superior	Name of KPI being measured
Acceptable	Description of what KPI is measuring
Marginal	How to measure KPI
Unacceptable	Description of why KPI is being measured
	The minimum acceptable score that the organization will accept from the supplier. This should be discussed and agreed with the supplier. Where an acceptable score is unknown, measure the agreed KPI for a minimum of three months then use the scores achieved by the supplier as a basis to agree on acceptable score. Ranges can be used to differentiate between excellent, good, marginal or poor performance.

Note. Adapted from "Nuclear Contracting Toolkit Supplier Scorecard Instructions" by International Atomic Energy Agency, 2016.

Once the KPIs are determined, there should be an evaluation to ensure that the raw data is accurate and readily available to calculate each KPI. This can be based on the business organization's systems in place, including nonconformance processes, SAP, etc. Reviewing the KPIs prior to implementing them ensures that the measures chosen are quantifiable, feasible, and reasonably measured. The business organization creating the supplier scorecard should be able to apply their own model to calculate the overall supplier performance score without having to write custom software code within their quality management system. This is important, since the calculation and weightings evolve over time and should be able to adapt to the business and industry standards and requirements (MetricStream, 2018). This also ensures that extensive resources are not

required to manage, create, and manipulate the data required during the creation of the supplier scorecard.

Ranking and Weighting

The calculation results should be attainable and have ranges that can be given a value. The Likert scale can be used to determine a ranking system that includes ranges for each of the possible results of the calculation measurements. It is recommended that the key performance indicators have a color-coding scheme for each range of results to indicate if the key performance indicator meets the acceptable score or are below the requirements. For example, Table 10 can be used and manipulated to serve as a guideline for key performance indicators:

Table 10

Key Performance Indicator Rating Example

Likert Rating or Point Value	Description	Color	KPI Range
1	Unacceptable	Red	0% - 39%
2	Poor	Tan	40% - 69%
3	Acceptable	Yellow	69% - 79%
4	Satisfactory	Green	80% - 89%
5	Exceptional	Blue	90% - 100%

Note. Adapted from "Supplier Performance Ratings: Scorecards, Rankings, and Awarding Business," by M. Lindsey, 2011.; and "Boeing's Supplier Performance Measurement Rating System" by Boeing, 2012.

The next step for creating the scorecard would be to assign a composite weighting scheme to the different focus areas and key performance indicators. A suggested overall total score of 100 points could be used for the scorecard template. The key stakeholders could then rank the importance of the focus areas to determine how many points out of one hundred that each focus area would have. Ranking the importance of the chosen focus areas of the scorecard—based on business requirements and objectives—would allow the organization to determine the appropriate weighting and point or percentage that the factor would reflect on the scorecard. The performance rating scale that seemed to be most popular and effective were the scorecards where the focus areas and key performance indicators were weighted, based on a 100 point or 100 percent scale model.

Supplier Review Outcome

The different supplier scorecards reviewed in this study identified three out of the four scorecards (Northrop, Abbott, and Honeywell) that used the 100-point weighting scheme. The breakdown would first be completed by choosing the focus area categories and distributing the total overall point quantity between those focus areas. For example, if quality, delivery, cost, and service were the focus areas chosen, then the 100 points could be distributed evenly with 25 points for each. Then, the next step would be to determine which key performance indicators to use within each of the focus areas of the supplier scorecard. Once that was determined, then the focus area subtotal—which would be 25 points for this example—would be distributed to each of the different key performance indicators. The specific metric criteria and range for each key performance indicator would then be outlined with specific metric criteria and ranges. The description would be

matched with a color to help easily identify the overall rating. With this method, each KPI on the scorecard could be easily identified as drivers for the overall supplier performance rating on the scorecard. This could also help identify which areas of supplier performance that would require more focus or improvement, and which areas were meeting or exceeding business expectations and goals.

It was recommended to follow Boeing's overall composite scorecard color rating scheme, which was easily quantifiable for suppliers to see their ratings on the gold, silver, bronze, yellow, and red color rankings. Gold, silver, and bronze were universal rankings that could help suppliers push to receive an overall gold supplier rating. However, it was up to the organization to determine which colors they would like to choose that match with each rating definition.

Actionability

The last step of the supplier scorecard creation process was to ensure that the scorecard was actionable. This meant that the scorecard needed to be distributed and shared with the supplier on a set frequency and documented to easily identify areas of deficiencies, allowing suppliers the opportunity to correct them and improve. This would ensure that there was some type of post scorecard reward or consequence that would give the scorecard meaning and value. Without any type of post scorecard action to help drive improvements with the supplier, then the purpose or value of the scorecard would be diminished. In addition, actionability also would include recognizing or rewarding suppliers for achieving high performance ratings.

Based on the overall supplier recognition or rating scale, the suppliers should then be either awarded per the organization, or the supplier might need to be re-evaluated based on the supplier performance monitoring data. This could include a Supplier Risk Mitigation Plan, corrective actions, or the possible evaluation of a new source supplier—including the delisting or disqualification of that existing supplier--could also occur, based on the supplier management program at the organization.

Four-step Process Summary

In conclusion, this four-step process that outlined the supplier performance scorecard creation process could help guide medical device organizations that were in the process of developing their supplier quality programs and needed a way to begin supplier performance monitoring. Of course, because every medical organization had many variable factors, there was no "one-size fits all" type of scorecard. Due to several factors—such as organization size, resources, data availability, technological support, business objectives, medical device type, supplier base, supplier size, and business maturity—there were limitations as to the level of detail that this general supplier performance scorecard process could provide. However, by following the four-step process with the right identified key stakeholders to help determine the KPIs, execute and open communication lines with suppliers, and ensure accountability, there was a high potential for success in meeting the minimum requirements of 21 CFR 820 and ISO 13485:2016 purchasing control requirements for supplier performance monitoring.

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