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Mark Allen Durivage, editor

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Preface

The Certified Supplier Quality Professional (CSQP) certification provides valuable credentials to quality professionals in the growing field of supplier quality engineering. Due to globalization of the supply chain, supplier quality engineers are becoming more important in a broad spectrum of industries, including the manufacturing and service industries.

The purpose of this handbook is to prepare individuals for the CSQP examination and provide a reference for the practitioner. Throughout this handbook, examples are provided based on the collective experience and knowledge of the authors and editor. However, these examples are not explicitly specified in regulations, leaving decisions to the company, as well as the burden of justifying practices using sound scientific principles that provide the context of the rationale.

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Part I

Supplier Strategy

Chapter 1	A. Supply Chain Vision/Mission
Chapter 2	B. Supplier Lifecycle Management
Chapter 3	C. Supply Chain Cost Analysis
Chapter 4	D. Supplier Agreements or Contracts
Chapter 5	E. Deployment of Strategy and Expectations

Chapter 1

A. Supply Chain Vision/Mission

Today, the word *quality* appears on almost every product we come across—food, appliances, automobiles, aircraft, consumer goods, medical devices, pharmaceuticals, and software. No matter where you turn, you hear about quality. In fact, we demand a certain level of quality in everything we buy.

What is meant by the word *quality*? The American Society for Quality (ASQ) defines quality as “the totality of features and characteristics of a product or service that bear on its ability to satisfy given needs.” The features and characteristics of a product or service are how we as consumers evaluate how good that product or service is. For example, in a restaurant, the amount we leave as a tip is a direct reflection on the quality of the food and the service. In a supply chain the features and characteristics that define quality are translated into specifications and requirements.

We live in an age of globalization. Not only has the major industrial trend of outsourcing continued unabated, but outsourcing now has a truly global footprint. This has increased the importance of the supply chain in every industry but especially in regulated industries like medical devices and pharmaceuticals. For example, a drug can now utilize a key starting material that is manufactured in a Chinese plant, received and converted into an active pharmaceutical ingredient in India, and ultimately formulated into a finished drug product in the United States to be distributed in the United States, Canada, and the European Union (EU). The regulations touching this one product alone, not to mention the complexities of the supply chain and the technical challenges of manufacturing, are staggering. The importance of a safe, reliable, cost-effective, high-quality, integral, and nimble supply chain cannot be overstated. Equally critical are the supply chain processes (e.g., strategic, procurement, quality assurance, technical, regulatory) that ensure these requirements are met. By extension, then, the supply chain professional—notably, the supplier quality professional (SQP)—is of paramount importance as a creator, driver, and full participant in these business-critical activities.

As supply chain professionals, it is our job to add value to our organizations by:

- Ensuring that the quality of purchased components, materials, parts, and finished goods meets requirements
- Complying with applicable regulations and voluntary standards (RoHS, USFDA QSR, MDD, FMD, ICH, CMDR, and various ISO, ASTM, and other standards)
- Ensuring the integrity of the supply chain to maintain product purity (uncontaminated, not counterfeit)

- Minimizing interruptions and disruptions in the supply chain
- Adhering to manufacturing schedules and order fulfillment
- Ensuring cost-effective execution of processes (e.g., strategic, procurement, quality assurance, technical, regulatory)
- Effectively defining expectations, roles, and responsibilities through contracts and quality agreements
- Effectively managing the supply base over the lifecycle (selection, qualification, management, monitoring and measurement)

A supply chain strategy is the vehicle by which we accomplish this.

SUPPLY CHAIN STRATEGY

This is the first time in the history of business that you can be great at what you do today and be out of business tomorrow.

—Ken Blanchard and Terry Waghorn, *Mission Possible*

As supply chain professionals, we espouse the ideal that our supply base is an extension of our internal manufacturing—indeed, an extension of our business. As an SQP, you are part of the supply chain team that is responsible for ensuring the smooth operation and high-value proposition of the supply base. So how do we make that ideal a reality? Certainly it will not happen organically or accidentally. How, then? Precisely by *managing it*. That is to say, we must have a supply chain strategy. Such a strategy allows us to plan how the supply base will unfold and add value to our organization. It also characterizes the supply base itself: What will it look like? With whom will we choose to partner? Engage with? How much development work will we invest in the supply base? How will the links in the various supply chains connect and secure themselves? Strategy will determine all of this and more. In fact, having a good supply chain strategy can be a competitive advantage, even a competitive imperative. It can be the key to long-term success.

Strategy means different things to different people. In its simplest form, it is a way of maximizing the actions you can control and minimizing those you cannot. This means that any business must have a set of guidelines that dictates where they want to be at a given point (a vision), and this must be clearly understood by everyone (deployment and communication). For example, the strategy could be that the business will achieve the highest quality possible, or that the product will be recognized by others as being the best in the field, or that the product will provide an increase in market share. It is the function of the supply chain professional, including the SQP, to draft and deploy a strategy that achieves the stated objectives of the organization, whatever they may be.

BENEFITS OF A SUPPLY CHAIN STRATEGY

Drafting and deploying an appropriate supply chain strategy yields many benefits, ranging from reductions in cost, lead time, and recalls to an overall increase

in productivity and efficiency. When suppliers know what is expected of them (quality agreements) and how they are evaluated (measuring and monitoring), they can focus on improvements such as reductions in variation and cost. The cost reductions resulting from variation reduction will enable suppliers to enter into longer-term contracts while also accomplishing their financial goals. At the same time, suppliers are assured of a sustained partnership with the customer, a benefit to both parties.

Another component of a good supply chain strategy involves making the supplier a part of the design team developing new products. In such cases the supplier is expected to lend expertise to the design process as part of a mutual commitment benefiting both customer and supplier: The customer gets the latest technology in the supplier's specialized area, and the supplier gets an opportunity to increase business and improve relations with the customer. The supplier participates in design reviews, specification development, prototyping products, measurement assurance, and life testing. The supplier is given unique opportunities to have some control over new products. Furthermore, in many cases suppliers are aware of new technologies in their field, as well as the capabilities and limitations of their current products. As they learn the expectations for the product they are helping to develop, they can recommend changes in the product that will enhance its performance. For example, say a certain plastic part is to go into a copier. The supplier is brought in and finds that the part is to be located near a heating element that could cause the plastic part to warp over time. The supplier recommends a different composition of resins with a higher heat resistance. This results in an improved product and significant savings in potential redesign and service costs.

As we can see, strategy is without a doubt one of the most critical aspects of any endeavor, including supply chain. Surely with the complexities of global commerce and supply chains that span the world, supply chain strategy has to be a primary concern and focus of the supply chain professional, and therefore the SQP. The SQP must partner with procurement and other sourcing professionals to develop the most effective, efficient, and value-added supply chain strategy possible. This involves understanding the needs and capabilities of all stakeholders—internal and external, customer and supplier oriented—as well as the general technological and market conditions relevant to the product lines under development, manufacturing, or service. Although the specifics of business and market conditions are beyond the scope of this certification, general strategic concepts are not, and these must be understood to create the most efficacious supply chain strategy possible. Two of the most effective tools in developing, communicating, and deploying a truly effective strategy of any kind are mission and vision.

MISSION AND VISION

Knowing where you're going is the first step in getting there.

—Ken Blanchard and Terry Waghorn, *Mission Possible*

Many incredible books have been written on the subject of mission and vision. One of the most useful and easily understood is *Full Steam Ahead!* by Ken Blanchard and Jesse Lyn Stoner (2011). Blanchard has been called “the dean of leadership,”

and for good reason. In *Full Steam Ahead!* he lends his talents to a parable-style narrative that explains not only what vision is but why it is critical to leaders and organizations, and how to create a vision that energizes. Another very useful work is *The Servant Leader* by James A. Autry. In it he writes, “The mission question is simply, ‘What do we do?’ By extension, it’s ‘what do we do to fulfill our purpose?’ ” (Autry 2001, 28). As we will see, this definition of mission dovetails nicely with Blanchard and Stoner’s three key elements of a compelling vision. They begin the process of vision formulation with the concept of purpose as well.

Without the structure, definition, and direction that mission and vision provide, the supply chain will not function effectively and the organization’s options will thus be limited, sometimes severely. The development, communication, and deployment of a robust strategy employing the tools of mission and vision ensures that an organization’s supply chain will be consciously and deliberately developed and will therefore best serve the needs of the organization. The purpose defines the mission, and in turn the mission informs the vision. If crafted correctly, Blanchard and Stoner write, “The vision must benefit everyone it touches” (2011, 167).

Mission

If mission stems from purpose, and so too does vision, then our purpose is the foundation of our “why.” Our purpose serves as our anchor and the reason we come to work every day. In every good organization, a functional mission and vision flows down from the organizational mission and vision. This provides alignment and enables efficient execution of objectives and goals. It also drives the appropriate key process indicators (KPIs) and their associated metrics. Autry points out that the mission and resultant objectives can change over time, but the purpose should not (Autry 2001). Autry also agrees with Blanchard and Stoner (2011) that values are an important part of the mission and vision. Values are the bedrock to which the cultural anchors of an organization are fastened. Values provide stability, focus, and guidance, if not boundaries, over time. In the end, every professional needs to understand the purpose of their activities and their organization. To know and understand the purpose is to understand the mission. The purpose serves to ground people, anchor them, and focus their energies on the appropriate value-added activities. In this way, the supply chain professional understands each and every day what they are to accomplish and therefore what inputs will drive the desired outcome.

As a segue to the discussion of vision, let’s look at a purpose that is germane to supply chain and create a good mission statement. For example, if the stated purpose was concentrated on ensuring a supply of high-quality and high-value components and materials, we might construct the following mission statement:

To procure the highest-quality components from the most reliable suppliers at the best cost possible.

With this mission statement we can move forward to craft our vision statement. The vision statement is a fundamental leadership tool to ensure focus, cohesiveness, and cross-functional alignment. If crafted carefully and communicated and deployed effectively, it can be a powerful bonding agent between functions that must work toward a common goal. This is particularly true in the matrix

organizational structures that are increasingly popular. Given the diversity of supply chain, cross-functional alignment can be an invaluable strategic asset. How, then, do we progress from understanding our purpose to developing a compelling vision that can serve to not only inform the development of the supply chain strategy but also unite the diverse functions involved in supply chain activities to effectively deploy that strategy?

Vision

According to Blanchard and Stoner, “Vision is knowing who you are, where you are going, and what will guide your journey” (2011, 79). Further, they assert there are three key elements of a compelling vision:

1. Significant purpose
2. A picture of the future
3. Clear values

It is easy to see how applying these concepts to a supply chain strategy would increase its robustness, flexibility, and adaptability to inevitable changes, even on a global scale, by defining, inspiring, and guiding supply chain professionals as they seek to engage suppliers and potential suppliers in the supplier lifecycle management process.

Using the example stated above as our mission statement, “To procure the highest-quality components from the most reliable suppliers at the best cost possible,” the supply chain professional and SQP would focus their efforts on stable suppliers that have developed quality systems and are efficient and cost-conscious.

Inherent in the second element is the notion that vision is by definition forward-facing. Since the future has not occurred yet, it is sometimes difficult for people to see it clearly. It is nonetheless critical in the process of constructing that future to have a clear idea of what it looks like. A carefully crafted picture, rich with detail, can serve as a conceptual model of the desired future state, and it can also inspire if done correctly. Appeals to people’s passions, pain points, and better nature can be crafted into the future state that is painted in the picture. Using the same mission statement above, a picture could be painted in this way:

Two years from now I see an uninterrupted supply chain providing on-time delivery of quality components—such high quality that incoming inspection will no longer be required. Downtime will be the exception rather than the rule. We will partner with our preferred suppliers to keep costs to a minimum by collaborating to maximize efficiencies, drive out waste, and streamline demand planning as a joint activity.

In this picture of the future state are clearly embedded values: waste reduction, efficiency, implicit trust of the supplier, collaboration. These values will serve as cultural anchors in times of uncertainty, ambiguity, and change. These factors may distort the future-state picture as time goes by, but the values will remain timeless and immobile, providing secure ground from which to operate. Without this secure footing, time, conditions, and events might make it difficult to remain true to the vision and purpose of the supply chain organization. Clear values are the anchor to which we can all secure our understanding of our work, and they also give us all something to rally around.

Taking our purpose, picture of the future, and values, our vision statement might look something like this:

Maximizing value by focusing on quality, cost, and reliability in our supply chain.

See Table 1.1 for a summary of the process of creating a vision statement.

To further illustrate the point, here are some examples of actual vision statements:

To become a Center of Excellence in the supplier quality function by leading strategic partnerships with our suppliers and our internal customers through capable and committed people, focusing on improving product quality and compliant processes.

Be the most effective management organization that supports global suppliers, our partners and our customers, and meets worldwide compliance through:

- Supplier partnership
- Consistent and standard processes
- Reduction of costs
- Continuous improvement

Creating a reliable supply chain through unwavering commitment to quality and cost.

In summary, mission and vision are critical to providing structure, cultural anchors for stability, and commonality of purpose as well as a direction forward into the future. As we have seen, if crafted purposefully, the vision can also serve to inspire! This is critical if the supply chain strategy is to be deployed effectively.

Table 1.1 Summary table of steps in creating a vision.

Mission statement	Picture of the future	Clear values	Vision statement
To procure the highest-quality components from the most reliable suppliers at the best cost possible.	Two years from now I see an uninterrupted supply chain providing on-time delivery of quality components—such high quality that incoming inspection will no longer be required. Downtime will be the exception rather than the rule. We will partner with our preferred suppliers to keep costs to a minimum by collaborating to maximize efficiencies, drive out waste, and streamline demand planning as a joint activity.	Waste reduction, efficiency, implicit trust of the supplier, collaboration.	Maximizing value by focusing on quality, cost, and reliability in our supply chain.

Chapter 2

B. Supplier Lifecycle Management

World-class organizations understand that a planned and measured approach to managing suppliers is essential, and many models have been developed to support the need to manage suppliers. Supply chain management as a field has been around for decades, but the relatively new concept and analytical model of supplier lifecycle management (SLM) takes an integrative approach and explicitly plans for the acquisition of suppliers as well as natural (and unnatural) turnover in suppliers (see Figure 2.1). SLM supports and guides the business relationship from initial supplier discovery through qualification and onboarding to ongoing maintenance and possible termination or obsolescence. SLM is an integrated approach that considers business and quality needs of the organization. Its purpose is to recognize suppliers as a prime source of value to the organization and deliver that value by putting them at the heart of procurement strategy and management.

Many supply chain professionals are familiar with the supply chain management (SCM) model, and they may wonder: How does SLM differ from SCM? SCM is a set of system-focused approaches utilized to efficiently integrate suppliers, manufacturers, warehouses, and stores so that merchandise is produced and distributed in the right quantities, to the right locations, and at the right time in order to minimize systemwide costs while satisfying service level requirements. SLM is a systemic approach that is customer focused (service level) and intent on minimizing costs, but it considers all links in the supply chain that can affect either of the two main objectives. In this sense, there seem to be only minor differences between the concepts, perhaps the most significant being SLM's explicit planning for both the natural and unnatural turnover in suppliers. SCM focuses more explicitly on the entire supply chain, including lower-tier suppliers, across the entire enterprise, and focuses on managing and minimizing total systemwide costs.

Many supplier management professionals are also familiar with the supplier relationship management (SRM) model and may wonder how SLM differs from SRM. SRM is the systematic, enterprisewide assessment of suppliers' assets and capabilities with respect to overall business strategy, the determination of which activities to engage in with different suppliers, and the planning and execution of all interactions with suppliers in a coordinated fashion across the relationship lifecycle to maximize the value realized through those interactions. The focus of SRM is developing two-way, mutually beneficial relationships with strategic supply partners to deliver greater levels of innovation and competitive advantage than could be achieved by operating independently or through a traditional transactional purchasing arrangement.

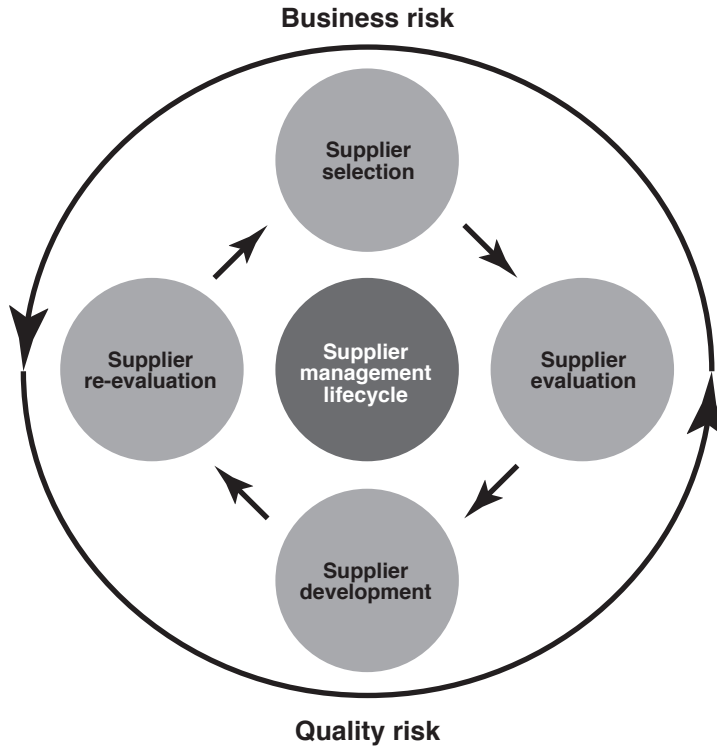


Figure 2.1 Supplier lifecycle management model.

In many fundamental ways, SRM is analogous to customer relationship management. Just as companies have multiple interactions over time with their customers, so too do they interact with suppliers—negotiating contracts, purchasing, managing logistics and delivery, collaborating on product design, etc. The starting point for defining SRM is a recognition that these various interactions with suppliers are not discrete and independent. Instead they are accurately and usefully thought of as comprising a relationship—one that can and should be managed in a coordinated fashion across functional and business unit touchpoints and throughout the relationship lifecycle.

In summary, SRM, as the name implies, is very much relationship focused, and less focused on regular transactions and their associated metrics.

Although it is not a complete supplier management paradigm, many supplier management professionals may have had exposure to supplier information management (SIM) solutions. SIM is a corporate or even enterprisewide IT solution that manages, retrieves, and organizes supplier information and maximizes supplier engagement and data quality across a global supplier base while ensuring minimum risk and high efficiency. As supply chain strategies are implemented that reduce cost and lead times and increase service level, the timeliness and availability of relevant information is critical. One alternative to using an enterprise resource planning (ERP) solution for supplier information management is the implementation of a multimode, cloud-based SIM platform. A dedicated SIM platform has both advantages and disadvantages compared with an all-in-one ERP solution that also includes a SIM module. However, SIM only focuses on

management of the information; it does not give strategic guidance on which information is important, unlike a full lifecycle model such as SLM.

The choice of an appropriate supplier management lifecycle and supplier management model is dependent on many things, including:

- Corporate strategy
 - May include strategic objectives to incorporate Six Sigma and lean methodologies, continuous improvement, or voice of the customer utilized separately from Six Sigma
- Company demographics
 - Size
 - Global presence
 - Company maturity
- Industry maturity and trends
 - Reliance on economies of scale for cost control?
 - Or push for one-piece flow for lean?
 - Demand stability and predictability
 - Demand for finished good versus aggregated component
 - Push-pull versus pull only or push only
 - Critical component/assembly lead times
 - Quality levels expected by customers
 - Tolerance for nonconformance
 - Taguchi loss function
 - Company location relative to critical resources
 - Skilled personnel
 - Universities and centers of innovation
 - Industry centers
 - Raw materials
 - Vertical integration/global insourcing versus contract manufacturing/outsourcing
 - Industry competition for goods as well as resources
 - Competition on price or differentiation of features
 - Cycle time to market
 - Short competitive cycle for “appearance” of new products?
 - Drive to deliver new real value that is less time driven?
 - Driven by technology cycle?
 - Disruption from new technologies/platforms
 - Virtual products replacing physical products

- Logistics considerations in the supply chain
 - Modes of transport—land/sea/air
 - Time in transport, economic value in transit
 - Tax implications

SUPPLIER SELECTION

Regardless of the supplier management model chosen, supplier selection methods and criteria are a core component. In this section we will discuss how to develop the process for supplier selection and qualification, including the identification of sub-tier suppliers.

The ASQ Customer-Supplier Division outlines the supplier selection process using nine steps:

1. Identify all possible sources
2. Evaluate reputations
3. Prepare bidders list
4. Request bids
5. Evaluate pre-award data
6. Select the supplier
7. Update approved supplier list
8. Prepare contract
9. Accept contract

Identifying candidates may involve a multitude of evaluation criteria. Over time, providers of goods and services build a reputation. This reputation may be for price, durability, variety, or any number of different attractors for that supplier's chosen market. Customers may learn about a supplier's reputation in various ways, including:

- Experience (e.g., seeing the supplier's components in other assemblies they have worked on)
- Professional engineering societies (e.g., quality, mechanical, plastics)
- The supplier's marketing (e.g., print, television, internet)
- Recommendations from trusted friends or colleagues or customer feedback ratings
- Sales agents and distributors

All of this input allows customers to develop a list of possible suppliers, often called a bidders list. The customer now needs pre-award data to make its selection from the bidders list. A common way to obtain these data is to send out a request for bid to four to six possible suppliers. This is called the short list. The functional specifications are sent (minus any proprietary information), along with quantity and delivery date estimates. If a supplier wishes to perform the work, they send

a bid back to the customer. Many types and pieces of information are included in the bid, so the customer can make an informed decision.

Pre-award data can also come from conversations with knowledgeable parties. Suppliers often have sales staff who can answer technical and pricing questions from existing and potential customers. Customers can also gather pre-award data by sending surveys (called self-assessments or questionnaires) to possible suppliers. Today, these questionnaires are often sent by e-mail or placed on a customer website for potential suppliers to complete online. Past performance history can also be used to make a supplier selection. If an item worked without problems before, it is likely to work again in the same environment. Sometimes the customer's customer provides a list of preapproved sources to use. This promotes efficiency in that the decision work has already been done. It also promotes consistency in that these preapproved suppliers are known performers. The practice of preapproving subsuppliers is common in the automotive and aerospace industries.

Once all the data are collected on the short list of possible suppliers, tools such as decision analysis or multi-criteria decision analysis tools can be used to compare the suppliers against the critical criteria, which are often weighted to help further differentiate suppliers (see Table 2.1).

Supplier Qualification

Some options for the qualification of a supplier include self-assessment, detailed supplier questionnaire, due diligence, and on-site audit/inspection/preassessment.

Self-assessment and remote review may be an appropriate method for low-risk or off-the-shelf sourced products. Certificates of compliance or conformance to a quality management system (QMS) standard such as ISO 9001:2015 may be sufficient to indicate that the company has controlled processes for quality conformance. For these products, the cost of additional qualification steps may not be warranted if information on the company and its products is readily available through public channels.

For higher-risk sourced materials or products, additional evaluation and qualification is likely to be required. Also, if the material will be single sourced, business continuity concerns in the event of a supply disruption should be addressed.

On-site inspections allow the purchasing agent to determine the capability of the supplier to provide the material and to convey the seriousness of the possibility

Table 2.1 Weighted decision analysis table.

	Semiquantitative factors:					Total
	Cost	Quality	Location	Reliability	Payment options	
Weights:	4	5	1	2	3	
Supplier 1	4	0	0	2	9	15
Supplier 2	0	15	2	4	3	24
Supplier 3	8	10	1	6	0	25
Supplier 4	8	15	3	6	0	32

of doing business with the supplier. The site visit also serves as a means to impress on the supplier that the customer expects the supplier to provide exactly what the customer wants.

PERFORMANCE MONITORING

Once a supplier has been selected and brought on board, ongoing performance assessment is an important part of managing the supplier lifecycle. In this section we will discuss the development of a supplier performance monitoring system, including expected levels of performance, process reviews, performance evaluations, improvement plans, and exit strategies.

Depending on the risk level of the material, performance monitoring and supplier rating can take many forms, ranging from simple measures of delivered quality level and on-time delivery to more complicated systems that may also include measures for innovation, risk sharing, supply assurance/continuity, and active collaboration. In the end, it is important that we not only measure the few items that make the biggest impact but also set a baseline of measurement so each party gains from the relationship. Without a win-win approach to sourcing, we lose out on key factors such as trust, respect, understanding, and communication, which are necessary for a high-performing supplier relationship. At the most fundamental level, without measures of supplier performance, we would have little idea of when requirements are being met and when corrective action is required to address nonconformances or poor performance.

Expected performance levels for suppliers will generally align with both financial and quality corporate objectives. You may also want to consider some of the measures under the four categories of supplier performance shown in Figure 2.2.

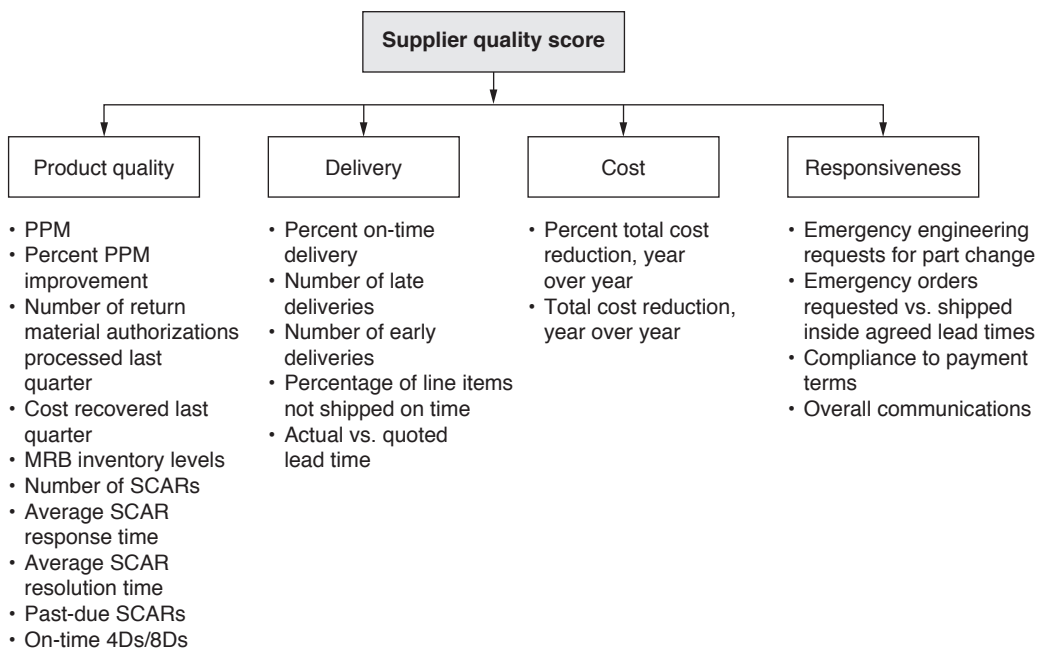


Figure 2.2 Supplier performance categories and metrics.

A scorecard system (e.g., Kaplan and Norton’s balanced scorecard) is a common method of combining data in such a way that performance can be understood at a quick glance; it also allows comparison between suppliers (see Figures 2.3 and 2.4). Perhaps more importantly, scorecards that are updated on a regular basis provide a means of tracking and trending supplier performance over time, allowing for regular performance evaluations with the supplier.

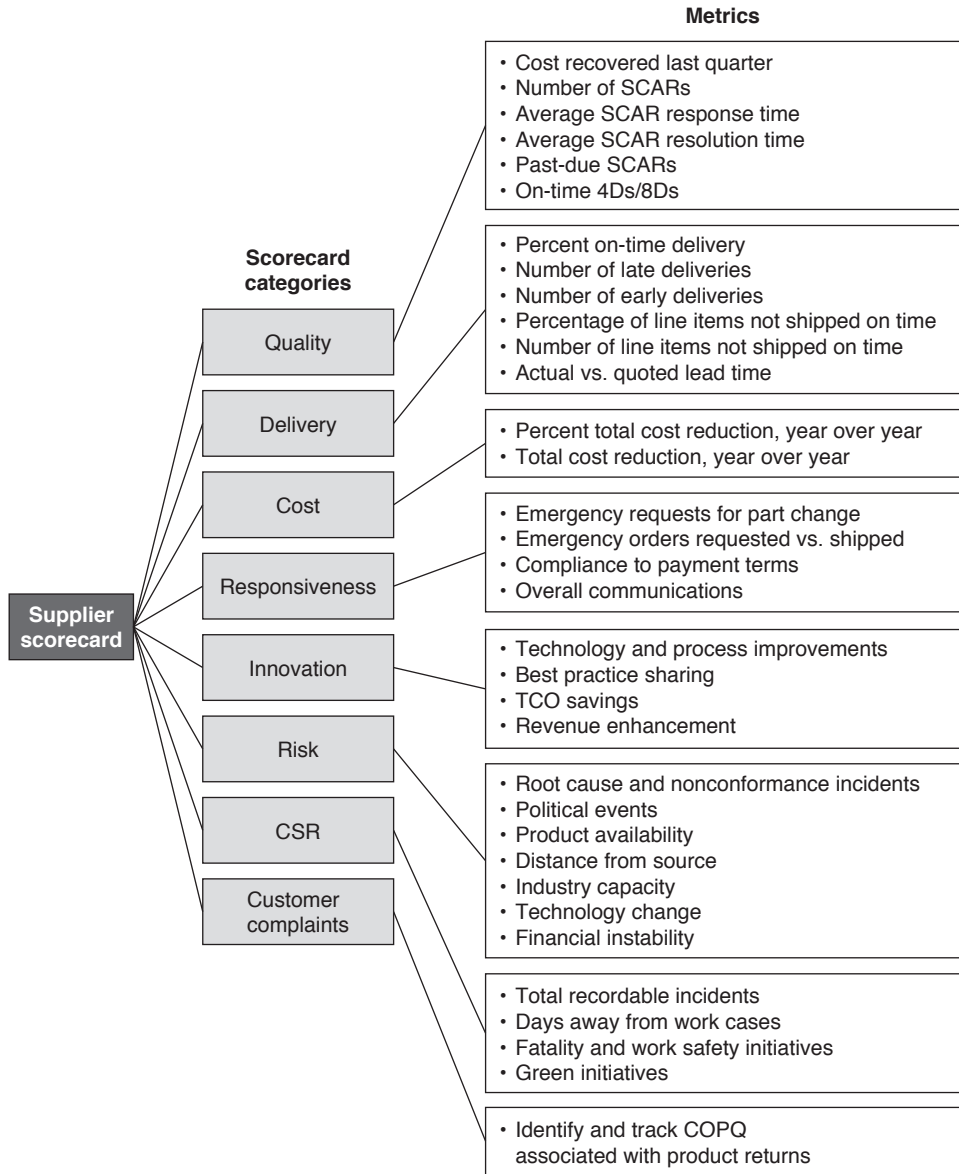


Figure 2.3 Supplier scorecard categories and metrics.

		KPI	Freq	Jan	Feb	Mar	Apr	May	Jun	Target
Financial	1	Supply chain cost (per unit volume)	m	\$1.70	\$1.69	\$1.68	\$1.65	\$1.57	\$1.55	\$1.60
	2	Cash—debtor days	m	16.2	17.1	18.3	16.5	14.6	16.0	15.0
Customer	3	Distribution coverage	m	76%	74%	78%	81%	82%	85%	80%
	4	Customer service, OTIF	m	91%	92%	89%	93%	96%	94%	95%
	5	Stock availability at distributor	m	97.6%	94.3%	96.5%	98.1%	98.7%	98.4%	98.0%
Process	6	Total stock (days)—producer, distributor	m	18.6	18.9	16.7	17.5	15.5	14.3	12.0
	7	Sales forecasting accuracy	m	64%	59%	58%	65%	76%	81%	90%
Learning and growth	8	Performance appraisal status	q	25%	25%	25%	65%	65%	65%	90%
	9	Competency attainment	q	40%	40%	40%	50%	50%	50%	75%

Figure 2.4 Sample supplier balanced scorecard.
Source: Adapted from Kaplan and Norton, 1992–2008.

Tracking and trending supplier performance may also provide advance warning of major problems before they occur, allowing for preventive or corrective actions. Continuous improvement plans can also use supplier scorecard status as a jumping-off point for the desired improvement. Scorecard warnings indicating negative trends can also be useful in determining when exit strategies should be considered with a troubled supplier, allowing time for the supplier management function to evaluate and bring on line an alternate supplier with little or no impact to the rest of the supply chain.

SUPPLIER STATUS AND CLASSIFICATION SYSTEM

In this section we will discuss ways to develop a supplier status and classification system. Supplier status is typically straightforward and follows the lifecycle steps: nonapproved or pending approval, approved, probation or warning, and phase-out, inactivated, or disqualified.

One method for establishing supplier classifications is to use the Kraljic Portfolio Segmentation Model, shown in Figure 2.5. This allows us to establish risk-based supplier selection, qualification, and performance monitoring processes to focus supplier lifecycle management activities on the riskiest and highest-impact products.

Kraljic recommends the following purchasing approaches for each of the four product quadrants:

- *Strategic products* (high profit impact, high supply risk). These products deserve the most attention from purchasing managers. Options include developing long-term supply relationships, regularly analyzing and managing risks, planning for contingencies, and producing the item in-house rather than buying it, if appropriate.

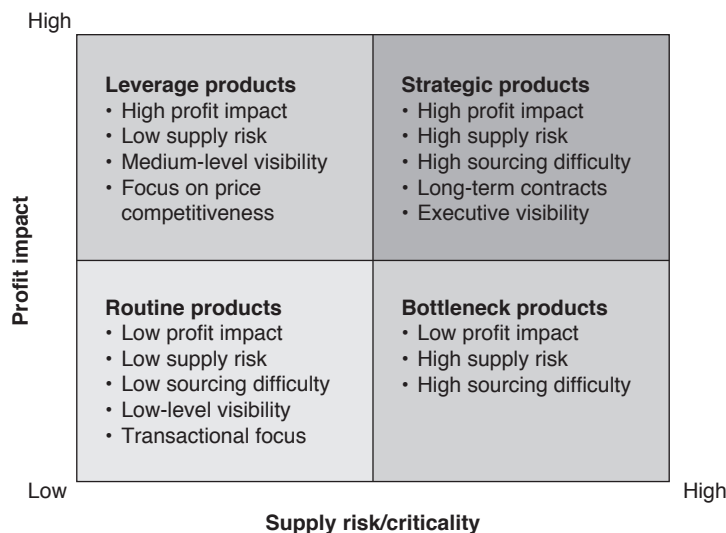


Figure 2.5 Kraljic portfolio segmentation model.

Source: Adapted from Peter Kraljic, "Purchasing Must Become Supply Management," *Harvard Business Review*, 1983 (<https://hbr.org/1983/09/purchasing-must-become-supply-management>).

- *Leverage products* (high profit impact, low supply risk). Purchasing approaches to consider here include using your full purchasing power, substituting products or suppliers, and placing high-volume orders.
- *Bottleneck products* (low profit impact, high supply risk). Useful approaches here include over-ordering when the item is available (lack of reliable availability is one of the most common reasons that supply is unreliable) and looking for ways to control vendors.
- *Routine products* (low profit impact, low supply risk). Purchasing approaches for these items include using standardized products, monitoring and/or optimizing order volume, and optimizing inventory levels.

PARTNERSHIPS AND ALLIANCES

In this section we will discuss how to identify and analyze strategies for developing customer–supplier partnerships and alliances. As shown in Figure 2.5, some sourced items will fall into the strategic products category. These products should be given more attention and are usually good candidates for developing long-term partnerships or alliances with the supplier. These partnerships may involve giving the supplier a preferred classification that offers them a significant advantage in winning additional business from the customer. The preferred strategy and choice of partnership or alliance may be influenced by the customer’s relative purchasing strength compared with the supply market strength, as shown in Figure 2.6.

Your strength as a buyer	High			
		Exploit	Exploit	Balance
		Exploit	Balance	Diversify
		Balance	Diversify	Diversify
	Low	Supply market strength		High

Figure 2.6 Kraljic purchasing portfolio matrix.

The other category of supplied products that may benefit from an alliance are the bottleneck products that have low profit impact but carry high supply risk. One way to help control vendor volatility is through an alliance, which could involve helping the supplier implement a stronger QMS, offering training and development in lean and Six Sigma techniques, or even providing financial support in the form of long-term supply contracts with regular payments.

Chapter 3

C. Supply Chain Cost Analysis

Sourcing strategy is critical to the SQP. The SQP must partner with procurement and other sourcing professionals and internal stakeholders to develop the most effective, efficient, and value-added supply base and sourcing strategy possible. This requires an understanding of the very real need for minimizing cost in the supply chain while maximizing value. Let's take a look at some of the concepts the SQP needs to be familiar with.

COST REDUCTION

Competition is global and very intense. Since a large part of the cost of goods sold is the cost of materials, the greatest opportunity to maintain a competitive edge is often found in the supply chain. It is important to understand the impact of various costs on the supply chain. The measures of cost and the cost of poor quality (COPQ) categories discussed below represent an opportunity to maximize cost reduction or minimize excess costs. Keep in mind that some of these can be hard to measure. But the only way to reduce costs is to identify them and to focus on them. Cost reduction should be approached as a project, utilizing proper project management principles and techniques. Further, cost reduction efforts need to be collaborative in nature, seeking a win-win outcome for customer and supplier. Internal collaboration is critical, too, ensuring that internal stakeholders (quality, operations, procurement, engineering/R&D, etc.) are engaged and committed and that we seek a win-win outcome for internal stakeholders, too. It is this win-win collaboration that is the key to minimizing cost while maximizing value in the supply chain. As we will see in this chapter, the opportunities for cost reduction in the supply chain are as real as the need for cost reduction in the supply chain.

Supply Chain Cost Concepts and Terminology

Spend

The total amount of purchased goods procured from a supplier constitutes the spend. This value is important and should be used to rate the criticality and importance of a supplier. It should indicate the amount of risk with that supplier as well. It is a key indicator of how much time, effort, and resources should be spent managing that supplier. Too, it should be a measure of the supplier's investment in the customer.

Logistics, Geography, and Geopolitical Considerations

Distance, transportation, and the current political climate are important considerations in any supply chain decisions and can have a profound effect on cost. Obviously transportation costs, import/export costs, and other logistics-related costs are important. Geography is also a consideration, especially in relation to travel costs, as well as the infrastructure of the countries involved. Related considerations include potential damage, number of reloads and transfers, supply chain security, material integrity (e.g., counterfeits, contamination), and theft. Natural disaster is also a consideration, although some natural disasters are more predictable than others. For example, if we are operating in an earthquake-prone area we can plan for that contingency, but it is difficult to prepare for an unexpected disaster such as the tsunami that hit Japan in 2011. Lastly, geopolitical instability is also a factor. Civil war and other conflicts can wreak havoc on infrastructure and production capacity and schedules, not to mention the availability of raw materials. All of these factors increase cost and risk. Much thought and planning must go into securing the supply chain, especially when considering this category.

Cost of Poor Quality Analysis

Quality is free. It's not a gift, but it's free. The "unquality" things are what cost money.

—Philip B. Crosby, *Quality Is Free:
The Art of Making Quality Certain*

Traditionally there are four categories of COPQ: internal failure cost, external failure cost, appraisal, and prevention. Failure cost is any scrap, rework, waste (muda), returned material, rejected material, line downtime, and so on. Appraisal is the cost of deciding whether product meets requirements. Traditionally this involves inspection-related costs: inspectors, equipment, redundant activities (e.g., 200% inspection), etc. Prevention cost is really a misnomer, as prevention is an investment if done correctly, in the sense that these activities both prevent failure costs and minimize or eliminate the need for inspection (appraisal). Prevention includes activities such as validation, poka-yoke, quality by design (QbD), Design for Six Sigma (DFSS), appropriate use of failure modes and effects analysis (FMEA), process characterization and optimization (e.g., use of design of experiments [DOE]), and process audits that focus on in-process control and prevention to reduce waste and rejections, such as the use of statistical process control (SPC) and automated inspections (e.g., vision systems, reversing conveyors, mechanical sorting, weighing).

It is important to remember that the more effort you put into prevention, the lower the cost will be for appraisal and for either type of failure. Keep in mind that external failure cost includes many intangibles, the most important of which is damage to the organization's reputation. The benefit of preventing this kind of damage is difficult to quantify, but certainly it will bear returns over the investment manyfold. If you were to Pareto chart the four categories of COPQ, ideally prevention would be the largest bar and failure and appraisal would be small. This would represent a mature system. If you are just starting out, you will first need to put effort into both appraisal and prevention to reduce external failure cost and then internal. Then you can gradually transition to greater investment

in prevention, transferring the money spent on appraisal to designing in quality, poka-yoke, validation, and SPC and DOE.

It is also important to remember that, as with all waste, quality costs can be hidden, not unlike the costs in the “hidden factory” in a lean manufacturing analysis, as illustrated in D. C. Wood’s *Principles of Quality Costs*. Wood uses the iceberg analogy—that most of the iceberg is hidden beneath the water’s surface—to illustrate the concept of hidden quality costs. According to Wood, “90% of most quality costs are under water” (Wood 2013, 7). Figure 3.1 contrasts the superficial and hidden costs, utilizing both data from Wood and data that are applicable to supplied material.

COPQ Analysis Applied to Suppliers

Applying the principles of quality costs to the supply base is just as important, and not that different from, internal COPQ analysis (COPQA). It is likely you will readily find cost reduction opportunities through application of COPQA principles to the supply chain.

It is important not to get bogged down in discussions of minutiae when compiling quality cost data, internally or externally. For the most part, COPQA should be used for comparative purposes and to assess the value that a supplier adds (or fails to add) from month to month, for both trend analysis and comparison with like suppliers. Therefore, 100% accuracy is not required. If the data are estimates, that’s OK, as long as we always estimate in the same way. For example, the wages for internal rework of supplier lots are a common sticking point. Different operators might earn slightly different wages. That can be a nightmare from an accounting standpoint from one rework activity to another. Luckily we are not doing COPQA as an accounting activity. Simply assign an average wage, use it in *all* calculations, and go do some quality cost analysis. Even if the analysis is not accurate to the penny, it will be an apples to apples comparison and thus allow us to do both meaningful trend analysis and comparisons to like suppliers. After all, the point is not to invoice the supplier but to determine its overall value proposition. That being said, how do we do our COPQA? We start by choosing categories based on customer pain points.

Link COPQA to Scorecard/Monitoring Activities

Quality costs are important in judging a supplier’s overall value proposition. One way to bring these data to light is to link them to the supplier scorecard. Categories

Superficial costs (<i>above the surface, easy to see and measure</i>)	Hidden costs (<i>below the surface, difficult to see and measure</i>)
Scrap Rework Warranty Incoming inspection rejections	Engineering time Time to process CAPAs/SCARs Management time Line and field downtime Increased inventory Decreased capacity Delivery problems Lost orders Lost reputation

Figure 3.1 Superficial and hidden costs.

could include nonconformance processing costs, excess inventory, reinspection costs, number of supplier corrective action requests (SCARs), line downtime, scrap costs, and any other category that represents a pain point to your organization. Socialization and voice of the customer (internal customers such as manufacturing and purchasing) will help to identify the pain points and consequent categories. Figure 3.2 shows a COPQA spreadsheet for a fictional Supplier A.

Figure 3.3 shows the same data for Supplier A graphically, this time as compared with overall spend (both in dollars and as percentages). This analysis is helpful when comparing the value propositions of like suppliers (e.g., comparing injection molders to each other).

Figure 3.4 shows these data incorporated into a monthly scorecard template. This is a balanced scorecard, containing categories for quality, manufacturing,

COPQA spreadsheet for Supplier A						
Elements	Jan	Feb	Mar	Apr	May	Jun
Appraisal						
Supplier audits and/or visits (<i>travel expenses</i>)						
Normal incoming quality inspection (<i>purchased material</i>)	\$ 1,998.85	\$ 898.34	\$ 1,547.25	\$ 1,470.80	\$ 1,636.59	\$ 1,056.00
Tightened incoming quality inspection (<i>purchased material</i>)	\$ 13.52					
Cost of samples (<i>if samples are not returned to the lot, i.e., destructive test</i>)		\$ 4,373.94	\$ 7,767.07	\$ 7,715.96	\$ 7,722.24	\$ 4,801.80
Total appraisal costs	\$ 2,012.37	\$ 5,272.28	\$ 9,314.32	\$ 9,186.76	\$ 9,358.83	\$ 5,857.80
Internal failure						
Rejected lots/units (<i>includes scrap</i>)	\$ 27.18	\$ 28.87	\$ 53.13	\$ 52.36	\$ 102.93	\$ 66.63
Inspection (<i>labor and related activities cost</i>)		\$ 1,082.27			\$ 2,792.70	
Line downtime (<i>includes line clearance</i>)						
Expedited material (<i>due to supplier's delivery and/or quality issues</i>)			\$ 7,205.00			\$ 7,635.89
Total internal failure costs	\$ 27.18	\$ 1,111.14	\$ 7,258.13	\$ 52.36	\$ 2,895.63	\$ 7,702.52
External failures						
Complaints (<i>includes complaints and supplier QA labor</i>)	\$ 1,132.30					
Field actions/recalls						
Total external failure costs	\$ 1,132.30					
Total quality costs	\$ 3,171.85	\$ 6,383.42	\$16,572.45	\$9,239.12	\$12,254.46	\$13,560.32

Figure 3.2 COPQA example.

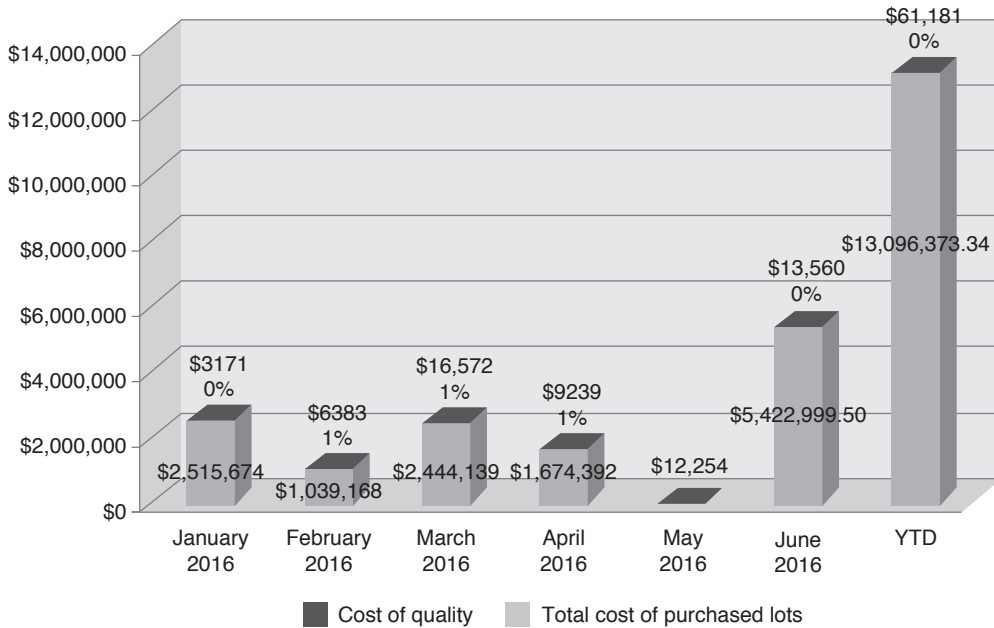


Figure 3.3 Quality costs vs. overall spend for a supplier.

		Jan	
Incoming lots			
Rejected lots			
Reinspected lots			
Metric	Points	Occur	Score
Supplier corrective action request (SCAR)	15		0
Repeated SCAR (last 12 months)	10		0
SCAR responsiveness	10		0
Reworked/reinspected lots	5		0
Lot conformance	5		0
Quality and operations	45		45
Appraisal	5		0
Internal failures	5		0
External failures	10		0
Costs	20		20
On-time deliveries	10		0
Expedited shipments	10		0
Purchase orders with documentation issues	10		0
Responsiveness	5		0
Purchasing	35		35
		Jan	
Overall performance	100		100%

Figure 3.4 Monthly scorecard template incorporating COQA categories.

and purchasing and based on a possible score of 100. Note the COPQA categories circled. These categories correspond to the spreadsheet and graph in Figures 3.2 and 3.3.

Roll-Up into Adjusted Purchase Price Variance and Total Cost of Ownership

It is almost certain your company knows the purchase price variance (PPV) for purchased goods. For emphasis and impact, the SQP can show an “adjusted PPV” by rolling in the COPQA data we just discussed. Focus on total cost of ownership (TCO) in your reporting to management.

ANALYSIS AND PROPOSALS TO REDUCE COSTS

As previously stated, cost reduction should be approached as a project, utilizing proper project management principles and techniques. Further, cost reduction efforts need to be collaborative in nature, seeking a win-win outcome for customer and supplier. Internal collaboration is critical, too, ensuring that internal stakeholders (quality, operations, procurement, engineering/R&D, etc.) are engaged and committed and that we seek a win-win outcome for internal stakeholders, too. It is this win-win collaboration that is the key to minimizing cost while maximizing value in the supply chain. We have examined opportunities to reduce costs using COPQA. Supply chain rationalization is another tool, although it yields far more value than mere cost reduction. We also will look at make/buy decisions. These decisions can save a great deal of money if made wisely.

The key is to look at the data from your various analyses and show return on investment (ROI). Every cost reduction is an investment—it takes resources to plan and execute as well as to maintain safety stock. Never forget excess inventory, which ties up cash and reduces cash flow. Proposals must appeal to the business sensibilities of your partners. Each proposal should clearly show how much will be spent in money and human effort and what the organization will recover for that investment. A good rule of thumb is to recoup at least twice the investment in less than 12 months, but each organization has its own criteria for ROI. Yearly advanced operations planning, strategy, and budgetary planning sessions can be a great forum for presenting your proposals. Just remember these key things: Leverage your stakeholder relationships (both internal and external), strive to add value, utilize project management principles, and collaborate to achieve a win-win outcome. In this way the SQP can have a meaningful business, quality, and compliance impact on the organization while demonstrating leadership and vision.

SUPPLY CHAIN RATIONALIZATION

As supply chains grow over time, suppliers for certain core manufacturing or service processes will proliferate. It is important to look at the supply base from time to time to understand what the right size is for your particular supply chain needs and make corrections if necessary. This involves not only looking at each category of suppliers but also harmonizing the supply chain with your strategy. How many suppliers do you need for process X? (What is the right number of

suppliers? Is dual sourcing or multiple sourcing appropriate?) Who among them will help you achieve your strategy and vision? (Who are the right suppliers? Who meets your requirements best? Whom might you wish to partner with?) How can you maximize your value proposition by increasing leverage (competitive price, good service), increasing influence, and balancing that with contingency planning to protect the integrity of the supply chain (dual versus single sourcing in the event of an emergency)? This is the essence, and the value, of supply chain rationalization.

Optimization

The objectives of supply base optimization are cost reduction, risk reduction, and increased quality. The utilization of data and a data-driven decision process are the most critical components of any rationalization effort. Obviously quality costs are a major data source in this decision process. Consolidation, partnerships, and collaboration will help to optimize the supply chain.

Consolidation of Suppliers and SKUs

Consolidation of suppliers is one way to reduce costs and increase leverage and importance, investment and ROI, and incentive and cooperation. Consolidation and standardization of stock keeping units (SKUs) will save money and requires a partnership with R&D/design and procurement. Consolidation of suppliers is a matter of finding the right number of suppliers in each spend category or outsourced process (e.g., plastics or injection molders). Then work with partners internally to find the best suppliers in those categories and transition to them. This will take buy-in and planning from all stakeholders. Working together, you can determine the right suppliers and the correct number of suppliers to ensure supply integrity, decrease costs, and increase quality and leverage with the suppliers in one fell swoop. This can lead to partnerships, drive truly value-added investment, and reduce the overall risk in the supply chain. The same process used for make/buy decisions (discussed later in this chapter) can be used to determine the best suppliers. Obviously COPQA data will be useful in this decision as well. Raw material rationalization and centralized buying are also great optimization opportunities. You can reduce costs and simplify the overall supply chain by leveraging economies of scale made possible by increasing spend on core materials by consolidating them and by securing the best price. This effort could go hand in hand with consolidating SKUs. Simplification always brings cost reduction opportunities. Any of these initiatives will help to optimize the supply chain.

Partnerships and Collaboration

The importance of partnerships and collaboration, both internal and external, cannot be overstated. But it is worthwhile to consider the words of Dr. W. Edwards Deming on this topic. We would be remiss if we failed to point out that customer-supplier collaboration is not a new concept. In fact, in his classic book, *Out of the Crisis*, Deming taught us that collaboration with suppliers bears significantly more fruit than basing the procurement relationship on price alone. His famous 14 points include a plea to “end the practice of awarding business on the basis of price tag

alone. Instead, minimize total cost" (Deming 1982, 31). *Out of the Crisis* provides an extensive explanation of this concept, focusing on the differences between the procurement strategies of Western and Japanese firms in the late twentieth century. Deming viewed sourcing strategy as a strategic advantage as well as a benefit to any firm. Some of his major arguments include:

We can no longer leave quality, service and price to the forces of competition and price—not in today's requirements for uniformity and reliability. (Deming 1982, 31–32)

What one company buys from another is not just material: it buys something far more important, namely engineering and capability. (Deming 1982, 40)

MAKE/BUY DECISIONS

To outsource or not to outsource? Make/buy decisions are perhaps the most crucial any organization can make. To make the best decision, the following tools should be applied equally and without bias to both the external and internal organizations.

Process Analysis

Core Competencies

The core processes and services offered by the supplier need to be analyzed in order to understand the value the supplier offers, which should be compared with the internal value offered. A subject matter expert (SME) or technical expert (TE) should be involved in this effort to ensure a thorough and accurate analysis. A complete process audit should be conducted focusing on the supplier's technical competence in the particular process (manufacturing or service) being considered. Technical competence includes current best practices, knowledge, training, education, and experience of technical staff, as well as proper deployment and execution of sound scientific and engineering practices. This includes personnel and practices from the functions of manufacturing, procurement, engineering/R&D, quality, and maintenance. Additionally, applicable regulations and voluntary standards must be considered as a facet of technical and core competency. If environmental systems are important, then competency with ISO 14000 is essential. In a regulated environment such as medical or pharmaceutical, competency with current good manufacturing practices (cGMP) regulations is essential. So if the supplier is a medical molder, then that supplier must be an expert in cGMPs and molding. Consequently, so does your company.

Control Systems

The same principles apply to control systems. Control points, decision points, and methods for preventing defects, mix-ups, errors in traceability and labeling, and other critical errors must be incorporated into the competency audit. If there is a control plan, utilize it as an anchor in the process audit, along with any other

inspection planning documentation. Ask where decisions (e.g., accept/reject) are made, if they occur in the right stages in the process, and if they are effective. Look for poka-yokes and automated inspection. Don't overlook process controls such as critical processing parameters being controlled and validated statistically, as well as safeguards against process errors such as using cameras to prevent a "mold crash."

Internal and External Capability Analysis

Of course, one of the most effective indices of competency is capability. Statistical data on control (statistical process control or SPC) and capability (short-term process capability [C_{pk}] and long-term process performance [P_{pk}]) need to be analyzed. Compare the internal and external processes and their respective capabilities.

Historical Performance Analysis

Key data sources for analyzing historical performance include SCARs, corrective and preventive action (CAPA), internal nonconformances, historical capability, and results from regulatory, ISO, and customer inspections and audits. Planned or scheduled maintenance, age of equipment, historical downtime, first time yield, and rolled throughput yield are also great predictors of success. In the end, it is most likely that future performance will reflect historical performance.

SWOT Analysis

It may be helpful to use strengths-weaknesses-opportunities-threats (SWOT) analysis as another decision input. For the project, or alternately for each organization, list the associated strengths, weaknesses, opportunities, and threats. In this way a comparison can be made. The SWOT analysis usually takes the form of a box divided into four quadrants; see Figure 3.5 for an example.

Pareto Analysis

Pareto analysis may also be useful. Pareto analysis is a ranking of categories of interest used to identify the "vital few" categories in order to focus on them, thereby maximizing effectiveness and results (see Figure 3.6). An example might be to rank historical data and compare two organizations.

Strengths • Processing, training competence • Quick changeover expertise	Weaknesses • Regulatory risk • Infrastructure risks
Opportunities • Simplify the supply chain: rationalize and reduce costs • Eliminate logistical issues by insourcing	Threats • Low-cost competition • Long lead times

Figure 3.5 SWOT analysis example.

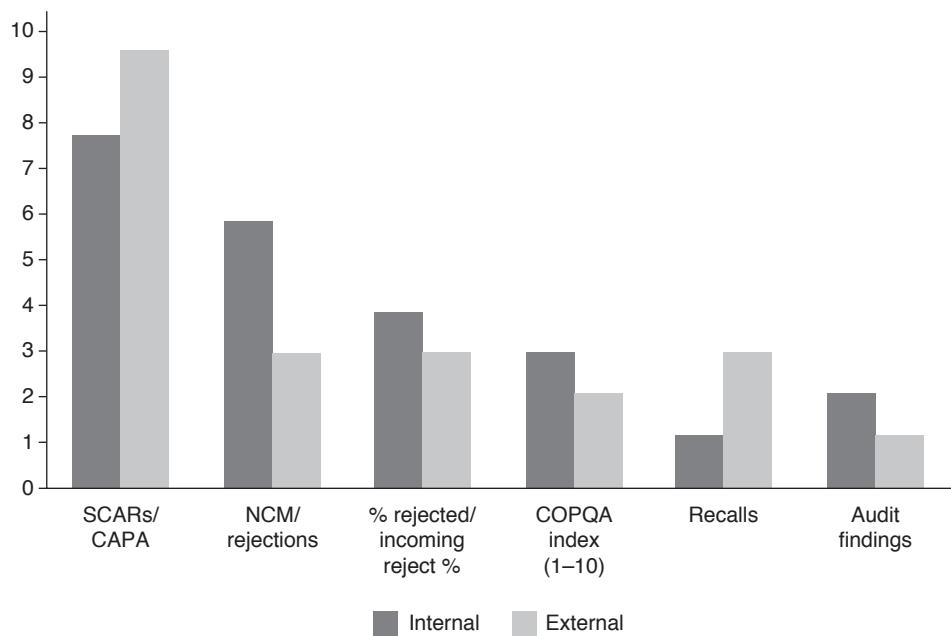


Figure 3.6 Pareto analysis of historical data.

Chapter 4

D. Supplier Agreements or Contracts

Principal supply contracts are vital for manufacturing organizations seeking to assure a consistent quality and flow of incoming materials. The agreements provide a mutual understanding of the expectations for the supplier and customer.

Agreement terms should be understood by all involved in the supply chain to minimize risk while reaching the desired outcome. Too often the agreement negotiation focuses on price alone to the exclusion of an understanding of quality, production, safety, and delivery risks. Taking a supply team approach by incorporating the viewpoints of manufacturing, quality personnel, designers, supply chain logistics, purchasing, and legal allows for risks to be reviewed and reduced, assuring a smooth supply flow for long-term results for all parties.

In order to create an agreement for goods and services, a definition of the requirements must be understood by all parties prior to signing off on any paperwork. Customers that wish to protect their intellectual property may require a nondisclosure agreement (NDA) to be signed by a potential supplier. An NDA—also known as a confidentiality agreement (CA), confidential disclosure agreement (CDA), proprietary information agreement (PIA), or secrecy agreement (SA)—is a legal contract between at least two parties that outlines confidential material, knowledge, or information that the parties want to share with one another for certain purposes while restricting its access by third parties. It is a contract through which the parties agree not to disclose information covered by the agreement. An NDA creates a confidential relationship between the parties to protect any type of confidential and proprietary information or trade secrets. As such, an NDA protects nonpublic business information. NDAs can be “mutual,” meaning both parties are restricted in their use of the materials provided, or they can restrict the use of material by a single party (“unilateral”).

Other liability agreements that may come into play before business parties start to share requirements or visit each other’s facilities include indemnity agreements and hold harmless agreements. Indemnity is compensation for damages or loss. Indemnity in the legal sense may also refer to an exemption from liability for damages. The concept of indemnity is based on a contractual agreement made between two parties, in which one party agrees to pay for potential losses or damages caused by the other party. The agreement may include requiring specific types and minimum amounts of insurance the supplier must carry before they can do business. In addition, a properly drafted agreement will indicate that the supplier must furnish evidence that they are complying with the indemnification and insurance requirements. This is typically accomplished by requiring a certificate

of insurance from an insurance company or agent. A hold harmless agreement is a contract between two parties designed to release one or both parties from legal claims. Most often, one party agrees not to sue the other party for any expenses, damages, or losses arising from a transaction or activity between the two parties.

Requirements are identified in different manners. The requirements can be distributed to the supplier on a separate supplier requirements document, which is then referenced in the purchase order, contract, or agreement. In some cases, the requirements are stated directly on the purchasing document, which suppliers should review to ensure they can satisfy the stated requirements.

DEFINE REQUIREMENTS

The supplier is not obligated by contract to satisfy the expectations of the organization if they are not properly identified and is not bound by contract to any requirements that are not documented. If there are any ambiguous, deficient, or inaccurate supplier flow-down requirements, the supplier has to contact the organization (the supplier's customer) to gain further detail for clarification prior to accepting the order, because ambiguous requirements can put both the organization and the supplier at risk.

When an order is placed with a supplier for any product or service, the organization should give the supplier a clearly written specification with a sufficiently detailed description of needs and requirements as well as terms and conditions (the output of the design control program).

It is very important to ensure that the supplier has received, reviewed, and acknowledged or confirmed the requirements. By doing so, the organization will have a greater degree of confidence that the supplier is capable of fulfilling the order requirements. If the purchasing requirements are not properly managed, this will have a cascading negative effect on delivery, cycle time, quality, and cost throughout the supply chain.

Purchasing information describes many aspects of the product and services to be delivered by the supplier, including, but not limited to, the following:

- Description of the product
- Quantity
- Delivery due dates
- Agreed-on price, rate, or fee
- Approval of product, procedures, processes, and equipment
- Qualification of personnel
- Management systems such as those for quality, safety, environmental, and risk management
- Relevant drawings and process data (technical data), and revision level
- Requirements for test specimens
- Record retention

- Sub-tier supplier flow-down requirements
- Notification of changes in management or management systems
- Right of access
- Notification of nonconformances
- Shipping, labeling, and packaging requirements
- Product shelf life and age control requirements
- First article inspection (FAI)
- Source inspection
- Certificate of conformance, analysis, or compliance requirements
- Payment terms such as invoicing, timing, and method
- Shipping requirements including imports, exports, and customs
- International Traffic in Arms Regulations (ITAR) and Export Administration Regulations requirements
- Identification and traceability requirements for possible recall and investigation

THE STATEMENT OF WORK: KEY POINTS

In developing service requirements, the statement of work (SOW) identifies the part of the contract where all the operational aspects of a service are described. This document contains—expressed in terms your organization understands—the definitions developed in brainstorming sessions of what a good service is. Drafting a good SOW is critical to success.

In some cases, the SOW is a separate exhibit; in other cases, it is embedded in the body of the contract. Whichever form is used, always bear in mind that a contract is a single entity, and due attention must be given to the balance and harmony of all its parts. Blind cut-and-paste exercises, where a SOW is inserted into some boilerplate clauses, are the shortest path to disaster. Nevertheless, for our discussion, it helps to think of the SOW as a separate document that must have certain traits in order to be successful.

It is normal for a supplier to offer its own version of the SOW. Though this document should be considered as background information, it is not advisable to sign it without close scrutiny.

A detailed study on how to draft SOWs is beyond the scope of this chapter; however, there are some key points the SOW must cover. Not all of them are relevant in every situation, but it is always a good idea to go through this checklist:

- *Service definition and scope.* There must be a clear definition of the service you are contracting. All relevant contractor obligations must be listed. Emphasis must be placed on the end results to be accomplished, giving the contractor as much leeway as practical to decide how to organize its work.

- *Deliverables.* Define clearly what service deliverables your company expects to receive. The contractor must be made responsible for these deliverables, and its compensation (payments) must be tied as much as possible to their timely production. Also, acceptance criteria must be set forth for these end products.
- *Company-provided inputs.* In some cases, your company will provide goods or services necessary to perform the work. Examples might be office space, computers, travel expenses, and electricity. These must be clearly defined.
- *Contractor-provided inputs.* Conversely, it might be the contractor's responsibility to provide certain materials. For example, in outsourced plant maintenance services, the deliverables might include provision of spare parts and lubricants. Once again, be careful to list these.
- *Performance evaluation—bonus/penalty clauses.* Performance review mechanisms must be defined and applicable penalties or bonuses stated. A correct definition of performance indicators is vital to close the feedback loops essential for a successful outcome.
- *Price and payment.* The amount of money to be paid for the services and the form and date of payment must be specified.
- *Warranties.* Any warranties must be clearly spelled out. For example, in computer programming, the contractor might agree to correct any software bugs that appear within the first 12 months of software operation.
- *Contract changes.* The only sure thing in business nowadays is that everything changes. Consequently, contracts must allow for flexibility.
- *Confidentiality.* Clear rules must be set forth regarding what use the contractor can make of information your company supplies. You must indicate that all blueprints, data sheets, and related information cannot be shared with third parties without your organization's written consent.
- *Key personnel.* In specialized, high-value services (for example, consulting), service quality is heavily dependent on the individuals assigned to the project. The contracting organization must, in these cases, specify the persons who will perform the work and set down its right to request personnel changes if performance is not acceptable.
- *Software and patents.* If the work involves using software, provisions must be drafted to cover its use. Similar concepts apply to any patented processes, procedures, tools, and other intellectual property the contractor will use for its work.
- *Termination clauses.* In case of substandard performance and/or repeated failure to comply with the agreed performance level, provisions must be in place for contract termination. Minimum performance levels must be defined such that, should the contractor not be up to par, corrective action can follow.

INITIATING THE SUPPLIER SELECTION PROCESS

An organization can use a number of documents to initiate the supplier selection process. They may include:

- *Request for information (RFI)*. Used to collect information from potential suppliers regarding products, services, and options
- *Request for proposal (RFP)*. Formal request for suppliers to submit a quote to supply a particular product or service

These documents may include information regarding:

- Product or service characteristics
- Product or service performance requirements

Sourcing, contracts, and other purchasing decisions are at the tactical level of supply chain management, as are production decisions, inventory decisions, and transportation strategy. When an organization has many potential suppliers and significant leverage, however, sourcing can also be a very strategic decision. A contract is a legally enforceable promise or set of promises made by one party to another. It is a legally binding agreement concerning a bargain that is essentially commercial in nature and involves the sale or hire of commodities such as goods, services, or land.

PURCHASING FUNCTION

The purchasing (also called procurement) function in an organization has two primary and essential tasks: to select and contract with suppliers, and to establish terms of purchased goods and services needed by the organization. Some organizations also assign responsibility for supplier development and improvement to the purchasing function.

Many organizations labor under the false belief that they have no options other than to buy from the first supplier they can find or, in some cases, their traditional supplier, and to pay the supplier's price. Some industries still have the luxury of passing costs on to one or more end customers or users. These are industries in which customers have poor leverage, a concept that is discussed later in this chapter. Other industries do not have this luxury and have to work diligently on cost reduction and efficiency to compete.

Where the organization has an option, it is best to purchase needed products directly from the supplier that has the most "value add" in the product. For example, when buying a metal casting that must be subsequently machined, if the machining costs more than the casting, the organization should purchase from the machining company to maximize leverage. In some cases it makes sense to purchase from distributors, but organizations will not have as much leverage on price with them as they will with original suppliers. There may be other benefits of or reasons for using distributors, however. In the case of an electrical connector, the manufacturer will produce large quantities of connectors to achieve economy of scale. It may not be interested in selling small quantities of connectors to end users, so use of a distributor would be the best, if not the only, option.

Legal Aspects of Purchasing

Since contracts are enforceable in a court of law, they are subject to regulatory requirements. These requirements can vary by jurisdiction. For purchases on which you can't afford to lose, you should seek legal advice from a competent source when developing terms and conditions to govern the transaction, including any remedies that may be needed.

The US Uniform Commercial Code (UCC) is a set of statutes governing the conduct of business, sales, warranties, negotiable instruments, loans secured by personal property, and other commercial matters. It has been adopted with minor variations by all states except Louisiana. The UCC is a model code, so it does not have legal effect in a jurisdiction unless UCC provisions are enacted by individual legislatures as statutes.

The UCC consists of rules for different transactional areas under articles based on types of transactions:

- Sales (amended Article 2)
- Leases (amended Article 2A)
- Negotiable instruments, previously known as commercial paper (revised Article 3)
- Bank deposits and collections (amended Article 4)
- Fund transfers (Article 4A)
- Letters of credit (revised Article 5)
- Bulk sales, previously known as bulk transfers (revised Article 6)
- Documents of title (revised Article 7)
- Investment securities (revised Article 8)
- Secured transactions (revised Article 9)

For supply chain management, these four areas are especially relevant:

- Warranties
- Transportation terms and risk of loss
- Seller's rights
- Buyer's rights

AWARD CONTRACTS

The UCC establishes each party's rights and obligations according to common business practices based on the principles of fairness and reasonableness. Fairness and reasonableness also serve when a particular term is not defined in the contract. The law is not applicable outside the United States, but most other countries have similar commercial codes. English contract law is a body of law regulating contracts in England and Wales. It shares a heritage with countries across the British Commonwealth such as Australia, Canada, and India.

EU law (commonly referred to as Union Law and historically called European Community law) is a body of treaties and legislation such as regulations and directives that have direct or indirect effect on the laws of EU member states.

The United Nations Commission on International Trade Law developed its Contracts for International Sale of Goods (CISG) treaty in 1980. As of May 2016, it had been ratified by 85 countries. It is similar to the UCC.

COMPETITION

Competition in economics is a term that encompasses the notion of individuals and firms striving for a greater share of a market to sell or buy goods and services. A supplier that monopolizes the market for its product or service has no incentive to reduce cost or improve quality or service. Competition makes all competitors better because they have to improve to survive. Organizations should develop a number of potential suppliers for all critical purchased products. The efforts will pay off in both the short term and the long term. Even when an organization elects to award all its volume for a given purchase to a single supplier, having a number of bidders will ensure that the successful supplier understands the requirements and is providing a competitive price.

A practice is anticompetitive if it is deemed to unfairly inhibit free and effective competition in the marketplace. Examples include cartels, restrictive trade agreements, predatory pricing, and abuse of a dominant position.

TERMS AND CONDITIONS

Most organizations have a standard set of terms and conditions that govern supplier relationships. These vary depending on the size of the organization, the annual spend amount, the amount of leverage the organization has, and regulatory requirements.

Potential suppliers need to take care in reviewing the purchaser's terms and conditions prior to signing agreements. Some purchasers include an evergreen clause, which means the contract will automatically be renewed unless one party disagrees, sometimes within a limited specified time frame.

When there is potential for significant warranty or recall costs, agreement on any limitation of supplier liability for the remedies in the event of a purchased product or service failure should be agreed upon up front. Different industries handle warranty differently. In the passenger car market, the automakers provide warranty for their product, including purchased product for end users. In the heavy truck and aerospace industries, parts suppliers offer warranty to their customers' customers.

This limits warranty liability to the prime contractors or original equipment manufacturers (OEMs) but results in higher piece prices for purchased products. Regulatory requirements may also specify how product or service guarantees or remedies will be handled for a specified industry or commodity.

When it comes to purchased product, it has been said that he who has the gold wins. Organizations with a large annual purchasing spend can dictate more terms and conditions than others. This is generally an advantage for the organization,

but large organizations can fall into the trap of creating too many customer-specific requirements, which actually drives cost up. When a supplier has multiple customers in the same or a similar industry, additional resources are needed to meet customer-specific requirements. The cost of these extra resources have to be recovered from one or more customers.

Some purchasers now have environmental requirements for suppliers. The World Trade Organization (WTO) has cautioned that these can impede trade and even be used as an excuse for protectionism. It adds that WTO member governments consider the protection of the environment and health to be legitimate policy objectives, and thus they recommend taking an approach that helps exporters meet standards and requirements.

To avoid proliferation of customer-specific requirements, organizations should participate in and make use of any standards that are applicable and available. There are standards at the international, national, industry, and product levels. Standards development organizations such as the International Organization for Standardization (ISO), the American National Standards Institute (ANSI), the American Society of Mechanical Engineers (ASME), and the Society of Automotive Engineers (SAE) offer many voluntary standards that organizations can use in specifications for their purchased products. Industry trade associations (e.g., the Automotive Industry Action Group [AIAG]) also produce harmonized customer requirements that can be used to avoid non-value-added costs in the supply chain.

UNDERSTANDING COST

Cost control is important to organizations. Cost plus margin equals price. Two main elements of cost control are cost estimating and actual cost tracking. Organizations must account for costs and have a way of recovering them in their revenue. Some industries use competitive benchmarking and tear-down of competing products to better understand the design and estimate costs. This can involve tracking and use of data on costs such as raw materials and labor by region. At a minimum, organizations should estimate potential costs, then compare actual costs with the estimates and make adjustments to pricing or costs as necessary to ensure organizational commercial viability going forward.

Most sectors once operated with a pricing model based on cost plus margin. In sectors in which competition is significant, the pricing model has to be market based (i.e., what customer organizations are willing to pay regardless of cost). This puts incentive on the producer to reduce costs to maintain or increase margin.

SPECIFICATIONS AND DESIGN RESPONSIBILITY AND APPROACH

Prior to the Industrial Age, customer organizations and suppliers were close enough geographically to do business personally, face-to-face. The Industrial Revolution created a proliferation of manufacturing organizations and purchased product requirements, which created a need for a new intermediary tool, the specification, to replace the direct communication between customer and supplier. In its essence, a specification describes and prescribes requirements for a purchased product or service that can be used in a contract with a supplier.

In many sectors today, design responsibility for a product or service lies with the supplier rather than with the customer organization. The party in the contract with responsibility and authority for establishing and maintaining the design records (i.e., the specification) is responsible for the design. Where this is the customer organization, it is best to not overengineer the design or specification up front. Even when suppliers are not responsible for the design, they often have valuable input to offer for design consideration. For example, they often can provide input that would improve the design or the cost of manufacture, such as:

- The manufacturability of the design
- Establishing nominal specifications and tolerances on dimensions, percentage of active ingredients, features, and various performance-related specifications
- Alternate materials or manufacturing processes

A supplier might have certain equipment and capabilities that influence the optimum design approach or requirements. When this is the case, the customer should send out an RFP rather than a request for quote (RFQ) to solicit ideas from potential suppliers to incorporate into the final design for later quoting. On the other hand, the customer should avoid specifications that only one supplier can meet.

TYPES OF AGREEMENTS

There are several tools an organization can use to make an authorized purchase. These typically depend on the spending level and include:

- Spot buys (onetime purchases for special or emergency situations)
- Contracts (formal documented arrangements with a supplier due to risk)
- Expense reports (minor office and travel expenses charged against a budget)
- Acquisition cards (a preauthorized spending tool)
- Evergreen contracts (formal arrangements with suppliers that automatically renew)
- Blanket contracts with releases (formal arrangements with suppliers that require specific follow-up information before execution of the contract, such as releasing quantities over time)

TEAM SUPPLIER SELECTION

Purchased product often represents a significant cost to an organization. When this is true, the sourcing selection should be the result of work of a cross-functional team. The criteria for sourcing should include quality and service as well as price. This requires the purchasing function to consult with and comprehend feedback from other disciplines such as quality, manufacturing, operations, risk, engineering, and after-market service in the sourcing decision.

NEGOTIATION

Chester Karrass is credited with saying, “In business as in life, you don’t get what you deserve, you get what you negotiate.” Negotiation is a learned skill. While some are naturally better at it than others, everyone can benefit from some training in the art of negotiation. The results of your negotiations with suppliers will depend on your negotiation skills and your leverage. Because leverage is usually on the customer’s side prior to an organization award, this is likely the best opportunity to reduce the cost of purchased products.

Buyer leverage is the amount of bargaining power buyers have when purchasing goods and services. The amount of buyer leverage relative to the bargaining power and leverage of the seller depends on the information the seller and buyer have about the product, the relative scarcity or abundance of the product, the availability of product substitutes, and many other factors. In some cases there may be grants, discounts, or government subsidies to promote trade for certain products, services, or industry sectors. The relative leverage of buyers and sellers determines the price and terms of transactions and the nature of business relationships.

Many organizations work to create or improve leverage for their purchases. There are some things you can do to get a better deal for your organization. These include:

- *Part number rationalization.* Part number proliferation fragments your total volume requirements across part numbers and drives up cost by causing extra manufacturing setups, start-ups, changeovers, inventory, warehousing, scheduling, tracking, and servicing. When it comes to part numbers, fewer is better.
- *Bundling awards.* Organizations that make repetitive purchases or use several purchased products that could come from one type of supplier can create leverage by requesting bids on more than one item at a time or by sourcing one item number on a long-term contract rather than as a spot buy.

PURCHASE ORDER PROCESS

To secure good quality of purchased materials, adequate and complete documentation should be issued to the supplier. A signed purchase order is a contract. To start the purchase order process, an individual or group (operations, engineering, district office) that requires the materials or components should prepare purchase requisitions and forward them to the procurement or purchasing manager. The purchase requisitions should reference the following:

- Material specifications with revision level
- Identification requirements
- Documentation requirements
- Need to send an inspector to witness source inspection

The purchase requisitions and purchase order or contract must incorporate these important points:

- All technical documentation defining the products, such as standards, specifications, and drawings, should be clearly identified, on the correct revision level, and enclosed when required.
- Adequate quality records, such as testing or inspection certificates, statistical process data, quality system certificate, and warrants, should be explicitly required in the purchase order.
- Requirements for notification of changes including source and/or composition of materials; manufacturing location; production, processing, or testing; certifications; or licensure.
- When purchasing toxic, hazardous, or otherwise restricted substances, the procurement or purchasing manager should include in the purchase order a request that the supplier provide a warrant or certificate that the substance and its packaging comply with governmental and safety regulations. Safety Data Sheets for all components should be supplied and reviewed by the firm's safety and environmental personnel to assure limited risk.

The procurement or purchasing manager should review and approve all purchasing documents prior to release, issue the inquiry to the suppliers in accordance with the purchase requisition, and select and issue the purchase order to the most appropriate supplier. Routine or repeat purchases can be approved for a specified quantity or period of time (blanket purchase orders). Sufficient data on requirements for product characteristics or service specifications should be clearly defined or attached.

CONTRACT RISK MANAGEMENT

Risk management and organization continuity planning should significantly drive purchasing contract strategy. When it comes to purchased goods and services, an organization can do a few things to mitigate risk. The following strategies have advantages and disadvantages:

- *Multiple sourcing.* Multiple, or dual, sourcing reduces supply risks, but it is expensive. When purchased product and services have to be qualified or validated, this requires redundant activities that drive up cost. It also divides the organization's total volume requirements over more than one supplier, which can result in forfeiture of any volume discounts. In special cases where the customer controls the design of a product, a duplicate set of tools, molds, or production equipment should be kept in a separate location to protect against potential disasters such as earthquake, fire, or flood. Having tooling and molds manufactured in an emerging market may be more cost-effective but may not provide comparable quality. One of the benefits of multiple sourcing is the ability to determine if changes in the process are operations related compared with supplier related if the multiple supplier's components are traceable in the process.

- *Build inventory.* Inventory is not a bad thing. Excess inventory is a bad thing, whether it is raw material, work in process, or finished goods. Excess inventory is one of the types of waste recognized by lean manufacturing, but carrying more inventory provides safety stock in case of an unforeseen problem. Dividing the inventory among multiple distribution warehouse sites may reduce risk. When customers elect to re-source a current production part or material, building inventory to use while qualifying the new supplier is usually a necessity.

Like multiple sourcing and dual tooling, building inventory can be costly. An organization should determine which of the options is most effective in mitigating risk at the optimal cost.

- *Qualify alternate part numbers or material.* This approach is used in industries such as commercial electronics in which several commodities can be readily and effectively substituted for a given application. This can also add cost by requiring multiple validations or qualifications. Many customers require suppliers to receive customer approval prior to shipping a new part or material to their locations. This requires the supplier to complete the customer-specific requirements for this approval, which also adds time and cost. In exchange, both the customer and supplier have a ready alternative if needed.
- *Supplier management requirements.* Contracts can include requirements to implement and maintain a management system certification. Assessment/certification of a supplier's management system gives the customer more confidence that the supplier will meet ongoing customer requirements but does not necessarily mitigate the risk of a sporadic outage or shortage.

Some sectors have developed sector-specific quality standards, such as IATF 16949 (automotive), AS9100 (aerospace), and ISO 13485 (medical devices), with third-party certification requirements for suppliers. Use of standards as a baseline for supplier management can minimize cost to organizations but usually falls short of including all the customer-specific requirements they would like.

Contracts can also include requirements for the supplier to maintain a documented and effective disaster recovery plan or to demonstrate it is prepared for a fire, cyberattack, or natural disaster.

PERFORMANCE RULES

Supplier performance results should be used by the customer to prioritize supplier development, establish an escalation or exit strategy, and influence future sourcing. Some customers effectively use contract incentives such as higher pricing for delivery by a specified date to drive better performance or, conversely, pricing penalties for missing a required timing deadline.

Supplier performance, including pricing, delivery, and service, is key to customer satisfaction. Customers and suppliers both need to work on it whenever possible. Open and timely communication and collaborative planning and problem solving are necessary to achieve the best performance over the life of a contract.

CONTRACT/ORDER REVIEW

The objective of contract review by the organization is to ensure that the contract requirements are adequately defined and the supplier has the ability to meet the defined requirements. This review ensures three things:

- Order requirements, including delivery schedule and the requirements for delivery and post-delivery activities such as handling, storage, installation, operation, and maintenance, are adequately defined and documented
- Contract or order requirements differing from those previously expressed are resolved
- The supplier has the ability to meet the defined requirements

Many low-risk and common products or services are purchased based on supplier catalog descriptions. Even for such products or services, however, the descriptions should be clearly referenced when ordering.

If a supplier received the order verbally and does not have the order requirements documented, there is a possibility that the supplier's performance will be unsatisfactory and result in a dispute or legal action.

CONFIRM REQUIREMENTS

The supplier should confirm the order requirements before acceptance by documenting the contract terms and specifications in some appropriate manner with the supplier's signature and submitting it for confirmation.

AMENDMENTS

When the organization changes product or service requirements, suppliers need to know about the change. These changes are normally amended to the original contract as a change order.

For customized products such as chairs, every order must be reviewed and verified due to lot-to-lot or batch-to-batch variations in color, size, mechanisms, fabric, and ergonomics.

In summary, a good supply agreement assures all parties have a thorough understanding of what is expected of each party for the mutual benefit of both.

Chapter 5

E. Deployment of Strategy and Expectations

Supplier strategy captures the set of guidelines that dictate definitions and expectations. Such expectations may include specifications, deliverables, process or product yields, and other measurable outputs. Though at times the intent may appear one-sided, favoring the business (i.e., the customer), the ideal supplier management relationship is based on mutual benefit. The customer provides the requirement of the provision of consistently high quality, and in the process of achieving this, the supplier learns to increase productivity in its manufacturing operation, which results in reduced internal costs. The customer is then able to control the incoming product quality (Bossert 2004, 9). How can this ideal state be achieved?

The key to successful deployment of supplier strategy is good communication, internal and external. It is best to think of the relationship as more of a synergic one, wherein the actions of the business (i.e., the internal side) are linked to the supplier (i.e., the external side). Figure 5.1 shows how the two are linked and the various points that an organization should consider when seeking a successful approach to the supplier management relationship.

INTERNAL COMMUNICATION

The need for a supplier typically arises in the product development phase. At this point the business should begin to evaluate what its exact need is, whether it be a material or a service.

Identifying the roles and responsibilities of the business is the next step in internal alignment. In this discussion, the business should determine what boundaries

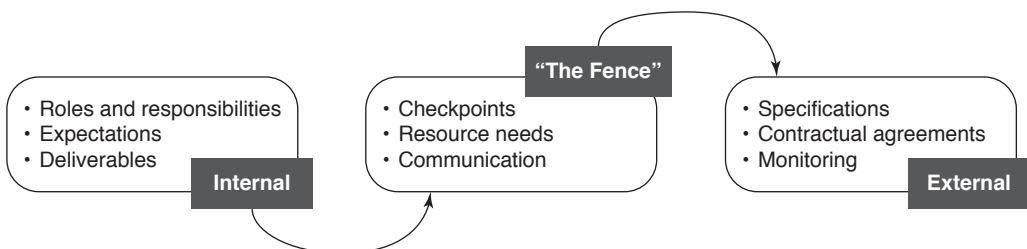


Figure 5.1 The link between the internal and external partners in developing a successful supplier management relationship.

to set in the supplier relationship. In cases where the business is simply looking for a solution and has no set requirements, the provision of materials or services originates from the supplier. It is difficult to evaluate quality and acceptability in these circumstances, as the business does not have the necessary technical knowledge and competence. On the opposite end of the spectrum, a business may produce specifications (e.g., design, working parameters) with an expected output in mind. They are able to provide acceptability levels and easily identify opportunities during the production process. In both cases, the business needs to identify and agree upon its various roles and associated responsibilities from the beginning of the supply chain to the end.

Once roles and responsibilities are established, expectations can be laid out as to how execution will occur. The business should list attributes leading to what it wants, assess potential areas of risk or failure, perform any necessary financial analysis (e.g., budget review), and determine when the business has achieved its goals. Once the responsibilities and expectations are aligned, a set of deliverables can be documented and passed on to the supplier.

Knowing what the supplier needs to achieve and having organizational alignment is the ideal scenario. The deliverables should include the material or service requirements at a given time and at a given price. When obtaining consulting services, for example, the business must define what exactly the consultant will be doing and for how long, what the end goals are, and what the rate and maximum amount are.

THE FENCE: BRIDGING THE INTERNAL AND EXTERNAL

Once aligned, the business is ready to execute the next phase of supplier deployment. It is at the “fence” where the project manager (or whoever is leading the supplier development) must prepare the information for their external partner (i.e., supplier).

As a verification that the business is ready to deliver its deployment strategy, checkpoints may be set up to evaluate the list of checkpoints. Figure 5.2 shows a table that captures items that are part of a business’s “go-live.”

The team should also determine whether additional resources will be needed at either end (i.e., internally or externally). If the roles and responsibilities in the

Enter √	Must-haves for deployment
	Business points of contact: quality, operations, procurement (roles and responsibilities)
	Definitions and terms
	Material/service specifications
	Pricing
	Contractual agreements (drafted and include all requirements and deliverables for supplier review and acceptance)
	Terms of completion (should also specify how incomplete or unacceptable work will be managed)

Figure 5.2 Go-live checkpoints.

supplier engagement add work that none of the internal team members can take on, the business must think of a way to address the issue. One solution is to pass this work on to the supplier. However, the business needs to recognize that this will be an added cost.

When suppliers provide a bid or a standard price for what it would take to deliver a material or service, they generally consider how the work will impact their existing resources. They ask themselves the following questions:

- Would we need inventory space?
- Would we need to hire more people?
- Can we source the material that our customers want at the anticipated price point?
- Can we meet the customer's deadline with our existing setup?
- Would additional or new equipment be needed?

Nothing beyond what is disclosed in the SOW is accounted for in the process. This is why the business has to be transparent about everything it needs to ensure a successful deployment. This includes the request of meeting quality requirements. Product certification, for example, may appear to be a simple task, but the additional time needed to collect the data, analyze them, and document for certification at every order is an added cost to the supplier.

Communication is key to success in any partnership, including one between business and supplier. The information provided must be delivered in whole and in agreement. Negotiations may take place between the business and supplier in order for both parties to meet at an agreeable point; this is expected. However, this will not happen until the next phase, when the business moves forward with its external partner and delivers the information.

EXTERNAL COMMUNICATION

When a business comes to a supplier with a need, the supplier sees an opportunity—an opportunity for additional income as well as an opportunity to showcase its expertise. A mature supplier organization, however, knows that its success can be achieved only through preparation, planning, and organization.

As SMEs, suppliers know how to provide the end product. It is the details that they are most concerned with, since they need to ensure that customer requirements are met. For this reason, the first information the supplier should receive from the customer are specifications. Specifications should include the acceptance criteria, tolerances (if any), material limitations (e.g., substance maximums/minimums, microbial organisms), test standards, quality requirements, and any other applicable information. This allows the supplier to know whether it can meet the requirements.

When a supplier has determined that it can meet the requirements, external communication should next include contractual agreements. The agreements convey to the supplier the terms of providing the material or service of choice. The terms, as mentioned earlier, may be subject to negotiation. A supplier's legal representative may also be asked to review the document.

Once everything is agreed upon, the success of the supplier deployment can be measured through monitoring. It is best practice to consider the type of monitoring and the metrics to be monitored. The supplier truly becomes a partner when it is aware of all expectations, especially those that are measured. In some cases, the monitoring phase becomes an incentive for suppliers to improve their processes and hopefully gain more business. The feedback begins a two-way conversation when requirements are not met. The reality is that expectations in writing may not always match up with actual production data. The practice of making changes without proper documentation can lead to issues that may damage the relationship.

Successful supplier deployment strategies must originate from the business internally before expectations are delivered externally, as communication is only as good as the information being provided. Ideal situations may not always occur, but by using a proper approach, it is possible to meet a material or service need without causing frustration on the customer or supplier side.

Part VIII

Appendices

- Appendix A** Certified Supplier Quality Professional
Body of Knowledge
- Appendix B** Sample Risk Assessment Template
- Appendix C** Acronym List
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Appendix A

Certified Supplier Quality Professional Body of Knowledge

The topics in this body of knowledge (BOK) include subtext explanations and the cognitive level at which the questions will be written. This information will provide useful guidance for both the Exam Development Committee and the candidate preparing to take the exam. The subtext is not intended to limit the subject matter or be all-inclusive of the material that will be covered in the exam. It is meant to clarify the type of content that will be included on the exam. The descriptor in parentheses at the end of each entry refers to the maximum cognitive level at which the topic will be tested. A complete description of cognitive levels is provided at the end of this appendix.

I. Supplier Strategy (22 Questions)

A. Supply Chain Vision/Mission

Assist in the development and communication of the supply chain vision/mission statement. (Apply)

B. Supplier Lifecycle Management

1. Supplier Selection

Develop the process for supplier selection and qualification including the identification of sub-tier suppliers, using tools such as SIPOC and decision analysis. (Create)

2. Performance Monitoring

Develop the supplier performance monitoring system including expected levels of performance, process reviews, performance evaluations, improvement plans, and exit strategies. (Create)

3. Supplier Classification System

Define a supplier classification system, e.g., non-approved, approved, preferred, certified, partnership, and disqualified. (Create)

4. Partnerships and Alliances

Identify and analyze strategies for developing customer-supplier partnerships and alliances. (Analyze)

C. Supply Chain Cost Analysis

1. Cost Reduction

Identify and apply relevant inputs to prioritize cost reduction opportunities. (Analyze)

2. Supply Chain Rationalization

Interpret and analyze the optimization of a supply base to improve spending and leverage investments into supplier quality, or risk reduction. (Analyze)

3. Make/Buy Decisions

Provide input on make/buy decisions by using internal and external capability analysis. Apply tools such as SWOT analysis and use historical performance to analyze requirements. (Analyze)

D. Supplier Agreements or Contracts

Review and provide input for developing terms and conditions that govern supplier relationships to ensure quality considerations are addressed. (Apply)

E. Deployment of Strategy and Expectations

Communicate strategy internally and communicate expectations to suppliers externally. (Apply)

II. Risk Management (14 Questions)

A. Strategy

1. System

Develop a risk-based approach to manage the supply base, including business continuity and contingency planning. (Create)

2. Product/Service

Develop and implement a risk mitigation plan to minimize, monitor, and/or control risks. (Evaluate)

3. Prevention Strategies

Identify and evaluate strategies and techniques such as supply chain mapping, avoidance, detection, and mitigation used to prevent the introduction of counterfeit parts, materials, and services. (Evaluate)

B. Analysis and Mitigation

1. Analysis

Identify, assess, and prioritize risks to supplier quality using tools such as decision analysis (DA), failure modes and effects analysis (FMEA), fault tree analysis (FTA), and process auditing. (Evaluate)

2. Mitigation Control

Develop and deploy controls such as inspection and test plan. Prioritize mitigation activities and sustain a risk mitigation plan appropriate to the risk of the product/service. (Create)

3. Mitigation Effectiveness

Verify the effectiveness of the control plan and improve if necessary, using continuous improvement methods such as plan-do-check-act (PDCA), lean, and product auditing tools. (Create)

III. Supplier Selection and Part Qualification (30 Questions)

A. Product/Service Requirements Definition

1. Internal Design Reviews

Identify and apply common elements of the design review process, including roles and responsibilities of the participants. (Apply)

2. Identifying Requirements

Identify and apply internal requirements (e.g., interrelated functional business units) for product or service in collaboration with stakeholders, including the requirements for supply chain and sub-tier suppliers. (Evaluate)

B. Supplier Selection Planning

1. Supplier Comparison

Evaluate existing suppliers' capabilities, capacities, past quality, delivery, price, lead times, and responsiveness against identified requirements. (Evaluate)

2. Potential Supplier Evaluation

Assess potential new suppliers against identified requirements using tools such as self-assessments, audits, and financial analysis. Verify third-party certification status and regulatory compliance and analyze and report on results of assessments to support the supplier selection process. (Evaluate)

3. Supplier Selection

Evaluate and select supplier based on analysis of assessment reports and existing supplier evaluations, using decision analysis tools and selection matrices. (Evaluate)

C. Part, Process, and Service Qualification

1. Technical Review

Interpret and evaluate technical specification requirements and characteristics such as views, title blocks, and dimensioning, tolerancing, and GD&T symbols as they relate to product and process. (Evaluate)

2. Supplier Relations

Collaborate with suppliers to define, interpret, and classify quality characteristics for the part/process/service. (Evaluate)

3. Process and Service Qualification Planning

Develop a part/process/service qualification plan with supplier and internal team that includes calibration requirements, sample size, first article inspection, measurement system analysis (MSA), process flow diagram (PFD), failure modes and effects analysis (FMEA), control plans, critical to quality (CTQ), inspection planning, capability studies, material and performance testing, appearance approval, and internal process validation. (Analyze)

4. Part Approval

Understand the production part approval process (PPAP) requirements and ensure suppliers understand the processes required to produce parts with consistent quality during an actual production run at production rates. (Understand)

5. Validate Requirements

Collaborate with internal team to interpret the results of the executed qualification plan for the part/process/service. (Evaluate)

IV. Supplier Performance Monitoring and Improvement (30 Questions)

A. Supplier Performance Monitoring

1. Supplier Metrics

Define, implement, and monitor supplier performance metrics such as quality, delivery, cost, and responsiveness. (Evaluate)

2. Supplier Performance

Analyze supplier performance data (e.g., warranty analysis/field returns, defect rates) and develop periodic reports (e.g., scorecard, dashboards). (Analyze)

3. Supplier Process Performance

Apply lean principles and applications such as 5S, kaizen, value stream mapping, single-minute exchange of dies (SMED), kanban, muda, standardized work, takt time, and error proofing to reduce waste and increase performance. (Evaluate)

B. Assess Nonconforming Product/Process/Service

Assess and evaluate nonconforming materials to determine whether a material review board (MRB) requires disposition. Conduct risk assessments to prevent future discrepancies. (Evaluate)

C. Supplier Corrective and Preventive Action (CAPA)

1. Root Cause Analysis Tools and Methods

Evaluate the root cause analysis of a problem using tools such as cause and effect diagrams (CE), Pareto analysis, 5Y's, fault tree

analysis, design of experiments (DOE), brainstorming, check sheets, measurement system analysis (MSA), production records, and review of process flow. (Evaluate)

2. Collaboration with Supplier

Evaluate and implement corrective/preventive action and review its effectiveness and robustness with supplier. Understand the process of updating failure modes and effects analysis (FMEA) and process control plan, statistical process control (SPC), and product and process design change. (Evaluate)

V. Supplier Quality Management (30 Questions)

A. Supplier Quality Monitoring

1. Supplier Audit

Describe and distinguish between the stages of a quality audit, from audit planning through conducting the audit. Understand and apply the various types of quality audits such as product, process, and management system. (Apply)

2. Audit Reporting and Follow-up

Apply process audit reporting and follow-up, including verification of the effectiveness of corrective action. (Apply)

3. Supplier Communication

Evaluate various communication techniques such as periodic reviews, metric and performance indices, change management, notifications, recalls, change requests, and business updates. Maintain active communication with suppliers to assess risk and take appropriate action. (Evaluate)

4. Supplier Development and Remediation

Identify and analyze present and future training needs and gaps using quality methods and tools such as kaizen and benchmarking. Use process improvement tools such as DMAIC, cycle time reduction, defect rate, and cost reduction. Evaluate supplier remediation to develop and manage improvement plans. (Evaluate)

5. Project Management Basics

Understand and apply various types of project reviews, such as phase-end, management, and retrospectives or post-project reviews to assess project performance and status, review issues and risks, and discover and capture lessons learned from the project. Apply forecasts, resources, schedules, and task and cost estimates to develop and monitor project plans. (Apply)

B. Teams and Team Processes

1. Team Development

Identify and describe the various types of teams and the classic stages of team development: forming, storming, norming, performing, and adjourning. (Apply)

2. Team Roles

Define and describe various team roles and responsibilities for leader, facilitator, coach, and individual member. (Understand)

3. Performance and Evaluation

Describe various techniques to evaluate training, including evaluation planning, feedback surveys, and pre-training and post-training testing. (Understand)

C. Compliance with Requirement and Supplier Categorization

Understand and evaluate compliance with regulations (e.g., RoHS, governmental regulatory authorities), specifications, contracts, agreements, and certification authority (e.g., UL, TUV). Evaluate and categorize suppliers based on risk and performance. (Evaluate)

VI. Relationship Management (14 Questions)

A. Supplier Onboarding

Understand and apply processes for orientation of suppliers such as providing overview of company, vision, mission, guiding principles, overall requirements, expectations, and criticality of product, service, and delivery requirements. (Apply)

B. Communication

1. Techniques and Mediation

Identify and apply communication techniques (oral, written, and presentation) specifically for internal stakeholders and suppliers to resolve issues. Apply different techniques when working in multicultural environments and identify and describe the impact that culture and communications can have on quality. (Evaluate)

2. Reporting Using Quality Tools

Use appropriate technical and managerial reporting techniques, including the seven classic quality tools (Pareto charts, cause and effect diagrams, flowcharts, control charts, check sheets, scatter diagrams, and histograms), for effective presentation and reporting. (Analyze)

C. Leadership and Collaboration

Understand and apply techniques for coaching suppliers through regular communications, influencing without authority, and negotiation techniques and establish clear roles and responsibilities of internal stakeholders and suppliers. (Evaluate)

VII. Business Governance, Ethics, and Compliance (10 Questions)

A. ASQ Code of Ethics

Determine appropriate behavior in situations requiring ethical decisions, including identifying conflicts of interest and recognizing and resolving ethical issues. (Apply)

B. Compliance

Understand issues of compliance and their applicable policies, laws, and regulations (e.g., conflict of interest, confidentiality, bribery). (Apply)

C. Confidentiality**1. Organizational Policies**

Apply organizational policies for executing appropriate agreements such as nondisclosure, quality, and change notification agreements. (Apply)

2. Intellectual Property

Apply procedures for protecting the intellectual property of an organization and its suppliers. (Apply)

3. Illegal Activity

Understand and interpret policies for reporting observations and deviations that could be perceived as illegal activity. (Apply)

LEVELS OF COGNITION BASED ON BLOOM'S TAXONOMY—REVISED (2001)

In addition to content specifics, the subtext for each topic in this BOK also indicates the intended complexity level of the test questions for that topic. These levels are based on “Levels of Cognition” (from Bloom’s Taxonomy—Revised, 2001) and are presented below in rank order, from least complex to most complex.

Remember

Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.

Understand

Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Apply

Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.

Analyze

Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

Evaluate

Make judgments about the value of proposed ideas, solutions, etc., by comparing the proposal to specific criteria or standards.

Create

Put parts or elements together in such a way as to reveal a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.

Appendix B

Sample Risk Assessment Template

Step 1: Risk identification	Step 2: Risk assessment		Step 3: Managing risks					
Possible risks	Impact (H/M/L)	Likelihood (HML)	What are we already doing about it?	What more can we do about it?	When will it be done?	Who will do it?	How will we review progress?	Reviewed level of risk

Person/group responsible for review	Date to be reviewed

Appendix C

Acronym List

AAR—appearance approval report
ABC—anti-bribery and corruption
AIAG—Automotive Industry Action Group
ANOVA—analysis of variance
ANSI—American National Standards Institute
API—active pharmaceutical ingredient
APQP—Advanced Product Quality Planning
AQL—acceptable quality level
ASAP—as soon as possible
ASL—approved supplier list
ASME—American Society of Mechanical Engineers
ASQ—American Society for Quality
ASTM—American Society for Testing and Materials
AVL—approved vendor list
BOK—body of knowledge
BoM—bill of materials
CA—confidentiality agreement
CAPA—corrective and preventive action
CCP—critical control point
CDA—confidential disclosure agreement
CFR—Code of Federal Regulations
cGMP—current good manufacturing practice
CISG—Contracts for International Sale of Goods
CLEAR—collaborative-limited-emotional-appreciable-refinable
CMDCAS—Canadian Medical Devices Conformity Assessment System
CMDR—Canadian Medical Device Regulation
CO—change order

COA—certificate of analysis
COC—certificate of compliance
COGS—cost of goods sold
COPQ—cost of poor quality
COPQA—cost of poor quality analysis
COTS—commercial off-the-shelf
CP—control plan
C_{pk}—process capability index
CPP—critical process parameters
CQ—component qualification
CQA—critical quality attribute
CQI—continuous quality improvement
CR—capability ratio
CSD—Customer-Supplier Division
CSQP—certified supplier quality professional
CTQ—critical to quality
DCO—document change order
DFSS—Design for Six Sigma
DHR—device history record
DMAIC—define-measure-analyze-improve-control
DMF—drug master file
DOE—design of experiments
DPMO—defects per million opportunities
DQ—design qualification
ECHA—European Chemical Agency
ECO—engineering change order
EDMS—electronic document management system
ERP—enterprise resource planning
ESI—early supplier involvement
EU—European Union
FAI—first article inspection
FAL—first article layout
FAT—factory acceptance testing
FCPA—Foreign Corrupt Practices Act
FCR—facility change request
FDA—US Food and Drug Administration
FMA—failure mode analysis

FMEA—failure modes and effects analysis
FMECA—failure modes, effects, and criticality analysis
FTA—fault tree analysis
GD&T—geometric dimensioning and tolerancing
GIP—good importer practice
GMP—good manufacturing practice
HACCP—hazard analysis and critical control points
HAZOP—hazard operability analysis
IATF—International Automotive Task Force
ICH—International Conference on Harmonization
IM&TE—inspection, measuring, and test equipment
IP—intellectual property
IPC—in-process control
IQ—installation qualification
IQA—incoming quality assurance
ISIR—initial sample inspection report
ISO—International Organization for Standardization
ITAR—International Traffic in Arms Regulations
JIT—just-in-time
KPI—key process indicator
LCL—lower control limit
LSL—lower specification limit
MBNQA—Malcolm Baldrige National Quality Award
MBR—master batch record
MDD—Medical Device Directive
MRB—material review board
MRP—material requirements planning
MRP II—manufacturing resource planning
MSA—measurement system analysis
MSDS—material safety data sheet
MTBF—mean time before failure
NCM—nonconforming materials
NCR—nonconformance report
NDA—nondisclosure agreement
OEM—original equipment manufacturer
OFAT—one factor at a time
OIL—open issues list

OOO—out of calibration
OOS—out of specification
OOT—out of tolerance
OQ—operational qualification
OTS—off the shelf
PA—preventive action
PCI—process capability index
PCP—process control plan
PCT—Patent Cooperation Treaty
PDCA—plan-do-check-act
PHA—preliminary hazard analysis
PIA—proprietary information agreement
PID—project initiation document
PMBOK—Project Management Body of Knowledge
PMI—Project Management Institute
PO—purchase order
PPAP—production part approval process
PPQ—process performance qualification
PPV—purchase price variance
PQ—performance qualification
PQR—product quality review
PSW—Part Submission Warrant
QA—quality assurance
QbD—quality by design
QC—quality control
QCU—quality control unit
QFD—quality function deployment
QMS—quality management system
QSR—Quality System Regulation
QU—quality unit
R&D—research and development
R&R—roles and responsibilities
RACI—responsible-accountable-consulted-informed
REACH—registration, evaluation, authorization and restriction of chemicals
RFI—request for information
RFP—request for proposal

RFQ—Request for quote
RMP—risk management plan
RoHS—Restriction of Hazardous Substances
ROI—return on investment
RPN—risk priority number
SA—secrecy agreement
SAE—Society of Automotive Engineers
SC—supply chain
SCAR—supplier corrective action request
SCM—supply chain management
SEC—Securities and Exchange Commission
SIM—supplier information management
SIPOC—suppliers-inputs-process-outputs-customers
SKU—stock keeping unit
SLM—supplier lifecycle management
SMART—specific-measurable-attainable-realistic-timely
SME—subject matter expert
SMED—single-minute exchange of dies
SOP—standard operating procedure
SOW—statement of work
SPC—statistical process control
SQA—supplier quality agreement
SQAM—Supplier Quality Assurance Manual
SQE—supplier quality engineer
SQP—supplier quality professional
SRM—supplier relationship management
STS—ship-to-stock
SWOT—strengths, weaknesses, opportunities, and threats
TCO—total cost of ownership
TE—technical expert
TMV—test method validation
TRF—total risk factor
UCC—Uniform Commercial Code
UL—Underwriters Laboratories
USDA—US Department of Agriculture
USML—United States Munitions List

VMP—validation master plan

VOE—verification of effectiveness

WCT—WIPO Copyright Treaty

WEEE—waste electrical and electronic equipment

WIPO—World Intellectual Property Organization

WPPT—WIPO Performances and Phonograms Treaty

WTO—World Trade Organization

Glossary

A

acceptance sampling—Sampling inspection in which decisions are made to accept or not accept product or service; the methodology that deals with procedures by which decisions to accept or not accept are based on the results of the inspection of samples.

accreditation—The formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to international standards.

accuracy—The degree to which the result of a measurement, calculation, or specification conforms to the correct value or a standard.

action level—Specification or limit established in published regulation (or a guidance, guideline, or standard that is regarded by competent authorities as de facto regulation) that, when exceeded, requires immediate intervention, including investigation of cause, immediate remediation, and/or corrective action.

actual yield—The quantity that is actually produced at any appropriate phase of manufacture, processing, or packing of a particular product.

Advanced Product Quality Planning (APQP)—Quality process for developing new products that uses up-front quality planning and evaluates the output to determine whether customers are satisfied.

alpha (α) risk—The probability of erroneously claiming a difference in two averages or two variances; the risk that the decision will be made that a part is defective when it really is not.

analysis of variance (ANOVA)—Basic statistical technique for analyzing experimental data. It subdivides the total variation of a data set into meaningful component parts associated with specific sources of variation, including interactions.

appraisal cost—Cost associated with measuring, evaluating, or auditing products, components, and purchased material to ensure conformance with quality standards and performance requirements.

attribute measurement—Qualitative measurement that typically shows only the number of parts or the number of defects per part failing to conform to specified criteria.

audit—The on-site verification activity, such as inspection or examination, of a process or quality system to ensure compliance to requirements. An audit can apply to an entire organization or might be specific to a function, process, or production step.

B

batch number—Any distinctive combination of letters, numbers, or symbols from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of product or other material can be determined.

beta (β) risk—The probability of erroneously not claiming a difference in two averages or two variances; the risk that the decision will be made that a part is not defective when it really is.

bias—The difference between a measured value and a known or accepted reference value.

bilateral tolerance—Splitting of a tolerance by a median axis so that each side is identical.

business continuity plan—A document specifying tasks or activities needed to ensure that critical business functions in an organization will continue to be available to customers, suppliers, regulators, and other entities that must have access to those functions.

C

calibration—Comparison of two instruments or measuring devices, one of which is a standard of known accuracy traceable to national standards, to detect, correlate, report, or eliminate by adjustment any inaccuracy of the instrument or measuring device, as compared to the standard.

can—Indicates a possibility or a capability in regard to a standard.

capability ratio (Cr)—Measurement of the proportion of specification width that is consumed by process variation.

certification—The provision by an independent body of written assurance (a certificate) that the product, service, or system in question meets specific requirements.

change control—A written procedure that describes the action to be taken if a change is proposed to facilities, materials, equipment, and/or processes used in the fabrication, packaging, and testing, or that may affect the operation of the quality or support system.

cleanroom—A room that is maintained to be virtually free of contaminants, such as dust or bacteria, used in laboratory work and in the production of precision parts for electronic or aerospace equipment.

common cause variation—Causes of variation that are inherent in a process over time. They affect every outcome of the process and everyone working in the process.

confidence interval—Range within which a parameter of a population (e.g., mean and standard deviation) may be expected to fall, on the basis of measurement, with some specified confidence level.

consumer's risk—In sampling, the potential risk that bad products will be accepted and shipped to the consumer.

continual improvement—Ongoing activities to evaluate and positively change products, processes, and the quality system to increase effectiveness.

contract—An agreement entered into voluntarily by two or more parties with the intention of creating a legal obligation. It may have elements in writing, although contracts can be made orally.

control chart—A statistical tool including upper and lower control limits and the process average, which visually displays process performance.

control limits—The area three standard deviations on either side of the centerline, or mean, of data plotted on a control chart.

control number. See *batch number*.

control plan—Plan that establishes and maintains adequate written procedures covering all critical characteristics and key processes to ensure a consistent and acceptable quality product.

controlled area—A nonclassified room or operating area designed to control or minimize the presence, proliferation, and/or ingress of particulates, and in which specific environmental conditions (e.g., temperature, humidity, directional airflow, and viable and nonviable particulate limits) are defined and monitored to prevent contamination of exposed products.

correction—Repair, rework, or adjustment relating to the disposition of an existing discrepancy (also called *remedy* or *remediation*); usually the first step in a corrective action.

corrective action—Resolution of problems between user and producer arising due to product nonconformance.

critical process parameter (CPP)—Quantifiable equipment setting whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure that the process produces the desired quality, purity, potency, and safety.

critical quality attribute (CQA)—Physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

customer—Person or organization (internal or external) that receives a product or service at any point in the product's lifecycle.

customer complaint—Formal or informal allegation by the customer due to failure in meeting previously agreed-upon requirements by the supplier.

D

dashboard—Visuals used in manufacturing to identify good or poor performance of a process.

decision maker(s)—Person(s) with the competence and authority to make appropriate and timely decisions.

design of experiments (DOE) or experimental design—Statistical technique used for planning, conducting, analyzing, and interpreting sets of experiments, aimed at making sound decisions most efficiently.

design space—Multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality.

destructive testing—Measurement, testing, and inspection of product or material that damages or destroys the product or material so it is not usable. Contrast with non-destructive testing.

detectability—Ability to discover or determine the existence, presence, or fact of a hazard.

deviation—Process through which a producer is authorized to ship nonconforming products to the user with the user's concurrence.

discrepancy—Datum or result outside of the expected range; an unfulfilled requirement; may be called nonconformity, defect, deviation, out-of-specification, out-of-limit, or out-of-trend.

discrimination—Discrimination, or *resolution*, of a measurement system is its capability to detect and indicate even small changes in the measured characteristic. The main consideration when selecting or analyzing a measurement system.

disposition—Final arrangement or settlement of nonconforming product in an orderly way.

distributor—Nonmanufacturing source of product, usually where no transformation of product takes place; an intermediary between a manufacturer and retailer or customer.

drawing (blueprint)—Sketch of the product being produced with specified tolerances of each characteristic.

E

effectiveness—The state of having produced a decided-on or desired effect.

engineering support—Essential part of a good quality system that encompasses product design and development as well as reliability testing of new or revised products.

external failure cost—Cost generated by defective products in the field after having been shipped to customers.

F

failure costs—Costs resulting from materials, products, or services failing to conform to requirements or customer/user needs, or not manufactured in compliance with applicable regulations.

failure modes analysis (FMA)—A procedure used to determine which malfunction symptoms appear immediately before or after the failure of a critical parameter in a system. After all possible causes are listed for each symptom, the product is designed to eliminate the problems.

failure modes and effects analysis (FMEA)—A systematized group of activities performed to recognize and evaluate the potential failure of a product or process and its effects, identify actions that could eliminate or reduce the occurrence of the potential failure, and document the process.

failure modes, effects, and criticality analysis (FMECA)—A procedure performed after a failure modes and effects analysis to classify each potential failure effect according to its severity and probability of occurrence.

final inspection—Examination of a product to ensure that it conforms to all applicable specifications and requirements before it is packaged and shipped to the customer.

financial analysis—An assessment used to evaluate financial stability for continued business through the contract phase or financial stability to support the manufacturing process and resources.

finished product—Batch of product in its final pack for release to the market.

first article inspection (FAI)—The practice of inspecting the first item, part, unit, group, or batch produced from a production run. A complete, independent, and documented physical and functional inspection process to verify that prescribed production methods have produced an acceptable item as specified by engineering drawings, planning, purchase order, engineering specifications, and/or other applicable design documents.

flowchart—Diagram that shows step-by-step progression of a product through a manufacturing system showing all factors that could adversely affect quality at the point where they occur.

flow-down requirement—A supplier requirement that must be passed down or delegated to sub-tier suppliers. Material or service specifications are often flowed down or passed down to the supplier's suppliers.

frequency distribution—Tabulation of the number of times a given outcome has occurred within the sample of products being checked.

G

gage repeatability—Measurement of the consistency obtained with one gage when used several times by one operator while measuring the identical characteristic on the same parts.

gage repeatability and reproducibility (gage R&R)—The evaluation of a gauging instrument's accuracy by determining whether its measurements are repeatable and reproducible.

gage reproducibility—Measurement of the consistency of different operators using the same gage while measuring the identical characteristic on the same parts.

gage variability—Measurement of the consistency of at least two sets of measurements obtained with a gage on the same parts as a result of time.

guard banding—The practice of utilizing the gage R&R results to reduce the range of acceptance to ensure that features are within the prescribed specifications.

H

harm—Damage to health, including the damage that can occur from loss of product quality or availability.

hazard—Potential source of harm.

hazard analysis and critical control points (HACCP)—A QMS for effectively and efficiently ensuring farm-to-table food safety in the United States. HACCP regulations for various sectors are established by the Department of Agriculture and FDA.

housekeeping—General cleaning (including sweeping) and removal of accumulated process waste, dirty equipment, utensils, and other nonproduct.

I

incoming inspection—Inspection of purchased parts at the customer's facility after the shipment of parts from the supplier to ensure supplier compliance with specifications and contractual agreements.

in-process control—One of various control strategies that measures a critical quality attribute (CQA) at a particular point in a manufacturing process.

inspection—Process of measuring, examining, testing, gauging, or otherwise comparing the unit with the applicable requirements.

installation qualification (IQ)—Establishes, by objective evidence, that all key aspects of the process equipment and ancillary system installations adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are suitably considered.

internal failure costs—Costs generated by a producer in making defective and nonconforming materials and products that do not meet company quality specifications.

K

key process characteristics—Manufacturing processes deemed crucial in producing a product to meet its design intent.

key product characteristics—Properties deemed crucial by the user to satisfy the design intent.

L

laboratory—A test facility that can include chemical, metallurgical, dimensional, physical, electrical, and reliability testing or test validation.

lead time—The time between the initiation and completion of a process.

line clearance—A procedure used to prevent mix-ups and/or comingling involving product, packaging, and labeling.

lot—A batch, or a specific identified portion of a batch, having uniform character and quality within specified limits.

lot control—System that provides the means to trace pertinent information about the materials and/or components comprising a given product.

lot number. See *batch number*.

M

material certification—Process through which documented evidence establishes that a product is in compliance with designated specifications.

material review board (MRB)—Quality control committee or team, usually employed in manufacturing or other materials-processing installations, that has the responsibility and authority to deal with items or materials that do not conform to fitness-for-use specifications.

may—Indicates a permission/recommendation in regard to a standard.

measurement system analysis (MSA)—An analysis that considers operations, procedures, devices, and other equipment or personnel used to assign a value to the characteristic being measured.

measuring and testing devices—Equipment used to evaluate a product's conformance to its specifications.

must—Indicates a requirement in regard to a standard.

N

nonconforming material—Material that is not in compliance with specifications.

nonconforming report (NCR)—A permanent record—made in writing—for accounting and preserving the knowledge of a nonconforming condition for the purposes of documenting facts or events.

nonconformity—Deficiency in a characteristic, product specification, process parameter, record, or procedure that renders the quality of a product unacceptable, indeterminate, or not according to specified requirements.

normal distribution—Condition where measured variation is symmetric about a central value and has a bell-shaped form.

O

operational—Occupancy state in which the installation is functioning in a defined manner, with a specified number of personnel present and working in a defined manner.

operational qualification (OQ)—Establishes by objective evidence that the equipment process control limits meet all predetermined requirements.

outliers—Observed points that are distant from other observations; abnormal responses resulting from special causes or uncontrolled influences that occur during an experiment.

out-of-control process—A process in which the statistical measure being evaluated is not in a state of statistical control. In other words, the variations between the observed sampling results cannot be attributed to a constant system of chance causes.

out of specification (OOS)—All in-process laboratory tests that are outside of established specifications.

out of tolerance (OOT)—During calibration, an item that is not within specification limits.

P

Pareto chart—A graphical tool for prioritizing effects.

performance qualification (PQ)—Establishes by objective evidence that a process consistently produces a result and/or product that meets the predetermined requirements (reproducible and repeatable).

pest control—System for preventing, evaluating, and eliminating infestation by rodents, insects, birds, and other vermin.

precision—The number of significant digits to which a value has been reliably measured; the ability of an instrument to repeat the same reading when making the same measurement in the same manner and under identical conditions.

prevention costs—The cost of all activities specifically designed to prevent poor quality in materials, products, or services (e.g., validation, PPAP, capability analysis, quality planning, training and quality education, design review, FMEA, DFSS, quality by design).

preventive action—Action taken to eliminate the cause of a potential discrepancy or other potential undesirable situation to make such an occurrence less probable.

preventive maintenance—Service, cleaning, lubrication of parts, alignment, adjustment, functional test, repair, modification, and overhaul, as required, to ensure there is no deterioration of equipment performance.

procedure—The steps in a process and how these steps are to be performed in order for the process to fulfill a customer's requirements; usually documented.

process—Combination of people, equipment, materials, methods, and environment that produces output to a planned effect.

process audit—Analysis of elements of a process and appraisal of completeness, correctness, or conditions.

process capability—A statistical measure of the inherent process variability of a given characteristic. The most widely accepted formula for process capability is Six Sigma.

process capability index—The value of the tolerance specified for the characteristic, divided by the process capability. The several types of process capability indexes include the widely used C_{pk} and C_p .

process control—The method for keeping a process within boundaries; the act of minimizing the variation of a process.

process development studies—Experiments that help rule in or rule out the choice and sequence of specific unit operations and unit processes and their associated detailed choices of equipment models and critical process parameters for manufacturing.

process performance qualification (PPQ)—The collection and evaluation of data, from the process-design stage through commercialization, that establishes scientific evidence that a process is capable of consistently delivering quality products.

process survey—Survey used to evaluate whether a supplier has process controls in place to ensure that the supplier's process will manufacture quality products. Process controls include proper tooling, equipment, and inspection.

process validation—Establishing by objective evidence that a process consistently produces a result or product meeting its predetermined requirements.

procurement quality—Any and all aspects dealing with the purchasing of products.

producer's risk—For a given sampling plan, the probability of not accepting a lot, the quality of which has a designated numerical value representing a generally desirable level. Usually, the designated value will be the acceptable risk and quality level.

product audit—Quantitative assessment of conformance to required product characteristics.

product lifecycle—All phases in the life of the product, from the initial development through marketing and the product's discontinuation.

product/process characteristic—Any given attribute of a product or process.

product/service—Intended results of activities or processes; can be tangible or intangible.

purchase order—A commercial document issued by a buyer to a seller that indicates types, quantities, and agreed prices for products or services the seller will provide to the buyer.

Q

qualitative analysis—Testing performed to establish the composition of natural or synthetic substances.

quality—A measure of a product's or service's ability to satisfy the customer's stated or implied needs; also, the degree to which a set of inherent properties of a product, system, or process fulfills requirements.

quality agreement—Detailed quality requirements that establish and maintain the systematic business relationship and expectations of the customer and supplier relationship.

quality assurance (QA)—Proactive and retrospective activities that provide confidence that product requirements are fulfilled.

quality by design (QbD)—A systematic approach to development that begins with pre-defined objectives and emphasizes product and process understanding and process control based on sound science and quality risk management.

quality control (QC)—Steps taken during the generation of a product or service to ensure that it meets requirements and that the product or service is reproducible.

quality function deployment (QFD)—A focused methodology for carefully listening to the voice of the customer and then effectively responding to those needs and expectations.

quality management—Accountability for the successful implementation of the quality system.

quality objectives—Specific, measurable activities or processes designed to meet the organization's intentions and directions as defined in the quality policy.

quality plan—Documented result of quality planning that is disseminated to all relevant levels of the organization.

quality planning—Management activity that sets quality objectives and defines the operational and/or quality system processes and the resources needed to fulfill the objectives.

quality policy—Statement of intentions and direction issued by the highest level of the organization, related to satisfying customer needs. It is similar to a strategic direction, which communicates quality expectations that the organization is striving to achieve.

quality system—Formalized business practices that define management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill product/service requirements, customer satisfaction, and continual improvement.

quality unit (QU)—Group organized within an organization to promote quality in general practice.

quantitative analysis—Analytical techniques used to identify the amount or concentration of an analyte and quantify any compound or substance in a sample.

R

rating method—Quantitative method of evaluating systems and performance.

reliability—The susceptibility of a measurement device with a visual display to having its indications converted to a meaningful number, also expressed as the legibility of a visual display, normally defined as the minimum measure and increment that can be discriminated in the terms of the display.

request for information—An inquiry to a potential supplier about that supplier's product or service for potential use in the organization. The inquiry can provide certain organization requirements or be of a more general exploratory nature.

request for proposal (RFP)—A method of soliciting ideas from potential suppliers that may be incorporated into a final design of a product or service for a later quote; a document used to solicit vendor responses when the functional requirements and features are known but no specific product is in mind.

request for quote (RFQ)—An invitation to suppliers to bid on specific products or services.

resolution—The smallest change in input necessary to produce the smallest detectable change in output of the instrument under test.

risk—Combination of the probability of occurrence of harm and the severity of that harm.

risk acceptance—Decision to accept risk.

risk analysis—Estimation of the risk associated with the identified hazards.

risk assessment—Systematic process for organizing information to support a risk decision that is made within a risk management process (the process consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards).

risk communication—The sharing of information about risk and risk management between the decision maker and other stakeholders.

risk control—Actions implementing risk management decisions.

risk evaluation—Comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk.

risk identification—Systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description.

risk management—Systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating, and reviewing risk.

risk reduction—Actions taken to lessen the probability of occurrence of harm and the severity of that harm.

risk review—Review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk.

rounding—Used to shorten numbers by either increasing or decreasing a number to the next digit.

run chart—Plot of process output over time without superimposed control limits.

S

sample—In acceptance sampling, one or more units of product (or a quantity of material) drawn from a lot for purposes of inspection to reach a decision regarding acceptance of the lot.

self-assessment—Typically a questionnaire sent to a new supplier to gather information on capability, capacity, staffing, and resources available to support the potential procurement or contract.

senior management—Top management officials in a firm who have the authority and responsibility to mobilize resources.

sensitivity—The ability of a measuring device to detect small differences in a quantity being measured.

severity—A measure of the possible consequences of a hazard.

shall—Indicates a requirement in regard to a standard.

ship-to-stock (STS)—Program in which the supplier and customer work together for improved quality and conformance of manufactured parts to eliminate the need for incoming or source inspection of purchased parts or products. Under this program, individual products or processes are qualified as opposed to an overall supplier certification. Maintenance of this program is provided through audits.

should—Indicates a recommendation in regard to a standard.

significant digit—Any of the digits of a number, beginning with the digit farthest to the left, that is not zero, and ending with the last digit farthest to the right that is either not zero or that is a zero but is considered to be exact.

skip-lot—Plan in acceptance sampling in which some lots in a series are accepted without inspection when the sampling results for a stated number of immediately preceding lots meet stated criteria.

source inspection—Inspection of purchased parts at the supplier's facility by a customer representative to ensure supplier compliance with specifications and contractual agreements.

special cause—Source of variation that is not inherent in the system and can be prevented.

specifications—Specific limits or parameters that are required to ensure the success of a product to perform as designed.

spend—Cost to an organization for a given purchased product or service for a specified period of time.

stakeholder—An individual or organization having an ownership or interest in the delivery, results, and metrics of the quality system framework or business process improvements; also, any individual, group, or organization that can affect, be affected by, or perceive itself to be affected by a risk. Decision makers might also be stakeholders.

standard deviation/sigma—Measurement of the spread of dispersion of a set of values about their average value.

statistical control—A process is considered to be in a state of statistical control if variations among the observed sampling results can be attributed to a constant system of chance causes.

statistical process control (SPC)—Use of statistical techniques to analyze a process or its output to take required actions to achieve and maintain a state of statistical control and improve the process capability.

statistical process control chart—Plot of process output over time with a superimposed central tendency line and upper and lower control limit lines.

sterilization—The act or process, physical or chemical, of destruction or elimination of all viable organisms (including bacterial and fungal spores, viruses, protozoa) in the inanimate environment.

stratified sampling—The process of collecting a representative sample by selecting units deliberately from various identified locations.

sub-tier supplier—A supplier for the main supplier of a product of service.

supplier—A source of materials, service, or information input provided to a process.

supplier certification—Program aimed at qualifying suppliers already on an approved status to a higher level of approval called certification. This usually encompasses review of the supplier's past delivered product history and an in-depth quality system survey. Certification of a supplier usually is all-encompassing and covers all products. Once certification is granted to a supplier, the customer may institute reduced sampling at incoming inspection.

survey—Broad overview of a supplier's system or process used to evaluate the adequacy of that system or process to produce quality products.

sustainability—A process by which organizations manage their financial, social, and environmental risks, obligations, and opportunities.

system audit—Documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

system survey—Survey conducted to assess whether the supplier has appropriately controlled systems that will adequately prevent the manufacture of nonconforming products.

T

test method validation (TMV)—See *measurement system analysis*.

theoretical yield—The quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a product, based on the quantity of components to be used, in the absence of any loss or error in actual production.

tolerance—The maximum and minimum limit values a product can have and still meet customer requirements.

total quality costs—The sum of costs, representing the difference (delta value) between the actual (although not commonly captured in the accounting systems) cost of material, product, or service and what the potential reduced cost would be in the absence of poor quality. This “delta” value is where cost reduction opportunities will be found. This is a crucial input to the determination of total cost of ownership.

traceability—The ability to track the history, application, or location of what is under consideration from the origin of materials and parts, the processing history, and distribution, and location of the product after delivery.

trend—The tendency of a variable, attribute, or characteristic to increase, decrease, or remain unchanged over time.

U

unclassified area—A room or area not designated by grades but that needs to be designed and maintained such that its environment does not adversely impact the quality, purity, and integrity of the products. Unclassified areas may or may not be controlled areas.

V

validation—Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

validation lifecycle—Process, equipment, and facility assurance that depends on the following stages (separated in time) being executed properly:

Stage 1—Process, equipment, and/or facility design

Stage 2—Process, equipment, and/or facility qualification

Stage 3—Process, equipment, and/or facility continued verification/monitoring

Stage 4—Process, equipment, and/or facility retirement

variable measurement—Quantitative data in which physical properties are measured, such as hole diameters or coating thickness.

variables data—Measurement quantities that are measured on a continuous and infinite scale.

variance—The square of the standard deviation.

variation—A change in data, characteristic, or function caused by one of four factors: special causes, common causes, tampering, or structural variation. Sources of variation include time to time, part to part, and within-sample.

vendor rating—System of measurement of vendor or supplier performance against set goals or standards.

Venn diagram—A diagram that shows all possible logical relations between a finite collection of different sets.

verification—Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

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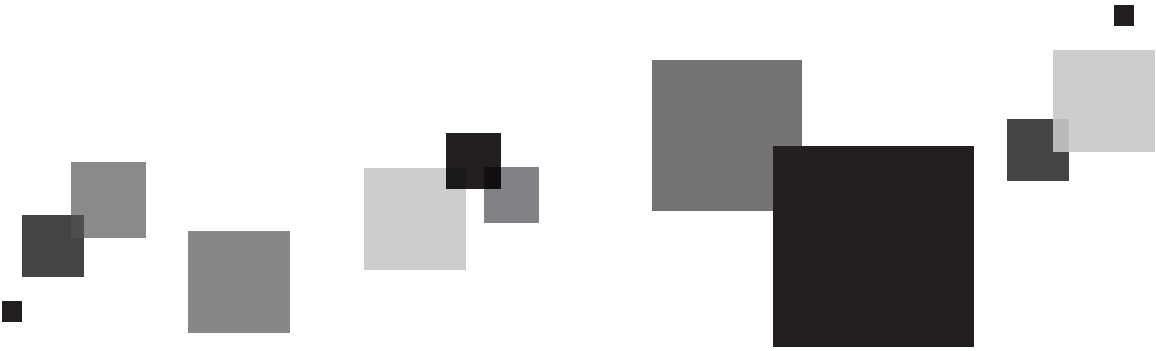
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