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# APPLYING A QUALITY SYSTEMS APPROACH TO IMPROVE SUPPLY CHAIN MANAGEMENT

Medical devices are comprised of an assortment of components that work together to deliver a desired function. The final device is only as strong as its weakest component. Ensuring the highest-quality material and components for a device starts with a robust supply chain management system that mitigates risk, which is a natural consequence of the purchasing process.

When you work with another company, you invariably surrender some control over the process. The potential pitfalls are numerous: quality issues, pricing instability and delivery delays are among the most detrimental. How a manufacturer manages its suppliers is critical to its success in managing quality, time-to-market and cost.

By applying quality system principles to supply chain management, medical device manufacturers can establish best practices for (1) selecting and qualifying suppliers, (2) segmenting them into categories based on potential risk and (3) monitoring them over the short and long term to drive continuous improvement. Considering that supplier controls have been among the most frequent causes of Quality System observations and warning letters, it's imperative to have confidence that the quality of a supplier and its products will not adversely impact your finished device.

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## SUPPLIER SELECTION AND QUALIFICATION

Manufacturers need to have an established, regimented system for identifying critical success factors before a new supplier is deemed acceptable. Every company is faced with finite resources and increasing regulatory concerns. Following a structured approach ensures that resources are properly allocated and that only the best suppliers end up in your supply chain.

Supplier selection precedes supplier qualification. A company should consider several suitable suppliers before selecting one to qualify. Given the amount of information that will be evaluated, it's important that purchasing departments collaborate with other functional groups such as quality and engineering to bring both breadth and depth of experience required to make sound decisions when selecting the supplier of choice.

Strategic purchasing processes tend to start with big picture attributes, then refine their focus. Big picture criteria should include the overall financial condition of the supplier, the ability of the company to supply on a continuous basis without external risks like union strikes or government unrest and whether the technology being considered is well established or new within the company. Each criterion should be evaluated and assigned a numerical score to minimize arbitrary or subjective assessments. Following a consistent selection process for each supplier helps ensure that they are being compared as objectively as possible.

At the same time, the purchaser needs to evaluate the supplier's quality system to ensure production readiness. Are their processes validated and capable? Have statistical principles and controls been put in place to ensure reliability? Can agreements be structured with the supplier to establish roles and responsibilities of each party? These are just a few of the questions that must be answered before the materials qualifications are even considered. As a whole, they are intended to provide a level of assurance that quality will be maintained.

It's important to remember that supplier selection and qualification are different than material or component selection and qualification. Generally, materials are qualified within the engineering function. Engineering works hand in hand with purchasing to ensure the materials conform to the specified requirements and meet the level of performance, in the end-product. During the selection process it is important to ask suppliers if they have the ability to collaborate with design engineers during product development. Based on the complexity of the product and the need for close technical interaction, this capability could be a requirement to move a supplier from the selection stage to the qualification stage.

An obvious, yet sometimes overlooked, question is whether an already-approved supplier is a potential resource for the component or material. Existing relationships where business practices and quality processes are already established can expedite the selection process. A solid track record of performance can help mitigate quality risk; the uncertainty of price and availability of the specific product, however, may still need to be vetted. Even with established suppliers, a strategic purchasing approach requires a complete and consistent assessment to make the process more quantitative and less qualitative.

Equally important is the concept of disqualifying a supplier – either one that has been previously approved or one that is being considered. In addition to looking for positive attributes, you must also look for indicators of negative performance. Disqualification reasons are numerous and could include:

- Significant supplier-derived issues that impact the safety, efficacy or purity of the resulting component or finished product, which would likely result in product complaints and potential recalls;
- The inability of the supplier to meet company or regulatory requirements; or
- A change in manufacturing location, process or raw materials that could impact quality, function or safety.

A solid supplier qualification process must include criteria for disqualification.

## SUPPLIER SEGMENTATION

Not all suppliers are created equally, nor is the criticality of the materials and components being purchased. Companies must have a way to classify suppliers from a risk perspective to separate the critical few from the trivial many. They need to take a risk management approach to the classification of suppliers so they can dedicate time and resources to those deemed most critical.

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For example, should a corrugated box supplier require the same level of qualification as a supplier that makes a raw material used in an implantable device? Is it necessary to conduct an onsite audit of the box company to identify and establish its quality controls? Meanwhile, suppliers that are providing critical components or materials should be subject to onsite audits to understand how they control their manufacturing processes, raw materials, testing processes, subcontractors and suppliers. The more risk there is, the more important it becomes to look further down the supply chain.

The qualification process should include supplier segmentation. A one-size-fits-all qualification process may inefficiently utilize resources on nonvalue-added activities instead of focusing them to areas of highest criticality.

Certainly, there are basic evaluations that every supplier must go through. But additional segmentation is feasible with an understanding of the importance of the material – such as "critical," "major" or "minor" – and aligning qualification efforts to the criticality.

## The consistency of the scorecard process

enables purchasing operations to compare vendors against one another and provide metrics for continuous improvement opportunities.

How does one determine the criticality of an item or material that's being considered for purchase? No one person is qualified to assess. It's best to establish cross-functional teams within an organization. Manufacturing can assess whether the item is central or ancillary to the process or if alternate materials are available. Engineering would understand how the product or material interacts with others and whether different materials or suppliers could easily provide an adequate replacement. Quality should assess the potential impact of material or component on the functionality of the finished product. The cross- functional team will ensure all perspectives are assessed.

Supplier segmentation may also consider annual volume or spend with a specific supplier. These factors can be combined with material criticality to determine the overall risk level for the supplier: high, moderate or low.

Inherent in the segmentation process is an understanding of a company's risk tolerance. Company personnel dealing with suppliers cannot effectively manage risk if they do not know what kind of risk the company is willing to accept. Some companies have a risk-averse culture. Some are risk-disciplined. Some are aggressive. Each company needs to define its risk-acceptance levels. The culture of the company will influence how many items would be classified as critical and where the other items would fall on the continuum of criticality. For a contract manufacturer, it's imperative to understand the risk tolerance of each customer. Open, honest communication during the initial stages of a project will help the contract manufacturer reconcile its own practices with those of its customers.

### SUPPLIER MAINTENANCE AND CONTINUOUS IMPROVEMENT

Manufacturers need to have a method for continuously evaluating their suppliers to make sure they are performing to the expectations established during the qualification stage and, where appropriate, as articulated in the supply and/or quality agreement.

Ongoing evaluation of the supplier should include periodic audits. The frequency of a supplier audit is usually a function of the segmentation process. For example, one may conduct a full audit of high-risk suppliers every year, moderate-risk suppliers every three years and low-risk suppliers whenever there is an issue or for-cause.

In addition to in-depth audits, many manufacturers are adopting more frequent supplier assessments to help quantitatively evaluate attributes like quality and delivery performance in addition to more qualitative measurements. The results of these assessments are generally documented in a supplier scorecard. The consistency of the scorecard process enables purchasing operations to compare vendors against one another and provide metrics for continuous improvement opportunities. Again, the frequency and content of the scorecards can depend on the risk level of the supplier and product. During the course of routine business with a supplier, the risk level may change due to ongoing performance, business strategy or product criticality. While scorecards provide a good mechanism for assessing supplier performance, business needs, company expectations and regulatory requirements should be periodically reassessed as these are not stagnant.

A typical scorecard may be broken into quantitative criteria and qualitative criteria. Quantitative criteria generally come from measured data: product quality, on-time delivery and quantity reliability. The attributes are weighted and put into a formula to arrive at a total grade. These proficiency ratings must then be compared to the previous period's results to determine whether a supplier is the same, better or worse since the last scorecard, while considering any changes in business since that time. Qualitative criteria generally include measures of responsiveness, price, continuous improvement initiatives and other characteristics that evaluate the health of the business relationship.

Scorecards serve three purposes. They are used within a purchasing department to objectively assess the performance of each supplier and influence action strategies based on performance. Scorecards also serve as a communication device. They are shared with suppliers to stimulate frank discussions about deficiencies or to reinforce strengths. Specific action plans can then be developed jointly with individuals responsible for tracking progress on each side of the transaction. Finally, all scorecards and action plans can then be archived as to present a clear, objective long-term picture of the relationship's health.

Of course, the issuance of scorecards to suppliers doesn't eliminate the need to monitor product quality on an ongoing basis. Quality metrics must be established as part of the quality agreement, which will specify roles and responsibilities for both the purchaser and the supplier, criteria for how both parties will work together and contingencies for when expectations are not met. Additionally, the quality agreement should define testing requirements, delineate data-sharing arrangements and provide clear expectations for ensuring the continued quality of the material being delivered. For example, the agreement might specify that the supplier share quality metrics on a quarterly basis for comparison with data collected by the manufacturer. The level of congruency in the data would influence the confidence one has with the supplier. This tracking over time will provide objective data for the supplier's scorecard and provide a mechanism for constructive, objective feedback.

The data cannot be a passive element of the supply chain. It's not just enough to give a supplier a scorecard. It must be leveraged to identify performance risks and used to drive continuous improvement through the supply chain. Are there opportunities to improve quality? Enhance reliability of delivery? Reduce waste?

While each supplier understands the products it makes and the specificationsto which it must conform, it may not always understand how critical the component or material is to a finished product and to its customer's ability to do business. Quality-driven supply chain management – with the help of objective measurement procedures – encourages partnership with suppliers to help them adopt the most significant improvements possible.

## CONCLUSION

The integration of quality systems into the supply chain management function is an important marriage of competencies within a manufacturing organization. A structured, methodical approach to supplier selection, qualification, segmentation and monitoring is vital to establishing, maintaining and improving the supply chain.

The process has evolved to bring an objective viewpoint to the supplier-purchaser relationship. It's a method of certifying trust that transcends personal relationships and handshakes. The level of trust a manufacturer has with a supplier will likely correlate with a company's performance over time on scorecards and audits. Once trust is established, organizations can work on opportunities for mutual improvement.

## How B. Braun OEM Division can be a resource

As a major medical device manufacturer, B. Braun has extensive resources throughout the organization – experts in engineering, materials, project management, packaging, quality systems, regulatory support and more. The B. Braun OEM Division can apply the organization's wide-ranging expertise to your contract manufacturing projects.

Because we're a full-service outsourcing partner, B. Braun OEM Division manages suppliers with the same level of control that we apply to end-products that carry the B. Braun logo. We are fully capable to manage the supply chain intricacies of complex projects such as device and kit assembly.

Contact us at (610) 691-6785 or visit bbraunoem.com to learn more about our capabilities and schedule an introductory discussion about an upcoming project.

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