

## Importance of Source/Second Source Qualification

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As market conditions change in the aftermath of the economic events from nearly two years ago, execution and efficiencies become ever more important to each and every business regardless of size or industry. The trend toward outsourcing 15 years ago was a business shift changing the way we do business permanently. Our latest challenge is to find innovative strategies to improve our manufacturing processes, efficiencies and overall execution. These three objectives apply to every aspect of daily and long-term business operation. It is no exception that they apply to source qualification/second source qualification, specifically secure material sources.

“The impact of supply chain disruptions is substantial. One study of more than 800 companies that announced a supply chain disruption between 1989 and 2000 found that these disruptions resulted in 33 to 40 percent lower stock returns relative to the disrupted companies’ industry peers.”

Reference 1, Getting SMART about Risk Management, Dirk De Waart

Regardless of how well documented and controlled your manufacturing process may be or how many control charts are generated and updated, your manufacturing process will never reach its full potential or be in control, unless the source(s) of incoming materials that feed your business (manufacturing line) is uniform, consistent and repeatable. The steps to a secure, consistent and repeatable source for materials begins long before they are required on the floor at the machine. Drawing upon cross functional coordination between many different departments within your organization will help to provide the keys to approve a secure prime and second source for critical materials. In turn, this will help control costs and lower the risks posed to your business and by extension your customers who rely upon you as a consistent, stable and secure source for their materials.

Each step added to your operations will add expense to your bottom line cost of doing business. However, just as your business has insurance policies in place to protect the viability of the firm from loss or liability claims, source qualification is an insurance policy against inferior materials entering the inner workings of your business operations and causing catastrophic loss or liability claims. Sometimes, justifying the efforts and expense of source/second source qualification is difficult to pencil out with regard to lower cost consumable materials such as cartridges, syringes, barrels, tips and nozzles. Difficulty stems from the intangible aspects of the associated risks that are difficult to quantify without supporting data to feed “risk analysis” or “lost opportunity” models that quantify the costs associated with not having a prime and second source for (raw) materials to feed your business/manufacturing process. No one wants to consider the costs associated with having a key account walk away from a strategic, long-term relationship. Costs considerations should include future losses due to lower revenue going forward as well as the sunk costs in efforts to win the business or secure replacement business to

fill the gap. Additionally, the potential impact to your firm's reputation and stock price bears consideration.

<b>EXHIBIT 1</b>		
<b>Supplier and Raw Materials Risk and Impact Attributes</b>		
<b>Example of Supplier Risk Attributes</b>	<b>Example of Material Risk Attributes</b>	<b>Example of Impact Risk Attributes</b>
<ul style="list-style-type: none"><li>• Quality Rating</li><li>• Financial Health</li><li>• Physical Location</li></ul>	<ul style="list-style-type: none"><li>• Number of Sources</li><li>• Demand Increase</li><li>• Shelf Life</li></ul>	<ul style="list-style-type: none"><li>• Where Used</li><li>• Lead Time</li><li>• Inventory</li></ul>

Reference 2, Getting SMART about Risk Management, Dirk De Waart

As you consider suppliers for critical consumable fluid dispensing products such as cartridges, syringes/barrels, pistons, plungers, etc., understanding the relationship between these components (how they work or fit together) is vital to making an informed source decision. While the cartridges, syringes/barrels pistons and plungers may look similar from supplier to supplier, there are subtle differences in fit and function that if substituted could result in negative dispensing performance. Ideally, components from different suppliers should not be mixed together in most situations.

A key aspect of the syringe/barrel to piston or cartridge to plunger relationship is the "interference" between these parts. Interference is the amount of resistance or tightness of fit between piston and syringe/barrel or plunger and cartridge. Each supplier works hard to maintain specific tolerance ratios between inside diameter of the syringe/barrel or cartridge to the piston or plunger so that the designed interference is consistently maintained throughout the entire fluid dispensing process. Specific interferences are vital for error-free dispensing of materials with certain viscosities. Use of matched combinations of syringe/barrel to piston or cartridge to plunger from the same manufacturer helps to ensure a consistent, repeatable dispensing process.

The lessons learned with regard to critical consumable product source qualification can be applied to hard lines like assembly tools and fluid dispensing valve. Assembly tools and dispensing valves should be selected based upon specific application requirements, field tested performance results and repair or spare part support logistics. With regard to fluid dispensing valves, many suppliers valves are similar in appearance and internal operational design, however, choosing a supplier with 'pioneer pedigree' often results in more reliable performance, greater consistency in 'shot size' (deposition volume) and longer service life. As with critical consumables (syringe barrels, cartridges, pistons and plungers, ...), sourcing of spare and preventative maintenance parts should come from the original fluid dispensing valve manufacturer and components from different suppliers should not be mixed together. Even though the 'O' ring, seals, auger, ... may look similar from other sources, there are tolerance, material selection and

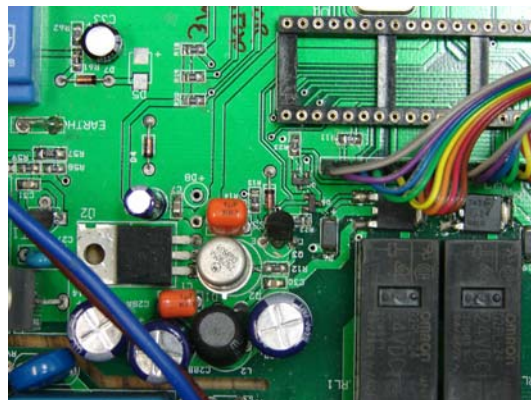
quality standard differences that can negatively impact dispensing valve performance and should not be mixed between manufacturers regardless of how close in appearance they may seem.

The ability to deliver a consistent, top-quality product or service depends on a stable and secure “raw” material(s) flow to your operations regardless of whether your end product is a specific product or service to your customer base. Interruption of your material supply chain is more than an inconvenience; it opens the door for your customers to seek alternative sources to satisfy their needs/requirements regardless of it being:

-Raw Materials Ref 3



- Printed Circuit Boards Ref 4



- Plastic Cartridges for Adhesive Packaging Ref. 5



These days with uncertain economic times ahead, it is important to strategically plan for the unexpected or unthinkable. Supply chain sources can be interrupted for numerous reasons beyond their control (Acts of God, financial stresses, excess demand, etc.) as well as those under their control as they adjust to the changes of our times. The best way to protect your business and the future of your business from the negative impact due to supply chain problems is to regularly qualify a “prime” source and do the work required to lineup a second source for the times when the prime is unable to execute.

Recently, a common driving force of “Risk Mitigation” was adopted as a first line of defense against the possible influences of supplier performance issues. Risk Mitigation is a strategy that addresses supplier performance problems after they have presented themselves and are used when the goal is to minimize disruption to your operations. The Risk Mitigation strategy failed to consider that at this point of supplier failure, your business is at the mercy of a new supplier and likely is forced to accept unfavorable terms (financial, quality, duration) just to get what is needed to carry on. As business evolves and our understanding of the impact supplier performance problems has grown, our approach to supplier source/second source qualification has taken a decidedly more proactive stance referred to as Risk Avoidance.

Risk Avoidance is a strategy in which prime source/second source qualification factors that could influence your business are studied before they pose a threat to the viability of your business. Each identified area with threat potential receives a countermeasure prior to catastrophic events occurring. By working in a proactive fashion, possible material source risks are avoided.

## **Conclusion**

Qualifying a first and second source for consumable materials that feed into your manufacturing process, packaging or fluid dispensing operation (syringes, tips, cartridges, etc.) is essential to ensure continuous production integrity and long-term viability for your business for many reasons. First, if the prime source has a production problem and is unable to deliver for any reason, it is advantageous to have a second source pre qualified and ready to step into the breach. Second, an alternative source can help maintain pricing parity for you and your customers’ bottom line by analyzing alternative options against each other. Second source qualification reduces the tangible and mitigates the intangible risks of doing business, helping to ensure a high-quality/reliable materials supply line and avoiding negative effects and unfavorable terms while securing a more stable materials structure.

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## References:

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