Protecting Your Brand by Improving Visibility in Your Supply Chain

How can you find and prevent serious defects in your supply chain before they damage your reputation?

With pressure to reduce costs in a complex global supply chain, manufacturers need to look at the capabilities of new web-based quality tools that provide real-time visibility of quality issues.

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1.0 Executive Summary

The globalization of manufacturing supply chains, together with the imminent retirement of experienced engineering and quality employees, requires an aggressive review of existing quality practices to avoid potential disaster and brand risk.

A small part in an auto assembly made by an unknown sub-tier supplier may save pennies, but could end up damaging the reputation for quality that the auto maker has built up over many years, as well as costing millions of dollars to mitigate. The recent multi-million dollar recall from General Motors involving a twenty cent switch is a prime example.

The failure of a single feature of a part, a flawed manufacturing process, or a tainted ingredient can erode years of brand value in an instant.

- A single defective titanium tube made by a sub contractor for a jet engine manufacturer has led to a major engine failure, leaving a serious impact on the reputation of the engine maker, the aircraft manufacturer, and the airline.

- A hip joint replacement manufacturer who failed to use a degrease process created a cascade of claims and litigation that almost destroyed the reputation of their brand.

- One unapproved ingredient mixed into a medication by a drug manufacturer could create a significant loss in public trust, this is especially true with many non-active ingredients being manufactured outside the control of regulatory authorities.

From automobiles and jet engines to medical devices and pharmaceuticals, quality escapements can lead to a global media frenzy that can wipe out a brand's value and reputation in seconds. Given the nature and speed of the internet, news spreads in seconds and cannot be isolated and quarantined as it was in the past.

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Given the risks, why don't the current quality management programs catch these problems? What conditions created these serious quality problems, and are they getting worse? What can we learn from these failures? What new tools can be implemented to change the quality paradigm from defect detection to true root cause analysis and defect elimination? Can these risks be eliminated?

2.0 The Drive for Lower Costs and Unintended Consequences

The supply chains of most major manufacturing companies have become more complicated and more geographically dispersed than ever before. The visibility is almost nonexistent as you drop down to the sub-tier levels. The drive to lower costs to remain competitive has accelerated this process while at the same time products are becoming more and more complex.

Global outsourcing of parts and materials continues to increase dramatically, yet the resources and tools to ensure their quality have not kept pace.

Local and regional specialty suppliers are increasingly being supplanted by lower-cost suppliers in remote parts of the world who can offer lower prices because of cheaper labor and low-cost global transportation. As Original Equipment Manufacturers (OEMs) press for lower supplier costs, the expansion of global sub-tier suppliers is reshaping the supply chain. The demand for cheaper parts, sub components, assemblies, and materials continues and will intensify as cost-reduction demand increases.

As a result, more suppliers and sub-tier suppliers are using brand new, untested suppliers to keep up with costs reduction. As these sub-tier suppliers multiply, ingredients for pharmaceuticals and parts assembled into large complex systems are increasingly likely to come from all over the world. This increase in world trade is only a problem if the capability to review and inspect these suppliers is not being effectively managed.

It used to be that an enormous amount of trust was built up between manufacturers and their suppliers. You could depend on local companies to act in your best interest and use traditional quality methods to stop defects from entering the supply chain. This system, although not perfect, did provide at least some protection for the OEM because their reputations were aligned with those of the OEM. With the disconnect inherent in using far-flung suppliers, this alignment is no longer there.

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According to the Aerospace Industries Association (AIA), overall imports for aerospace and aircraft manufacturing jumped 10% in 2010, with spacecraft, missiles, rockets, and parts increasing nearly 50% and imports for aircraft and engine parts up 14.3%. From engines to aircraft, aviation/aerospace OEM's are increasingly reliant on parts and materials from around the world.

The outlook for pharmaceuticals indicates a similar globalization trend. In the US Food and Drug Administration's 9/29/2010 draft white paper *Strategic Priorities 2011-2015, responding to the Public Health Challenges of the 21st Century,* the FDA recognizes the priority of strengthening the safety and integrity of the global supply chain. In Section 2, "Cross-Cutting Strategic Priorities," the FDA Commissioner identifies the global supply chain as one of the four strategic priorities that cut across all areas, based in part on their **forecast of over 20 million lines of imported food, devices, drugs and cosmetics in FY2010, more than 3 times the number of imports 10 years ago.** The FDA report goes on to describe the increasing complexity and volume of imports as a "serious challenge."

While manufacturing companies may have relied upon their traditional quality management programs in the past, many are increasingly aware that these methods are financially and practically untenable in today's climate. Quality departments—conservative by nature—are being forced to reexamine every aspect of how their quality missions are accomplished. Systems that were once adequate now look woefully out-of-date and have no place in the new supply chain universe.

The FDA recognized that with over 300,000 facilities in more than 150 different countries, the growing challenges of globalization of the supply chain has "far outstripped the nation's resources for inspection and quality monitoring." As a result, the FDA is focused on a "paradigm shift:" stopping threats before they are a reality

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using proactive tools, more inspections, and updated IT systems (IBID, Section 2.2, page 6).

The growing media attention to counterfeit parts and the increasing focus of Federal regulatory agencies such as the FAA and FDA on the risks associated with the global supply chain is evidence of the growing concern about this threat.

Recent very public quality disasters have reinforced the fact that it is the OEM's brand that ultimately pays the price; the culprit can shut up shop and reappear as another inexpensive no-name, no-reputation supplier down the street. The OEM's brand is left in ruins.

3.0 The Global Fragmentation of the Supply Chain

A "Stress Test" that may reveal vulnerabilities of current quality management programs

The lack of a consistent uniform method to ensure all manufacturing documentation and associated data is complete and accurate is a red flag.

Are your company's quality documents and procedures accurate and visible?

Most manufacturing processes require detailed documentation containing the specifications required to complete a quality buy-off of the product. For example, the AS/EN 9100 (aerospace quality standard) requires that "first articles AS9102" specifications, details of the first manufacturing run (the first article) material certification, etc., be completed before the item goes into production. It's virtually impossible to check these without vast quantities of paper changing hands. The additional paperwork required by increased tiers in a supply chain eliminates much of the hoped-for savings. While many of these sub-tiers implement traditional paper-based production quality systems, they are very difficult to monitor and check without sending personnel halfway around the world to do the checking. From part specifications and tolerances to processes and coatings, meeting the quality standard requires complete and comprehensive documentation. But how often does this actually happen and where is the documentation for the sub-tier suppliers? Who has inspected the documentation and checked it? What is the audit trail and chain of custody of these critical documents? Were the measurements accurate and did they use appropriate metrology for specification requirements? If the wrong measuring device was used, the result have no value.

The answers to these questions are often unclear due to the lack of a consistent, uniform, and cost-effective way to collect, inspect, and manage this complex documentation. In the past, manufacturers typically relied on in-house experts who were intimately familiar with the products and long-time suppliers whose performance had always been trusted. Now they have to rely on a patchwork system of paper that is impossible to verify except by occasional audit. These audits normally only happen after a serious incident has occurred, in effect closing the door after the horse has bolted. Even more troubling is when a detailed review of the process has been completed. Were measurements made on a first-run part? Were they recorded with an exact amount, or just a pass/fail? What type of instrument was used? Were the tools calibrated? Who calibrated the measuring tool?

Without this information being readily available and verifiable, many of the data elements required for approval may be suspect. A global supply chain makes this problem even more difficult to manage.

Traditional quality programs and go/no-go inspections are ineffective at reducing and eliminating defects.

There is substantial evidence to show that traditional quality programs fail to establish significant and sustainable quality improvements over time. Every escapement not only indicates a process failure, but also may be the tip of the iceberg. It also shows defects found, not defects manufactured. The key word is "sustainable:" most activity-based programs that rely on training and documentation fail to change practices and behavior because they lack a quantifiable feedback loop. Human activity changes for a time period but—like a rubber band—snaps back to the familiar and comfortable practices of the past. When these quality programs

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are delegated to suppliers, they're even more difficult to sustain and are often viewed by the supplier as imposed mandates that require additional work and expense rather than something that is truly beneficial to their operation. Discovery of defects or flawed ingredients after they are produced and shipped is evidence of a process breakdown, not a solution. Compounding the risks of defect escapement quality programs, quality managers often rely too heavily on inaccurate statistical data to prove that their quality programs are working.

A historical lack of detected defects has always been used by companies as a metric to reassure themselves that their quality systems are working. But the world has changed, and even if that confidence was somewhat justified in the past, it's no longer valid in today's climate. Future problems will likely be the result of a single characteristic of a single part buried deep in the sub-tier assembly. Because it is also likely to be a detail characteristic, the defect will not reveal itself in the up-line inspection process because the part will be fully assembled, defect and all. This will then produce the worst type of defect, the "latent defect." This defect will only reveal itself in a massive in-service failure and will require an expensive recall and re-inspection of all other in-service products that use that item. This will draw much unwanted attention to the brand and the OEM; the culprit manufacturer could disappear into thin air.

It's obvious now that the traditional systems are not equipped to solve these problems. Real-time observation of all manufacturing processes, including a detailed analysis of all defects that have been manufactured, not just escapements, is now essential to mitigate these risks. With ever more complex global supply chains, who is actually inspecting the key features of each part, and how are they doing it? Do large manufacturers really know whose parts or ingredients are in their product and whether each key feature and essential characteristic has been inspected?

Manufacturing quality processes often rely on experienced in-house personnel and not bulletproof processes; these very same people are headed for large scale retirement in the next few years.

To add to the OEM's challenges, their last line of quality defense is now crumbling. Many manufacturing teams have relied on experts who "know how it's done" and are comfortable with long-term relationships between suppliers and their personnel. Instead of thoroughly documented and measurable manufacturing specifications and processes, many companies rely on the legacy expertise of their employees.

Tribal knowledge is kept tucked away and not documented to increase employment value and job security. With the imminent retirement of the baby boom demographic, processes and tribal knowledge need to be documented immediately in addition to adding a more robust quality system that doesn't rely on in-house expertise and judgment calls. As the saying goes, "your intellectual property walks out the door every day." As the baby boom generation retires, the exodus of knowledge will be of biblical proportions and could result in the complete disintegration of companies that don't adequately prepare. Will your brand survive when this exodus occurs, and what steps must be taken to document and institutionalize their knowledge?

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Conflicts between cost reduction initiatives, risk mitigation, and quality programs:

As the constant pressure for market share and stock appreciation increases, cost reduction often becomes the prime focus. With manufacturers unwilling to spare anything from scrutiny, quality programs with their personnel and systems are often viewed as cost centers that must justify their value. Using "silent evidence" (the lack of past major quality escapements), companies may be tempted to conclude that the current programs are "good enough." Meanwhile, the quality managers using traditional "defect detection" systems recognize that the expanding global supply chain requires more personnel and more travel for inspections this may be financially unacceptable in the current cost reduction climate.

Are the risks associated with a fragmented global supply chain fully understood and accounted for?

Corporate compliance and legal departments are also recognizing the growing regulatory and civil liability risks that arise as a result of the fragmentation of the global supply chain. If supplier documentation (for every supplier at every tier) is spotty, validation of data lacking, and inspections limited, tough questions must be asked. Is the company doing everything it can to identify and mitigate risks? Is the corporation properly disclosing the extent of risk associated with potential quality problems from global suppliers, and are sufficient funds being allocated? Is it more costly to react to problems later than to prevent them now? Is there a need for higher warranty or recall reserves? ***The fact is that without addressing the tough questions and reexamining traditional quality systems, these companies are exposing themselves to unnecessary risks that are increasing exponentially.***

Summary: "The Stress Test"

Unreliable documentation, limitations of current quality programs, the mass retirement of the manufacturing quality experts, and the lack of integration of corporate initiatives dealing with quality all compound the risks associated with the fragmentation and globalization of the supply chain. Further concerns arise from the lack of verification and documentation, the weakness in traditional statistical measurement methodologies, and the underestimation of the potential catastrophic financial impact of a defect in a single feature of a single part or ingredient.

Are unknown parts and materials in complex assemblies like the toxic mortgages that were rolled up into AAA-rated bonds?

For many years financial institutions and their government regulators utilized highly sophisticated financial modeling systems and risk profile management to detect problems. This was considered more than adequate until recently when all of their assumptions were destroyed in a few weeks because they failed to look at the details and assumed that because problems had not occurred in the past that they would not occur in the future. The failure to examine the quality of the mortgages at a detail level created the subprime mortgage crisis which almost destroyed the global financial structure.

Will current AAA-rated manufacturers similarly implode because no one knew what was in the detail parts? Companies must know the details of their products, not only to catch defects, but to monitor them in real time so that defects can be prevented. Just as most asset-backed security investors did not know the extent of the toxic mortgages inside their AAA-rated bonds, do manufacturers really know who made the parts that are rolled up in the subcomponents and assemblies that now comprise their finished products? The odds are, with a rapidly expanding global supply chain and an increasing trend toward integrated assemblies provided by suppliers (i.e., pushed down the supply chain), the parts or materials that are actually in a final product are

increasingly difficult to verify. It's simply not possible to achieve this with current paper systems and traditional quality management methodologies. Defects that are undetected at any level in the manufacturing process can now become latent defects, causing in-service failures and all of the negative publicity and brand damage that that entails.

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4.0 The Solution:
Real-Time Global Supply Chain Visibility across the Production Lifecycle

"2011 will be the year that businesses embrace the app revolution for purchasing, logistics, supply chain, management, and sales providing real time information" according to Daniel Burrus, author of the Flash Foresight (Wall Street Journal, "A Look Ahead 2011, Trends That Will Shape Next Year", page B6, December 15, 2010).

An increasing number of manufacturers and suppliers are discovering a new level of visibility via web-based software that connects all suppliers to a single server complex. From aviation/aerospace and medical device companies to electrical component manufacturers, OEM's are leveraging web applications to augment and extend their in-house systems and processes. Real-time visibility is the name of the game. Companies need to have instant and accurate real-time information to stop defects at the source and monitor real-time deviations of process.

With anytime/anywhere access and consistent, uniform electronic documentation that can be checked and verified in real-time, applications now offer tools to combat the challenge of global manufacturing fragmentation. First articles, bills of materials, and all other specification documentation of parts and materials can now be rapidly and accurately compiled, reviewed, and verified, not just for the primary suppliers, but for every supplier in the sub-tiers. With the power of hyperlinking documentation (parts and components can be linked with larger assemblies enabling an OEM to see every detail of every part going into their finished product),web-based visibility tools solve the challenges that traditional quality programs and systems cannot. Details of a product can be extracted from a solid model and placed in an

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electronic document, creating complete configuration control. Leveraging this data, web-based applications can provide the capability to collect and aggregate real-time status of supplier activities, such as all of the quality data and the manufacturing status of the parts. These visibility tools offer new supply chain and quality management capabilities that focus on preventing defects before they enter the supply chain. These applications can also provide robust security and access control to ensure compliance with international trade and security regulations (ITAR -EAR) that may pertain to control of data to US citizens.

Visibility down the entire supply chain can be enabled by web applications that offer real-time quality and manufacturing status for all quality requirements and metrics.

Furthermore, they can be used to determine the capability of a supplier before they are entrusted with manufacturing key components. This allows the OEMs to determine capability before issuing a PO, not after.

Manufacturers and suppliers both are benefitting from these innovative web applications. Manufacturers can now focus resources on preventing defects instead of trying to discover them on the assembly line, or worse, during an in-service failure.

Web applications provide real-time data about parts, materials, and processes down to the smallest sub-tier suppliers across the globe. Real-time monitoring of production process variations now enables quality management resources to address root causes immediately when automatic alerts are received. Such critical quality management activities as root-cause analysis and production of Pareto charts can now be done automatically as manufacturing defects occur, rather than as a post-facto management reporting function. Not only do manufacturers gain unprecedented levels of visibility and control over their global supply chain, but they also gain complete, accurate real-time information, providing new levels of rigorous quality control and risk mitigation. Finally, with these new capabilities, manufacturers can reduce costs without risking quality, reduce global travel costs for inspections, and lower

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supplier costs by eliminating replacements, scrap, and rework. This results in the redeployment of quality resources from documenting and managing the after-effects of defects to real value-added root-cause analysis and defect prevention.

Suppliers benefit because they gain a uniform, consistent, and labor-saving way to prepare and manage their quality-related documentation. Suppliers at all tiers also have the ability to become more visible and credible based on the caliber of their online documentation and quality record. As suppliers reap the advantages of lower costs and improved quality by using uniform quality procedures they increase their competitive edge with better products and lower prices based on efficiencies, not cut-rate labor.

5.0 Conclusion

Manufacturing organizations have long been active in implementing and managing "quality" programs, such as Six Sigma, Lean, and other quality methodologies/programs, including specialized legacy quality systems and software to track defects and quality information. Many manufacturing organizations have invested millions of dollars in the fashionable Six Sigma programs that had a cult-like following until they failed to produce the expected ROI. Even when progress was made, rarely were these improvements sustainable and systems frequently morphed back to their original comfortable state. The expensive analysis required to monitor the processes often stopped after a time and when no longer monitored, processes returned to their status-quo.

"Defect detection methods," using documentation and measurements that often contain a wide range of variability and accuracy, are not sufficient to address the problems of a more complex global supply chain. The inspection process must remain consistent between different suppliers in the supply chain to avoid creating quality problems that are nothing more than differing interpretations of the same data. Against the reality of the OEM's drive for cost improvement, suppliers are driving cost reduction to their own sub-suppliers in order to look for opportunities to further lower their own costs. This trend opens the door for cost-driven suppliers to seek even lower cost components, materials, and labor.

When all it takes is the failure of a single characteristic of a single part to erase millions of dollars in brand value, the fragmentation and lack of visibility of the global supply chains can no longer be ignored.

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With new web-based quality applications that provide complete, detailed real-time visibility of the entire supply chain, manufacturers now have the ability to respond to the growing challenge of global supply chain fragmentation. At the same time, expertise and tribal knowledge can be documented electronically and risk mitigation and regulatory compliance can be integrated and harmonized. As defect detection and on-site facility inspections are replaced by real-time automated manufacturing process control, all parts and processes can be completely visible. Government regulatory compliance can now be augmented by automated and fully documented processes, demonstrating a new level of control, record-keeping and visibility that meets and exceeds current levels of compliance requirements.

Suppliers now have the web-based tools to lower costs and compete on quality, not just competing with low-cost labor.

Suppliers gain new confidence by making their production quality and documentation readily visible and accessible to all customers at all tiers. In addition to lowering quality management costs and improving production efficiencies (less scrap and rework, lower warranty costs, in-service failures, etc.) suppliers can sustain healthy margins even at a lower price point.

Now is the time to closely examine how your global supply chain can put your brand at risk, and whether current quality programs and in-house systems are enough to prevent a risk to your reputation. Is your brand one quality escapement away from being seriously damaged? What steps can you take to mitigate the risk? Can you make sure that everything that goes into your product is known and visible? Do you know the reputation and quality of all the sub-tier suppliers in your supply chain? New web-based quality systems can provide the answers to many of these questions.

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Mike Dunlop has been in manufacturing for over 30 years, and has worked with aerospace supply chain issues as a component supplier and software architect for the last 25 years.

14 years ago, Mike designed Net-inspect for his own aerospace component manufacturer in Portland Oregon. The system rapidly transitioned into a SaaS (software as a service) platform and has now become the most widely used quality software in the Aerospace industry. Currently there are over 6,000+ companies using the service in 48 countries, this number will increase to over 9,000 companies with the implementation of the supply chain of a major OEM this year.

Mike has always been very interested in the unique capabilities and potential of global web apps, especially in the areas of complex manufacturing supply chains. With the unique capabilities of the Internet, he feels there are opportunities for quality improvement and supply chain visibility that were not possible even a few years ago.