



Sparta Systems

3 Steps to Supplier Collaboration and Improved Quality

Leveraging the Quality Business Network to
Cut Costs and Reduce Risks

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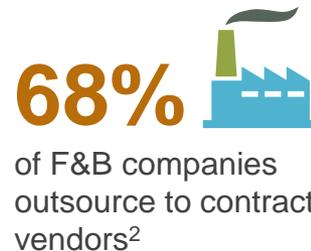


Introduction

With the globalization of manufacturing and supply chains, the number of quality events continues to mount. New technology based on the concept of **a quality business network** can stem the tide through transparency and improved supplier quality management.

Whether it's pharmaceuticals, food and beverages, medical devices, technology, or some other sector, everyone in manufacturing is aware that times have changed. Monolithic, vertically integrated, geographically centralized manufacturing has given way to a dispersed eco-system, where multiple tiers of suppliers participate in a global supply chain that ultimately delivers products to the consumer.

Consider these statistics on global supply chains:



These numbers would have been shocking not many years ago. Now they simply confirm the new reality. We live in a world of global supply chains.

¹ U.S. Government Accountability Office – www.gao.gov

² *Global Manufacturing Outlook. Competitive advantage: Enhancing supply chain networks for efficiency and innovation.* KPMG & Economist Intelligence Unit. May 2013.

Growing Complexity, Growing Risk



But although the responsibility for raw materials sourcing, manufacturing and even new product development has in many cases been ceded to external suppliers, the responsibility for quality remains squarely with lead manufacturers and brand owners. If anything, the regulatory trend is towards shifting even more responsibility to these brands.

For example, FDA guidance related to the Code of Federal Regulations (Title 21, Parts 210 and 211) assigns more accountability to brand owners than ever before when it comes to cGMP compliance by their contract manufacturers (CMOs).

These trends put lead manufacturers and brand owners in a dilemma. In order to expand, serve new markets and above all cut costs, they must continue to add new suppliers and CMOs on an ongoing basis. Unfortunately, each addition makes their supply chain more far-flung, more complex, more difficult to monitor for quality, and therefore more susceptible to risk.

The end results of this lack of control are discouraging to say the least. They include:

- ↑ an increase of 78 percent in the number of warning letters issued by the FDA between 2007 and 2013¹
- ↑ an increase of 135 percent in recalls during the last decade¹

Warning letters, and even the Form 483 notifications that precede them, can be expensive. They usually require that a manufacturer evaluate and revamp processes, resulting in significant cost and time lost. According to various sources, when time to market is delayed companies can risk losing as much as 8 million dollars per day.

Recalls are even more devastating, with costs soaring quite literally into the billions of dollars.

These types of quality events are directly linked to the growth of supply chains. In one study conducted by Deloitte, 52% of all recalls were attributed to supplier/vendor issues. It appears that if the number of suppliers continues to grow, so will the number of quality events.



¹ Food & Drug Administration - www.fda.gov



This need not be the case. A close examination of the status quo in quality management shows that there is enormous room for improvement. Technology based on the concept of the **quality business network** can reverse the trend towards more and more recalls.

This eBook explores the key challenges associated with supplier quality management and identifies three steps that can break down the quality barriers across the supply chain, improving quality and efficiency while reducing costs and risk.

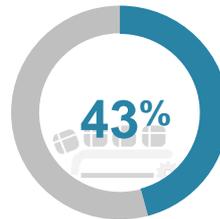
A System that's Living in the Past

Although collaboration is essential for quality - not to mention efficiency and profitability - most of the partners in today's supply chains continue to maintain their own methods of managing quality events. Their systems range from old-fashioned clipboards to Excel spreadsheets to home-grown applications to automated quality management systems. But whatever systems and communication channels they may be using, they all have one thing in common: *difficulty in sharing information*.

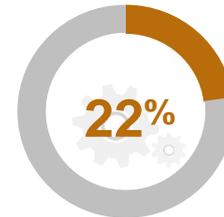
Rather than take advantage of the advanced technologies now available, electronic communication is relegated to fax and scanned PDFs. The consequences represent a serious breakdown in communication.



13%
of manufacturers have
'complete' visibility
past Tier 1 suppliers¹



43%
of manufacturers have
limited or no visibility
into their supply chain¹



22%
of companies see quality as
an integrated function of
their supply chains²

With this lack of visibility, it's hardly surprising that quality problems keep growing.

¹ Global Manufacturing Outlook. KPMG. May 2016.

² Quality: The Missing Link in Your Supply Chain Strategy. Gartner, S Jacobson. January 2015

Endemic Inefficiency

Another related problem is inefficiency. Consider how a supplier typically alerts a manufacturer of a change. There are a lot of steps, summarized by this timeline:



In most cases, manufacturers require that suppliers notify them of any change sixty to ninety days in advance. Assuming that the supplier is playing by the rules, a change notification will be issued. Unfortunately, it's normally the case that every supplier uses a different format for their change notifications.

Furthermore, these notifications can be sent as a simple email, an email with a complicated attachment, or a fax. If there are any questions or missing items of information – and there usually are – then a phone call is required, with all the typical back-and-forth it takes simply to get in touch. All these multiple formats and communication modes can make the tracking incoming change notifications complex and time-consuming.

Once the required information has been finally collected, it has to be transcribed into the manufacturer's EQMS (or other such system). This again is a manual process that takes a lot of time. Typos or mistakes that can cause problems down the line are hard to avoid.



The next step is another manual process: communicating to the supplier that the change notification was received and indicating how many days have been allotted to complete the tasks involved. This communication again takes place outside of the EQMS, so yet another separate tracking spreadsheet is required, not to mention plenty of mental math.

Once a change is in progress, manufacturers have no visibility into what's happening. Therefore, they have no way to track the change's status or know whether or not it will be completed on time. They have to wait for an email or fax confirmation, or ask for updates manually via email or telephone calls.

This not a one-time process. Most manufacturers have dozens if not hundreds of suppliers, and dealing with changes is a regular part of doing business with them, not to mention non-conformances, CAPAs and other quality events. The whole process is fragmented, with lots of time-consuming manual steps. In addition, it doesn't create an audit trail, a potentially huge problem in itself.

Lastly, because data is scattered in multiple locations in multiple formats, rolling it up to obtain metrics for supplier scorecards can take weeks. It's not only labor intensive and dependent on the often-overloaded IT department. It's apt to be out of date by the time it's ready for review.

Leveraging the Quality Business Network

The solution to all these problems lies in an interconnected, collaborative approach to quality: **The quality business network**. This approach is made possible by today's web-based technologies, but it goes far beyond technology. Manufacturers and suppliers alike are coming to realize that they are no longer well-served by the traditional adversarial relationships where a win for one side (on price, for example) is a loss for the other.

Collaboration on everything from design to scheduling can help all the members of a supply chain improve both operations and profitability, and collaboration on quality plays an important role. The quality business network allows suppliers to become part of the manufacturer's quality system, so they can be treated like internal quality employees.

Here are the three crucial best practices for success for overall quality across the quality business network:

- 1 Catch Problems Early
- 2 Streamline Quality Processes
- 3 Be Proactive

Step 1: Catch Problems Early for Risk Reduction

As the diagram below demonstrates, the cost of resolving an issue increase exponentially depending on whether a problem is identified during the design stage, at the supplier level, during manufacturing, at distribution centers or when it actually reaches consumers. With a collaborative approach, manufacturers have the visibility they need to catch problems early, when they are simply problems and not disasters.



The 1-10-100 Quality Rule

Suppliers are a critical collaborator in ensuring problems are caught and resolved early. To encourage this collaboration, brand owner should provide an easy to use system that prompts the supplier to provide the information needed to resolve quality events. This can eliminate much of the back-and-forth communication, the re-keying of paper-based data, and other hurdles that impact resolution timeframes.

Step 2: Streamlining Quality Processes to Reduce Costs

Particularly in the pharmaceutical sector, the cost of being only a few days late with shipments or a new product introduction can be staggering. Collaboration across the quality business network can eliminate a great deal of work involved in the communication between suppliers and manufacturers. In addition to eliminating a large amount of back-and-forth, it can also streamline the tracking of quality processes.

Traditional Timeline



Collaborative Timeline



By managing all quality-related communication within one quality system, it's easy to track the event resolution process and keep everything on schedule. Suppliers can actively play a role in the brand owner's quality management processes. The combination of streamlined communication and visibility into what's going on speeds time-to-resolution, or in the case of new products, time to market.

Step 3: Be Proactive

In order to collaborate, you need all the facts. Involve suppliers so that they have facts too.

With collaboration, there can be a comprehensive view of supplier quality around the brand owner's products – all in one system. With this, manufacturers can analyze supplier performance, and identify trends. Trends such as which suppliers take the longest to complete a task or which suppliers have the most quality issues assigned to them. This data can also be leveraged to automate supplier scorecards.

Instead of “cobbling” together data from multiple spreadsheets and outdated reports, manufacturers can leverage the quality data that is captured into one collaborative system to generate up-to-date reports and performance dashboards. They can then use this data to take action.



Supplier Collaboration Benefits

For Manufacturers / Brand Owners

Collaboration across the quality business network supports quick access to business information for decision support. All the quality data for the supply chain is in one place. From an operational perspective, this means that the information needed for short-term planning and decision-making is readily available, and known to be both current and reliable. If disputes arise, there is always a single source of truth.

From a longer term planning perspective, it allows manufacturers to be proactive instead of reactive when it comes to quality. They can easily evaluate and rank their suppliers according to a variety of quality criteria such as deviations, cycle times, and other metrics, and proactively address potential problems (e.g. if a particular supplier's performance is trending downward).

For Suppliers & Contract Manufacturers

The benefits of the collaborative approach aren't reserved to manufacturers. Suppliers also gain business benefits. To begin with, the hassle of the back-and-forth communication to deal with quality is as much a problem for suppliers as it is for manufacturers. As a member of a quality business network they can be sure that they're supplying all the necessary information the first time.

Also, speedy resolution of problems has important financial implications for suppliers. When quality events occur, suppliers are often compelled to shut down a production line until the issue is resolved, which can mean that expensive capital equipment sits idle. Even cash flow can be affected.

Collaboration enables suppliers to be aware of their performance (based on the data access permissions they've been granted) and also learn from the broader community in areas such as problem resolution and best practices. In fact, for many members of the supply chain, they will have a better quality system than ever before.

Time to Act

The quality problems and the risks associated with them are not going to go away by themselves. In fact, every indication is that more complex supply chains are on their way, with more quality problems than ever. Quality business networks can reverse this trend.

Effective supplier quality management through collaboration can impact:

-  **Visibility** - Identify issues early before they become costly quality incidents
-  **Traceability** - Understand the root cause and source of quality issues in the supply chain
-  **Accountability** - Ensure supply chain partners understand issues & resolution requirements in a timely manner
-  **Profitability** - Mitigate quality related financial risk and improve supply chain efficiency

With today's web-based technology they can be implemented easily and cheaply, with no need to involve the IT department or pay installation and maintenance costs. In short, the time to start gaining back control of quality problems is now.

Resources

To learn more about how supplier collaboration and the quality business network can reduce costs and minimize risks, please visit www.spartasystems.com or check out the following resources:



[**Webcast:** Improving Quality & Efficiency through Supplier Collaboration](#)



[**Video:** Take Control over quality in your supply chain](#)



[**Whitepaper:** The Rise of the Quality Business Network](#)

Founded in 1994, Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the solutions, analytics, and expertise that speed up quality and compliance. Our solutions help to lower risk, increase efficiency, and keep consumers safe while allowing manufacturers, suppliers, and distributors to collaborate in a seamless and integrated environment. Sparta is privately owned and headquartered in Hamilton N.J, with offices across Europe and Asia. We support close to 1 million users across 700+ implementations, in more than 30 countries. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta.

Global Headquarters

2000 Waterview Drive
Hamilton, NJ 08691
(609) 807-5100
(888) 261-5948
info@spartasystems.com

European Offices

Berlin | London
europe-info@spartasystems.com

Asia Pacific Offices

Singapore
apac-info@spartasystems.com

www.spartasystems.com
<http://blog.spartasystems.com>