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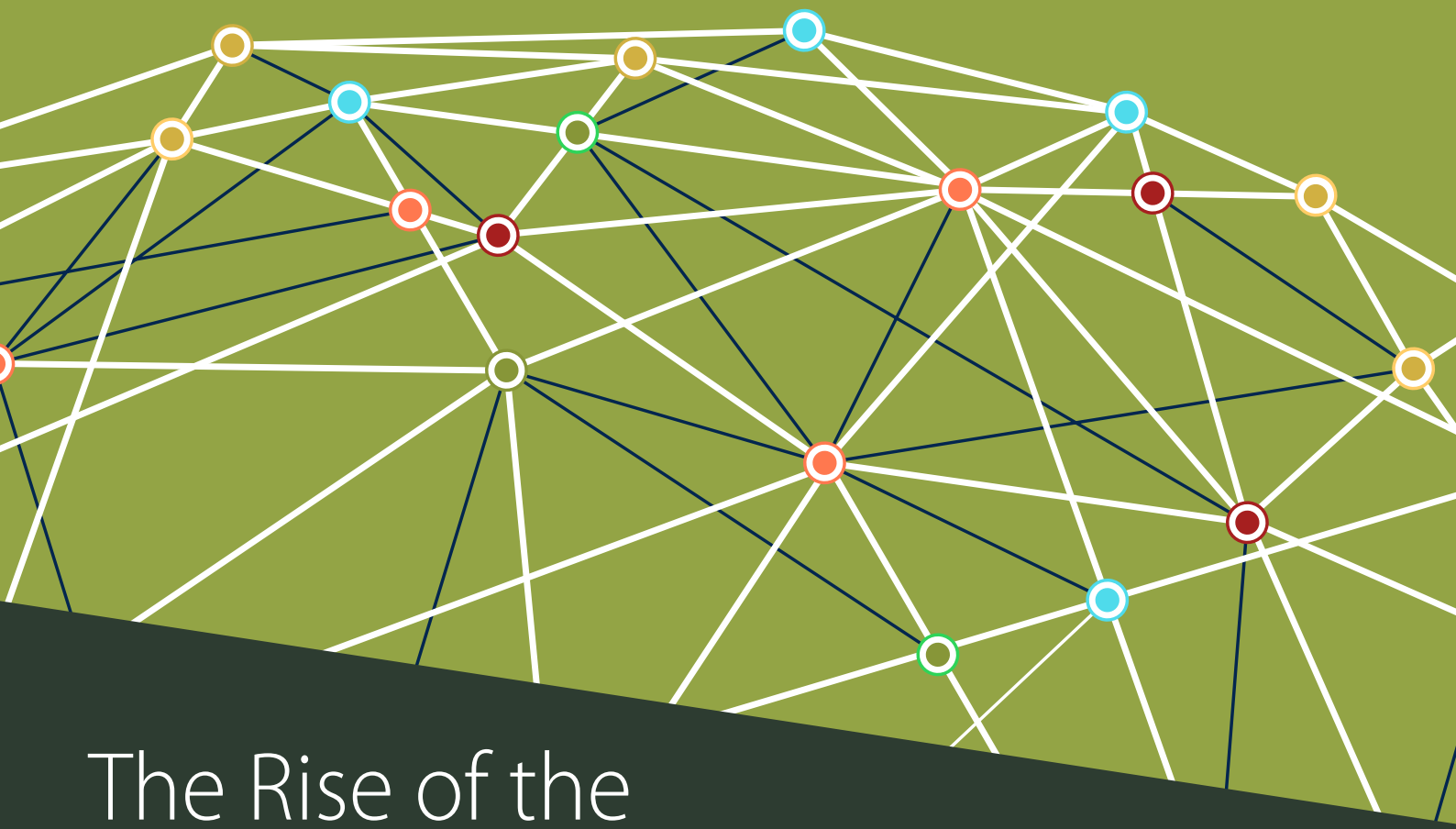

The Rise of the Quality Business Network

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WHITE PAPER

Executive Summary

Driven by market expansion, financial pressures and the need to accelerate innovation, today's manufacturers have expanded their global operations and increased the number of supply partners. This evolution has only amplified the manufacturer and supply chain relationship which is often characterized by a delicate balance between cooperation and adversarial negotiation. In this new era, stakeholders are required to connect, interact and integrate on previously unknown and unexpected levels. This paper makes the case that in one very important area - quality – this heightened need for collaboration and cooperation combined with the adoption of new hybrid technology approaches are fueling the emergence of a virtual connected quality business network . As such, manufacturers, suppliers and contract manufacturing organizations (CMOs) are seeking new and direct ways to collaborate efficiently and effectively in their handling of quality events in order to achieve the financial benefits which can be measured in hundreds of thousands of dollars in annual savings from operational efficiencies, not to mention millions of dollars from the avoidance of commercial recalls.

Offshoring & Outsourcing: Trends Accelerating Complexity

Outsourcing and offshoring continue to be important manufacturing trends today, and are not confined to huge multinational companies. A 2014 study by The Keystone Group consulting firm showed that two-thirds (65 percent) of U.S. mid-sized manufacturers with annual sales of less than $500 million have one or more offshore manufacturing operations.

According to a recent study by Contract Manufacturing, CMOs already account for 38 percent of the volume of fill/finish operations in the pharmaceutical sector. In the same study, 17 percent of the respondents projected increases in outsourcing budgets of 25 percent or more. 47% of respondents also indicated they would off-shore some manufacturing in the next five years.

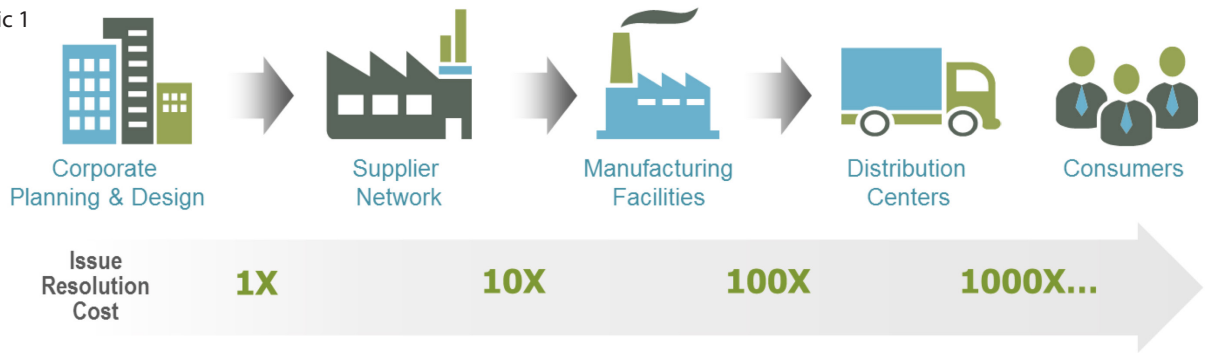
While offshoring and outsourcing both have important financial benefits, they also bring significant challenges, particularly in the area of quality. As the number of hand-offs increase from raw material to finished product, there is a higher risk of a quality event driven by GMP issues, direct or indirect product adulteration or lack of regulatory oversight. The quality systems in place at suppliers and smaller CMOs often lag behind manufacturers, but even if they don't, they are separate and disconnected systems relying heavily on manual intervention and the transposing of data between systems via fax and email. This is error prone and inefficient approach can lead to compliance gaps and seriously limits the visibility and transparency needed to identify and resolve quality issues. This lack of mature quality management has serious consequences. According to a joint industry report produced by Deloitte Consulting and sponsored by the Grocery Manufacturers Association (GMA), Food Marketing Institute (FMI) and GS1 US, 52 percent of all quality events are supplier-related.

The implication here is that as the amount of external manufacturing grows relative to in-house manufacturing, so will the number of quality events. And that is exactly what appears to have been the trend in recent years.

- From 1999 to 2011, the number of product recalls increased 135 percent.
- From 2004 to 2013, FDA drug recalls increased 600 percent.

Visibility and deep collaboration amongst all partners can reduce variability and therefore can reduce risk. This is a key aspect of the quality management philosophy of W. Edwards Deming: catch problems early, build quality into your processes, and proactively prevent against issues vs. react to them after the fact (see Graphic 1). Companies must look at their supply chain as an integrated function within their quality management practices however only 22% of companies see quality as an integrated function of their supply chains . In regulated industries the guidance documents and regulations are clear that the product owner is ultimately responsible. For example, the FDA states in ICH Q10 (Pharmaceutical Quality System) – "The pharmaceutical company is ultimately responsible to ensure processes are in place to assure the control of outsourced activities and quality of purchased materials". Therefore, manufacturers must find ways to manage supplier risk as a means to controlling their own risk.

Graphic 1



The Financial Pain of Quality Events

Recalls are an increasingly common scenario when it comes to quality events. A recall can cost anywhere from $10 million to as much as $90 million per event according to the above-mentioned report, and that does not take into account the devastating effect a recall can have on a company's sales, brand image and stock price. The cost of poor quality can have dramatic and sometimes unrecoverable financial and regulatory consequences, both internally and externally.

When a major quality event occurs, manufacturers can't ship the product in question. As an example, for the typical top 50 pharmaceutical company the average cost is $250 thousand per day - a very significant sum considering that it typically takes about 15 to 30 days to resolve a quality event in the best case, and sometimes as long as two months. For consumer goods manufacturers, the costs can be much higher - as much as $1 million per day. Quality problems with iPhones reportedly cost Foxconn $1.6 billion in replacement costs and created a 3-week "hole" in Apple's supply chain.

Manufacturers are not the only ones who bear the financial consequences of quality events. Suppliers suffer as well. Even a small quality event - a transient spike in temperature or humidity in a controlled manufacturing environment for example – can result in the immediate shutdown of the manufacturing line where the event occurred and usually lasts until the problem is resolved. During this period of time, the supplier or CMO involved can't invoice its customer. Pharmaceutical CMOs have the added burden of not being able to lease out use of the suite space developed and validated for a specific customer while the quality investigation is cleared. This obviously has a very negative effect on cash flow. It also ultimately impacts the supplier's ROI on the manufacturing assets that experience unscheduled down time.

A less visible quality issue affected by the growth of outsourcing is the management of audits and regulatory investigations. Everyone involved in manufacturing within a regulated industry is familiar with the angst and disruption that accompany an audit or investigation. Collecting the requisite data internally is difficult enough, and the problem is compounded exponentially when it's necessary to track down all related communications, such as e-mails, faxes, etc., from an outside source to establish what happened and when and prove to regulatory bodies that there is a sufficient level of control over quality processes and events in the supply chain.

Understanding The Sources Of Complexity

It's a fact of life that management of quality both internally and across a supply chain involves dealing with a high degree of complexity. This is what makes it so difficult. What companies need with respect to quality - visibility, traceability, accountability and profitability – hasn't changed. But these needs now cross often disconnected internal operations and extend beyond the four walls of the manufacturer and span across the whole supply chain, creating new complex issues that need to be understood.

Supply chain complexity, and by extension the quality stakeholder ecosystem, is driven by five primary factors:

Variables - How many variables must be monitored and controlled? The sheer number can be daunting.

Interactions - How many transactions are required and who needs to be involved? Are they manual? The more individuals who have to supply data or approve remedial actions, the more complex the process becomes.

Variety - What is the variability of each interaction, and what are the various levels of interaction required for problem resolution?

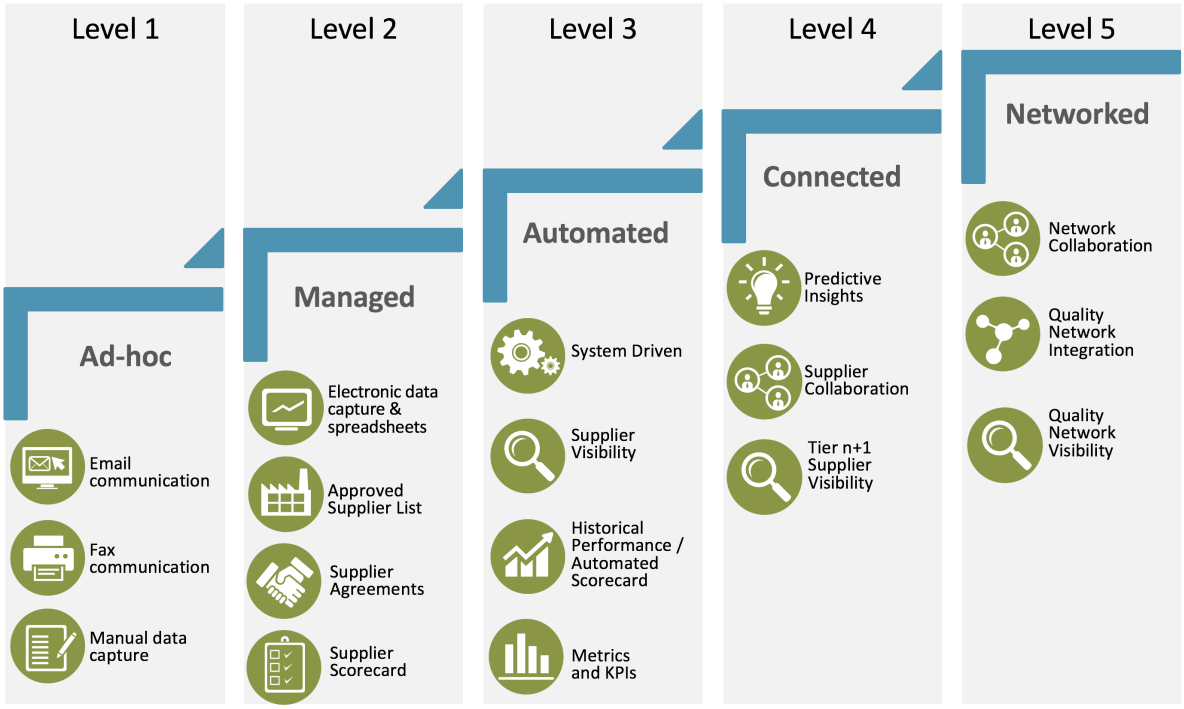
Visibility - How much visibility into the different interactions is required vs. what is available?

Change - Supply chains and the quality ecosystems they serve are dynamic and an issue in one part can impact many others. An example of this is the well-known bull whip effect, where customer demand impacts order and inventory fluctuations that build and magnify upstream in a supply chain. Do suppliers have a mechanism to notify the manufacturer of a change in meeting a specification? How does the manufacturer manage and communicate changes to a CMO or supplier. Is it automated or manual?

The Quality Maturity Framework

Before discussing how technology can improve quality and enable the quality business network, it's important to establish a very clear idea of how "improvement" is defined. To this end, Sparta Systems has created the Quality Maturity Framework (See Graphic 2). The five level framework puts quality management on an objective footing, and also incorporates specific best practices that enable manufacturers, suppliers and CMOs not only to establish their current level of maturity, but drive improvement as well.

Graphic 2



Level 1 companies respond to quality events on an ad hoc basis when they occur, more or less improvising as they identify the problem and seek to resolve it.

The worst aspect of this level is that it is slow. Processes are manual. Communications based on telephone calls, faxes and email are subject to all sorts of delays that are built into business life. People sometimes fail to check email. Individuals who are in a position to approve a CAPA plan go on vacation. The time zone differential between manufacturing facilities or between a manufacturer and supplier limit the time window for telephone calls. While these events may seem trivial in themselves, when taken together they can add days to the resolution time frame.

Another time-related problem is that communications coming from a supplier or CMO related to a quality incident are often unclear or lacking in important details. This adds another back-and-forth to the process - the request for clarification and the response - and that means more time is wasted.

At Level 2, there are defined processes for dealing with quality events. Manual data capture is replaced by electronic capture via fill-in forms that ensure a complete picture of quality events and enable repeatable processes. The data typically resides in spreadsheets. While this is an improvement, it is not an optimal approach. As anyone who has gone through the process knows, analyzing or comparing data using multiple spreadsheets can be an arduous, time-consuming process.

Beyond data capture, the other key element of Level 2 is better supplier/vendor management, including an approved supplier list and formal supplier agreements that define service levels, notification responsibilities, timeframes related to quality events, and agreements concerning who will pay for their resolution. At level 2, companies maintain supplier scorecards that provide an objective measure of supplier performance (although these scorecards may be updated only once a year or on an ad-hoc basis).

Level 3 is a system-driven approach characterized by centralization and automation. All data resides in a central database or system, such as an enterprise quality management software (EQMS) system, where it can be instantly accessed as required, either to speed remediation or for regulatory purposes. Quality events across the organization are now managed consistently and efficiently in this centralized system. A benefit for manufacturers is that all suppliers and CMOs are managed from a single point, making for easy comparison, with automated scorecards that reflect both current data and historical track records. Level 3 companies operate much more efficiently with regard to quality events, and are also well-equipped to deal with audits.

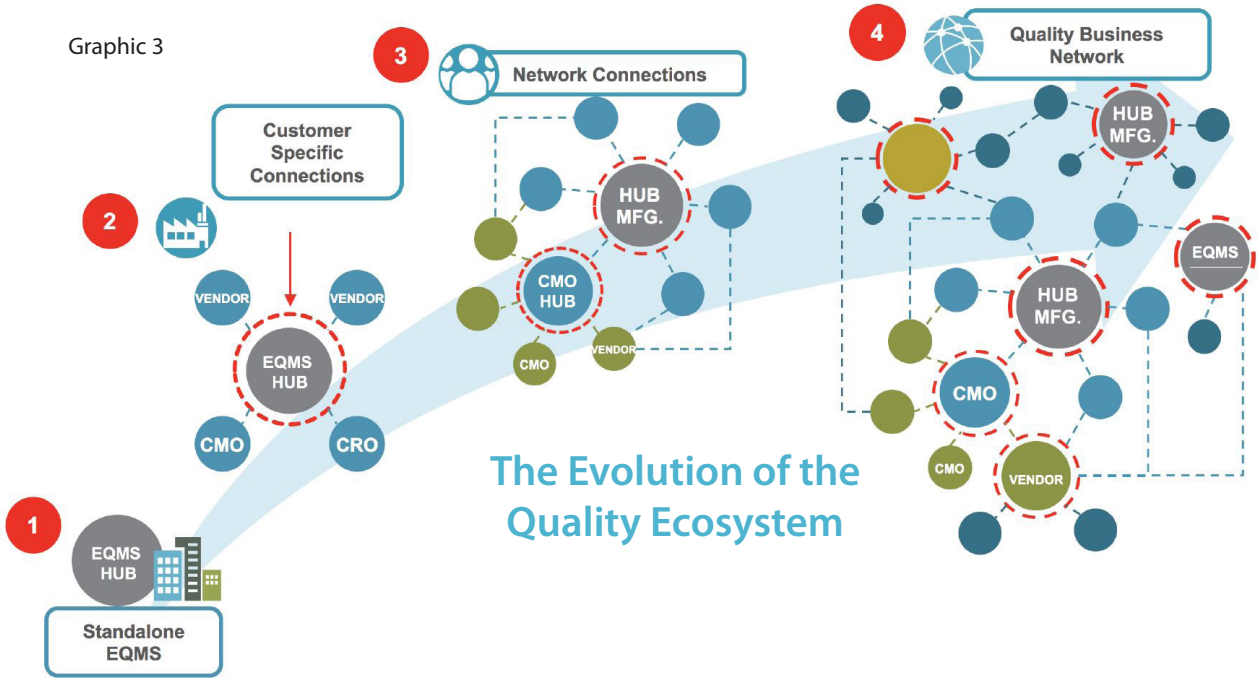
Level 4 extends the manufacturer's visibility into Tier 1 suppliers and CMOs so that they have direct access to data related to quality events. At Level 4, manufacturers and supply chain members connect and collaborate, not only to ensure quality but also to optimize resources. Managers can leverage predictive analytics and identify trigger events, i.e. patterns of data from multiple sources that indicate the likelihood of a problem, enabling them to take action before the problem actually manifests itself.

When problems can be indexed and resolved before they lead to supplier delays, CMO shut downs, late shipments by manufacturers or even recalls, everybody in the supply chain benefits, both from an operational and financial perspective. Operationally, cooperation that reduces the number of quality events improves productivity. The huge amounts of time and effort associated with resolving problems can be put to better use with activities that move the business forward, such as fine-tuning manufacturing processes and R&D. The ability to quickly provide regulators data from the entire supply chain with little effort has the same effect on productivity during audits and inspections.

Level 5 involves deep collaboration and an evolving interdependence among suppliers, CMOs and manufacturers, resulting in the creation of the Quality Business Network. In this network, members shift their focus from the value they derive from their own use of technology to the value derived from other companies' use of the technology. This includes better management of the growing and increasingly complex partner ecosystem, integration capabilities to connect network members, and analytics to turn data into actionable intelligence on the network – all of which contribute to network value. In this final stage of maturity, new and legacy technologies are combining as a disruptive force to connect quality ecosystem stakeholders in a virtual Quality Business Network. (See Graphic 3)

According to Sarnoff's Law, the value of a network is proportional to the number of viewers. In the case of the Quality Business Network, each additional participant increases the overall ability to uphold the same standards and efficiency for quality events inside and outside the four walls of a manufacturer. Moreover, stakeholders do not have to be at a Level 5 in order to participate. Companies with less mature approaches to managing quality can still connect to the network and therefore simultaneously benefit individually and expand the overall network value.

Graphic 3



New Technology Approaches Drive Innovation

There is no shortage of examples illustrating how the internet has created broad disruption that is driving change across all business functions. Ubiquitous connectivity and the free flow of information has opened up new ways to streamline and manage business processes and new ways to connect and share information.

While cloud computing is revolutionary in delivering applications as services, companies are adopting information technology solutions based on need and fit with the overall business and technology strategy. CIO's are increasingly combining an IT architecture that continues to leverage legacy investments while taking advantage of new technologies to enable improved collaboration and greater flexibility and efficiency. CIOs are demanding the ability to combine the best of cloud technology – both public and private – with core on-premise system investments.

In the area of quality management, manufacturers have long been investing in technology to obtain process automation and efficiency benefits. Application investments have not only automated processes but also enabled best practice adoption and enforcement.

For example, information can be conveyed using standardized forms that support accurate, comprehensive communication and eliminate delays associated with missing information. The use of technology has significantly reduced time-to-resolution for quality events, and this has translated directly into manufacturer cost savings. For example, participants in a study conducted by Sparta Systems reduced the average cycle time for quality events from 137 days to 66 days over a two-year period through EQMS automation. More than half the respondents in the study indicated that an EQMS could improve quality management process-related efficiencies between 20 and 50 percent.

Quality management practices have historically mirrored the industrial age practices of manufacturers with a make-sell business model. This linear and often siloed approach has fostered stakeholders to develop different approaches to managing quality events. These practices can range from (literal) paper processes to processes managed electronically via enterprise quality management software. Despite advances in technology and intra-company communication, inter-network communication or communication outside the four-walls on product quality is still in its infancy. There is often no true system of record, communication is point-to-point instead of a hub and spoke communication model, and electronic communication is sometimes relegated to fax and scanned PDFs. Companies are aware of the problem, but they have been unsure where to start.

Technology has caught up to the problem. While many manufacturers in regulated industries have been slow to adopt cloud technology citing data security and system validation as key concerns, the industry leaders and innovators are beginning to deploy cloud solutions as part of their quality management information technology strategy. As a result, quality management is becoming less about just internal process efficiency and visibility and more about connecting stakeholders in the virtual quality ecosystem. Manufacturers are now evolving more completely into the sense – respond business model of the Information Age where the visibility into quality issues is increased and the value to any individual member of the quality network is amplified as more manufacturers and suppliers connect. In this network environment, the ability to connect quality systems, communicate information and analyze quality data is critical. Manufacturers and suppliers will continue to demand choice in their technology. As such, integration and data management will increasingly underpin the success of quality management business and information technology strategies.

The Quality Business Network: Value Across The Ecosystem

As the relationship between internal quality management processes, supply chains and the customer experience becomes increasingly complex, stakeholders in the quality management value chain must connect, interact and integrate on previously unknown and unexpected levels. Small and large manufacturers alike are demanding solutions that can look beyond their four walls to integrate and connect systems, services, supply chain partners, customer feedback and quality management related processes and data to create more efficient and more powerful means of ensuring product quality and safety.

The benefits of this connected quality management ecosystem – the Quality Business Network – include:

- Increased visibility – instant awareness of quality issues from upstream and downstream partners
- Enhanced accountability – Make each partner accountable for its role in the supply chain
- Operational efficiency – all electronic systems make it easy to track and trend quality issues, which are reported real-time
- Product safety and compliance – ultimately, a healthy, quality supply chain enables production of safe products

In an effort to realize these benefits, manufacturers and suppliers are adopting cloud technology as part of a hybrid quality management information technology strategy. As a result, new paths to innovation are supporting the evolution of the Quality Business Network where internal quality management processes are connected to ecosystem partners delivering comprehensive visibility of issues from raw material through manufacturing to customer experience and back. The Quality Business Network is an emerging reality that no member of a manufacturing supply chain can afford to ignore.

Sparta Systems enables the virtual quality business network through a portfolio of technology solutions that connects internal quality management processes to quality ecosystem partners and delivers visibility, connectivity, efficiency, and a richer user experience on any device, anytime. Sparta Systems is uniquely positioned to connect the quality ecosystem and establish this Quality Business Network as a result of deep quality management domain knowledge and a network of 750,000 users across 30 countries. By standardizing business transactions and their associated data the Quality Business Network empowers collaboration and information sharing across quality management value chains. Ultimately providing customers with a greater ability to connect with others and take action. As a result, Sparta does far more than facilitate simple transactions – we help companies turn data into insight and insight into action by leveraging data for benchmarking, incorporating learnings into their business processes, and making better real-time decisions.

Sparta's industry leading solution portfolio includes:

TrackWise, an established leading enterprise quality management software (EQMS) solution, enables the Quality Business Network as a core quality management solution that optimizes quality processes, ensures compliance, reduces risk, and lowers operational cost.

123Compliance, a cloud solution that is fully validated and 21 CFR Part 11 compliant, enables quality and complaint management processes and extends the Quality Business Network to organizations seeking a quality and complaint management solution built on the Salesforce.com platform.

Stratas Quality Platform, a cloud solution built on Amazon Web Services, is comprised of Stratas Quality Management, Stratas Supplier Collaboration and Stratas Quality Network Integration Layer. Stratas Quality Management enables quality management processes and delivers a rich and intuitive user experience. Stratas Supplier Collaboration connects quality ecosystem suppliers and partners to internal quality management processes. Stratas Quality Network Integration Layer is a secure and scalable platform that delivers system integration and data sharing enabled by the patent pending data standardization QDIS (Quality Data Interchange Specification) message protocol. .

QualityView embeds self-service business intelligence and reporting tools directly into the enterprise quality management system. As a result, end-users gain insight into every aspect of quality across the enterprise.

QualityConnect is Sparta's portfolio of integration offerings designed to enable integration with a variety of enterprise systems such as Enterprise Resource Planning (ERP), Customer Relationship Management (CRM), Laboratory Information Management Systems (LIMS) and Manufacturing Execution Systems (MES).

[1]http://www.thekeystonegroup.com/documents/Middle_Market_Trends_Offshore__Mfg_and_Sourcing_vF.pdf
[2]http://www.contractpharma.com/issues/2015-01-01/view_columns/7-top-trends-in-biomanufacturing-outsourcing/
[3]Gartner, s. Jacobson, "Quality: The Missing Link In Your Supply Chain Strategy", January 2015
[4]http://www.theregister.co.uk/2013/04/22/apple_returns_iphones_to_foxconn
[5]Business Networks: The New Innovation Platform; IDC, March 2015

To learn more about this topic and how Sparta Systems can help, visit www.spartasystems.com

Eileen Martinson has over twenty years of enterprise software industry experience holding executive leadership positions at technology companies including SAP, Siebel, Oracle and Allscripts. Since assuming the role of CEO, Sparta Systems Inc., in 2011, she has become a trusted advisor to senior Life Sciences and Consumer Products executives on strategic quality management initiatives.

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