Sparta Systems

Extending Control and Transparency into Supply Chains:

How Cloud Technology Can Help With Supplier Quality

WHITE PAPER

Introduction

For companies that manufacture products, the quality of each supplied item in the manufacturing supply chain is critical to the ultimate quality of the commercial product and the success of the company as a whole. Over the past decade, as supply chains have become increasingly global, decentralized and complex, it has become more challenging to manage quality across this broad range of suppliers and contract manufacturers.

This paper will examine the evolution of the supply chain, enterprise quality management solutions (EQMS), the supplier quality relationship, and the increasing pressure placed on manufacturing for improved quality. It will also explore ways that companies can regain control of supplier quality within today's complex value chains through the use of cloud-based technologies.

The Increase of Manufacturing Scrutiny

Quality management in both regulated and unregulated industries alike has entered an era where it is utilized extensively in manufacturing around the world. By one estimate, well-implemented quality management practices have lowered the cost of poor quality and raised gross margin by as much as three percent. However, despite the adoption of these best practices in manufacturing, quality problems in the final packaged products continue to rise across the board.

One telling example: according to FDA statistics, there were 5,585 product recalls in 2007. In 2012, that number rose to nearly 10,000. This trend is expected to continue in the US and abroad. While the quality of the manufacturing process may be high, over 53%[1] of the issues found at the source of these recalls were caused by the quality of a supplied item. The implication is clear; the quality management of the supply chain is just as crucial as the practices used at the manufacturer.

Recent high-visibility quality problems range from peanut butter contaminated with salmonella, to lead-tainted toys, to batteries that cause laptop computers to burst into flame. Many less visible, but equally important examples are present in the life sciences market. Many had significant business consequences, and most can be traced back to supplier problems. In a recent study, the stock price of companies that announced a recall underperformed in their sector on an average of 2.3 percent the next day. The study indicated that companies who executed a recall poorly, could see stock price declines as high as 22 percent within two weeks. And more importantly, these quality issues often go beyond the manufacturer's reputation and bottom line to cause serious injuries or death.

No one wants quality problems, and yet clearly they are on the rise. The necessary business innovation and technologies required to keep a large, fragmented supply chain in check from a quality management standpoint have not been adopted. Lacking the infrastructure, process, or systems to achieve this control, manufacturers have depended on quality contracts and indemnification to keep suppliers and contract manufacturers held to quality standards. Given the growing number of recalls, this somewhat adversarial approach has been insufficient to resolve this growing problem, and a more cooperative, closed-loop and transparent approach is needed.

The Vertically Integrated Roots of EQMS

Prior to the advent of computer-based enterprise quality management solutions, quality management in general was a cumbersome process. Particularly in highly regulated sectors like pharmaceuticals, medical devices, biotechnology and more recently consumer goods, the root cause of a problem could often be discovered only in hand-written notes recorded in lab notebooks, log files from laboratory equipment, or Excel spreadsheets used to track discrepancies.

From the discovery of a problem, to its investigation, through to its resolution, communication took place via telephone, fax or email, often with no centralized tracking system to ensure that the process was moving forward in a timely manner, and without any closed-loop systems to ensure that the problem was truly fixed. The arrival of quality management systems changed all this. Comparative to current solutions, early systems facilitated and streamlined communications between all involved parties when something went wrong. More advanced solutions enforce a disciplined approach to core quality management processes such as corrective and preventive actions (CAPAs), deviations and non-conformances during manufacturing, change control, complaints, and a variety of other quality interactions.

Manufacturers had more or less complete organizational control over all the business units involved in quality. They typically owned most of their supply chain and manufactured virtually everything sold. In general, a "made here" mentality prevailed. They could implement a quality management solution by fiat, with no need to promote cooperation or build consensus and buy-in from external entities. Furthermore, engineering, operations and financial records were based on the same systems and data, using the same standards and metrics. Finally, the individuals involved, including the suppliers, all belonged to the same organization. While some degree of conflict existed between the various functional and business units in the enterprise, it was limited in comparison to the adversarial

[1]Recall Execution Effectiveness Report. Deloitte, GMA FMI and GS1. May 2010

relationships that can exist between companies and external suppliers, which has only increased with decentralization and globalization.

The Decentralization of Manufacturing

Recently, the globalization of manufacturing and supply has fundamentally changed the nature of the equation. Quality management solutions that had worked so well in the past have been undermined by these broad industry trends:

- Suppliers that were once geographically concentrated are now globally dispersed
- Manufacturers are asking suppliers to play a much greater role in product design and development, including sharing some of the financial risk
- Manufacturers must now manage quality in supply chains that are almost continually being redefined, expanded and adjusted
- Outsourcing of manufacturing, once a rarity, has become commonplace with many 'virtual' organizations

As a result of these changes, all the quality problems of the pre-EQMS era have reemerged, and in fact, they are more difficult to solve than ever. There is little doubt that these problems stem from this new externalization of supply chains. As mentioned, more than half of product recalls can be traced back to supplier and contract manufacturing issues.

Manufacturers are well aware of the problem, but it is extremely difficult to achieve transparency and traceability in an environment that has become so complex. For example, if the capsules for an over-the-counter medication are discovered to be discolored or malformed — problems typically caused by overheating — there are multiple potential causes. Did it happen during the filling, blistering, packaging, or shipment, or was a raw material not up to specification? It can take heroic efforts to solve a 'simple' problem like this, and throughout the process, the manufacturer is placed in the position of consistently waiting for responses, requesting updates, and managing the quality issue to completion.

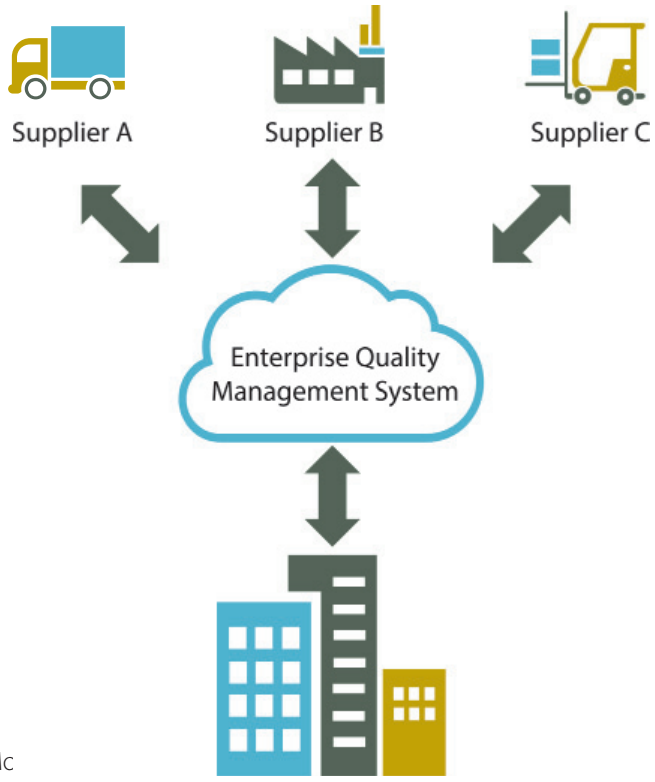
Data, Process Work Flows, and Communication

The collection of data is one of the biggest challenges in an environment where neither people nor data are co-located. The more external suppliers there are, the more likely different systems are involved, and these systems are typically incompatible. This means that in order to be aggregated, data has to be manually re-keyed by each party, a 'swivel-chair' process which is not only time consuming and expensive, but error-prone as well. In many cases, the data has to be converted to allow for comparable evaluations and benchmarking.

Another problem is the lack of sufficient data that is required to make optimal decisions. For example, the only quality metric that may be available for comparing suppliers is the number of deviations that occurred in a given time frame. This leaves numerous important questions unanswered:

- How divergent were the deviations from the mean?
- How long did it take for each one to close?
- How responsive were the suppliers?
- How often were suppliers cited for the deviation at an audit?
- Did the supplier close the finding in a timely fashion?
- What were the process impacts at the manufacturing plant?
- What were the financial impacts of each deviation?

Timeliness of response is a huge issue during the management of the deviation. Manufacturers all too frequently find themselves stalled because they have to wait for data.



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systems that prevail, there is often no single point of truth or system of record for the quality issue. This can force auditors to look into ancillary systems for the quality record, and call into question which system is accurate if there is any discrepancy.

Process enforceability is another issue particularly when operations are extended beyond the four walls of an organization. This is primarily due to a lack of process standardization, decentralized communications, as well as differences in overall business philosophies. When operations are "inside-the-four-walls," the processes associated with NCMRs and CAPAs can be standardized via an EQMS. The same EQMS will not only route communications, but also enforce process, time constraints, ensure closed-loop problem resolution, and collect statistics for the quality component of supplier scorecards. Communication and collaboration is another serious issue. In decentralized supply chains, communication is all too often a disorderly, ad-hoc conglomeration of telephone calls, fax, courier and email, with no formal tracking of who has communicated with whom and when. The simple fact that suppliers operate in multiple time zones and speak different languages is not a trivial problem, and unsecured fax and email is often the system of choice for this communication.

Security is yet another communications-related problem, and it can be quite serious. As manufacturers work more and more closely with suppliers to solve quality problems, it becomes increasingly likely that communications will include sensitive information that they would not want publicly shared. As mentioned, emails that may contain sensitive product specification or defect information sent out on the open Internet may be easily collected and cannot be considered in any way secure.

Manufacturers cannot afford to turn a blind eye to these multiple problems. The FDA has recently issued new draft guidance that reflects an increased focus on relationships between manufacturers and suppliers related to quality, and makes specific reference to the need to track communications and change management processes[2]. The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 provides express authority for the agency's heightened focus on supplier and contractor quality down to the level of raw materials. These developments make it clear that manufacturers are unambiguously responsible for quality, and that responsibility extends across the entire supply chain. In fact, there are hints that the Park Doctrine, which affirms that individual executives can be held personally responsible for violations of current Good Manufacturing Processes (cGMPs), may possibly be extended to supplier errors.

Leveraging Cloud Technologies

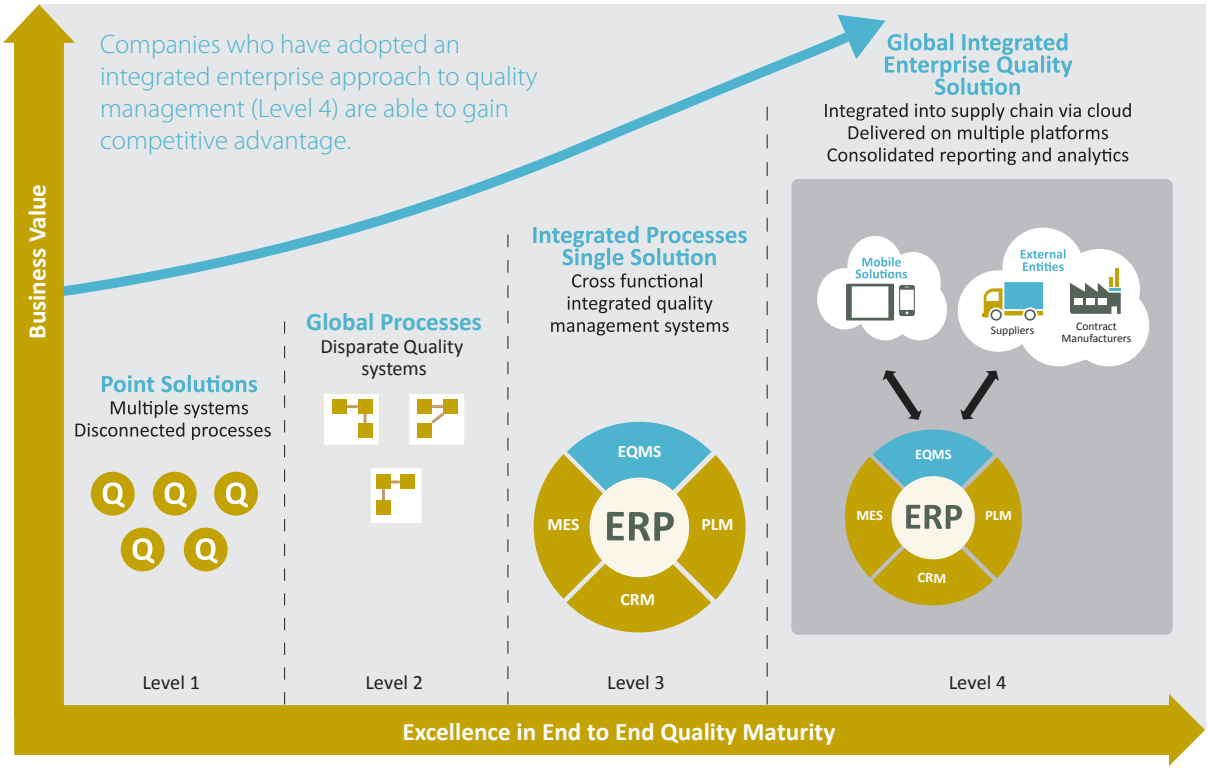
The easiest way to solve these problems would be to simply extend the features and benefits of an inside-the-four-walls EQMS outward to encompass the entire supply chain. In this vision:

- Suppliers and manufacturers would abandon their adversarial stances in favor of a collaborative approach to quality. (This is already taking place. In a recent Ernst & Young study, 70% of CFOs and 63% of supply chain leaders indicated that their relationship has become more collaborative over the past three years.)
- Suppliers would input quality-related data directly into a common database. That data would be complete, standards based, consistent, accurate and time stamped. It would serve as a single point of truth for both suppliers and manufacturers, and a trusted source from which manufacturers could easily extract data for the purposes of supplier evaluation and management, as well as regulatory compliance.
- Process work flows to support quality would be standardized for all the members of a supply chain, so that it would be easy for everyone concerned with an NCMR or CAPA to understand where things stood and what action may be required.
- Bi-directional communications would be traceable. Those related to moving a process forward (e.g. reminders or approvals) would also be automated.

Achieving a supply-chain-wide EQMS with this level of integration would have been extremely complex and expensive until recently, but new approaches to outsourcing combined with new technologies are converting this vision into reality.

The collection of technologies known more generally to

[2] Contract Manufacturing Arrangements for Drugs: Quality Agreements, May 28, 2013



industry as 'the Cloud' may contain part of the solution. These technologies are often limited to capabilities surrounding external hosting and infrastructure as a service, but most IT professionals consider the designation to include more generally Software-as-a-Service offerings, implemented as single-instance deployed websites, usually to provide a software service to multiple companies at once over the Internet. The central focus of these systems is to interconnect many global users and organizations to provide a single, central service of some kind. Often, these websites take advantage of advanced collaboration capabilities, social network-style identity and access management, support for multiple platforms and devices, and a consumer-grade user experience. Ideally, Cloud computing does not require any software to be installed, is always available, and can scale to meet most kinds of transactional demands from end-users.

These enabling technologies that barely existed only a few years ago are now available, mature and robust. These include global internet connectivity and browser standards, social technologies and federated authentication, SaaS technologies and business models, new approaches to the user interface and user experience that are easier to use and lack steep learning curves, and mobile devices that enable users to interact with their organization's quality system anywhere and at any time. From a technology perspective, cloud computing—and particularly the software-as-a-service (SaaS) model—provides an ideal medium for collaboration on quality. In the SaaS model, a manufacturer's existing EQMS is extended to suppliers through a cloud based application. Data is entered via the same screens and in accordance with the same business rules as those that prevail internally (with strict access and privilege restrictions). Communications related to specific quality processes like NCMRs and CAPAs take place within the same environment so they can be appropriately routed and tracked.

One of the key reasons why a new cloud-based EQMS approach shows so much promise is that it can integrate the quality efforts of the whole supply chain. Thus it can recreate the successes quality management software achieved at the time of its introduction into the marketplace, when the majority of the manufacturers adopting it were large, vertically integrated businesses.

Although the vision of 100 percent participation in an EQMS by every supplier in a supply chain may never be achieved, the vision of near-100 percent participation by Tier 1 and Tier 2 suppliers is not out of the question. Demonstrable business value combined with consumer safety and the technology to make it happen provide a compelling argument for the adoption of a comprehensive quality management solution that extends beyond the four-walls to encompass the entire supply chain.

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

Sparta Systems, an industry pioneer and leading provider of enterprise quality management software (EQMS) solutions, enables businesses to safely and efficiently deliver their products to market. Its TrackWise® EQMS, a trusted standard among highly regulated industries, is used by quality, manufacturing and regulatory affairs professionals to manage compliance, reduce risk and improve safety across the global enterprise. Headquartered in New Jersey and with locations across Europe and Asia, Sparta Systems maintains an extensive install base in the pharmaceutical and biotechnology, medical device, electronics manufacturing and consumer products markets.

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