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**E-Book**

## **Building an integrated workflow for quality control and compliance**

Global manufacturing and distribution create new challenges for quality control and compliance. With supply chains stretching overseas and customer requirements getting more stringent, manufacturers need fully integrated systems to measure and track product quality from raw materials through warranty service. This eBook explains the technical and organizational issues involved in providing key stakeholders with the visibility they need.

Plus:

- Understand the central role of product lifecycle management (PLM)
- Learn about integrating shop-floor manufacturing execution systems (MES)
- Read why cloud computing is key to global quality control and compliance
- See how continuous improvement and Six Sigma initiatives fit in

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# Building an integrated workflow for quality control and compliance

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## **Putting a global face on manufacturing quality control**

By Beth Stackpole, SearchManufacturingERP.com Contributor

Product recalls are every manufacturer's worst nightmare, and the headlines are full of stories about companies having to fess up and make good on manufacturing-quality-control disasters, from Baxter Healthcare's 2008 Heparin scare to Mattel's recall of toys made in China.

High-profile, quality-related incidents like these not only sully a manufacturer's reputation, they can do irreparable damage to the customer relationship, completely squashing demand for a product. While quality control has long been a top priority—albeit an ongoing challenge for manufacturers—the discipline has been made even more complex by the rise of outsourcing noncritical product development and manufacturing functions to an extended supply chain of partners that, more often than not, are scattered around the globe.

Global supplier networks that are multiple layers deep compound the quality issue for manufacturers in a number of ways. For one thing, they hamper their ability to respond quickly to market changes and evolving customer requirements because operations are far-flung and not under direct control. It also makes it more difficult to keep product costs down, which is an ongoing mandate for any manufacturer trying to maintain a competitive advantage in today's tough economic climate.

In many ways, the problem boils down to a case of reduced visibility. "The hard thing about quality and compliance when you have an extended supply chain is having the confidence that your supply chain partners are doing all the right things at the right times and in the right places," noted Peter Blok, a senior partner at Pharma Team USA, a Princeton, N.J.-based consulting company specializing in supply chain optimization and quality and compliance issues for the life sciences industry. "You need to have a quality system in place that not only qualifies a vendor when you initially contract with them, but you have to have an ongoing process and quality dialogue. Without this kind of visibility and communications, you need a tremendous amount of trust with your extended supply chain—and that's a hard thing to [achieve]."

## **Closed-loop quality-control systems**

It's especially hard to use traditional quality management and manufacturing systems to achieve the level of visibility that begets such trust. Conventional plant systems are just that—software and, more likely, paper-based processes that give some visibility into what's happening on a single plant floor without the context of what's happening in other areas of the business, let alone at outside partners.

Manufacturers are likely to have an array of siloed applications: document control systems, lab information systems, a handful of Six Sigma tools, maybe even some data mining programs that tap into historical data to analyze past quality trends. What's lacking in such setups is integration. The quality control tools are typically deployed within a company's four walls and even then are not synced up to share data with other enterprise systems that are critical to quality processes, such as ERP or supply chain management.

"There's never been any sort of closed-loop quality system; just about everything is lacking," said John Blanchard, principal analyst at ARC Advisory Group, a research firm based in Dedham, Mass. "All of the functions have been piecemealed together, and a lot of them have been manual. But due to the global nature of manufacturing operations, cost containment and response time is critical, hence the need for more visibility and better metrics."

The visibility problem is exacerbated when you factor in external partners. Typically, a manufacturer will receive a certificate of analysis that is intended to show that its supplier has passed certain quality or compliance standards. "But when I have an extended supply chain, I really want more data than a certificate of analysis," Blok said. Not only does this workflow fail to foster early collaboration between the manufacturer and supplier to prevent quality issues, it does little to foster a collaborative working arrangement to come up with a corrective action that will ensure the problem doesn't crop up again.

"We become highly dependent on our vendor's systems, and in order for me as a purchaser to be comfortable, it takes a tremendous amount of trust," Blok said. "That means my

quality people have to be talking to their quality people consistently, and today, that only happens when you're initiating the purchase or have a problem."

*Beth Stackpole is a freelance writer who has been covering the intersection of technology and business for 25-plus years for a variety of trade and business publications and websites.*

A close-up photograph of a woman with long, wavy blonde hair, wearing large, dark red sunglasses. She is looking slightly to the side with a soft expression. The background is a warm, orange-toned abstract image.

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## Experts share tips for shop floor quality control

By Beth Stackpole, SearchManufacturingERP.com Contributor

Looking to retool the shop floor so it can support the latest compliance and shop-floor quality-control best practices? The good news it might not require an extreme makeover and multimillion-dollar investment in high-tech gear.

Instead, manufacturers that integrate the plant floor into the rest of the IT infrastructure and shift away from a siloed focus to a networked plant view can position themselves well to respond effectively to quality issues – whether they occur inside the four walls or at a supplier on the other side of the globe.

“In the last year or two, there’s been a change in mentality for the manufacturing industry and a re-evaluation of IT on the plant floor,” said Pierfrancesco Manenti, research director for manufacturing in Europe, the Middle East and Africa (EMEA) at IDC Manufacturing Insights, a research firm based in Framingham, Mass. Manenti specifically called out manufacturing execution systems (MES), a key component in a company’s toolkit of quality-management software. “MES is becoming mainstream in the sense that in the past, this software was purchased and managed by the plants themselves. Today, it’s part of the IT portfolio and under the [domain of the] CIO.”

Creating tight shop-floor integration between MES and core enterprise systems like ERP and product lifecycle management is extremely important to facilitating quality programs. It helps create more of a closed-loop system, serving to accelerate engineering change management and helping to address potential quality snafus early in the cycle – well before production starts. Used in conjunction with traditional plant floor tools like statistical processing control systems, the newly integrated MES can help spot trends and identify and enforce standard operating procedures and workflows – from rolling out individual lines to bringing other plants on board. It can also aid in monitoring and enforcing processes that give guidance to plant floor operators.

“IT systems are really good at identifying and building in best practices, and tracking quality becomes just a side effect of the system,” said Julie Fraser, a principal industry analyst for

Boston-based consulting company Cambashi and co-chair of the Metrics Working Groups of MESA International.

### **Achieving cross-plant flexibility**

Standardizing this integrated MES and enterprise software portfolio across plants – not just having myriad systems in each plant location – is another requirement of promoting quality-management best practices. By doing so, companies establish a network of factories, as opposed to isolated plant floor operations. The benefits are twofold. Standardizing systems helps reduce IT costs, but perhaps the biggest benefit lies in gaining real-time visibility into what’s happening across all plant resources.

“This enables manufacturers to be more flexible in redistributing workloads,” Manenti said. “Manufacturers are trying to serve so many different countries and markets – demand is so variable. There is a need for flexibility across multiple plants so they can change workloads according to the variability of global demand.”

Beyond tighter integration of MES with enterprise IT, several emerging technologies promise to boost plant floor efficiencies when it comes to quality control and compliance.

Mobility is one such technology. While there have long been ruggedized computers on the plant floor, new smart devices like tablets provide a cheaper way to get computing power into the hands of machine operators while they are on the floor. In addition, the new touch-screen user interfaces of tablet devices open the door to new, highly focused and accessible apps – for example, business analytics – to help manufacturers capture and address quality trends at the point of failure.

“With these devices, people don’t have to be in front of a CRT screen to continuously monitor the state of a process,” said John Blanchard, principal analyst at ARC Advisory Group, a research firm based in Dedham, Mass. “They can use analytics to get alerts when there might be a problem.”

While new technologies will continue to play a role in improving plant floor operations, tried-and-true disciplines like lean manufacturing and Six Sigma remain critical cogs in the quality-management process. That's certainly the case at Instron, a Norwood, Mass.-based manufacturer of materials testing equipment. Instead of making huge investments in new technology or complex integration efforts, the company has devoted time and resources to revamping production processes for efficiency. The practice of cutting out unnecessary steps for its larger lean initiative has had a huge impact on quality even though it wasn't a direct result of a formal quality management program, said Cam Bickel, Instron's manager of document control.

"It's about getting the most out of the products we have and having the right processes to effectively deliver them," Bickel said.

## **Retool quality control software workflows for better products, compliance**

By Beth Stackpole, SearchManufacturingERP.com Contributor

With manufacturers more dependent than ever on extended supply chains, many are turning to new collaborative technologies and workflows to mirror the same visibility and traceability for quality control software and compliance as they have inside the four walls of their organizations.

Whether it's through high-tech systems or low-tech process change, the imperative is the same: Develop formal communication channels that support managing quality and compliance as a shared responsibility through every stage of the product lifecycle. "It really comes down to a matter of scale," said Peter Blok, a senior partner with Pharm Team USA, a Princeton, N.J.-based consulting firm. "If you have four suppliers, phones, faxes and emails may be fine. If you have 4,000 suppliers, that tends to be more difficult, and you likely need an IT system to address that."

Putting the systems in place to address quality management as a continuous process is one thing. But in this age of distributed supply chains, it's especially critical to design quality control workflows that identify and resolve possible quality issues at the onset of the design cycle, before any materials are procured and well ahead of when components, assemblies or recipes are manufactured or mixed on the production floor.

One solution is supplier networks that allow for a transfer of virtual product information between partners well ahead of when the actual components ship, which provides visibility all along and avoids last-minute surprises. That's not how it works in a traditional workflow, where manufacturing customers buy physical products from suppliers—assemblies, control systems, drivetrains, for example—and test for quality when the orders arrive.

If there's a problem with a physical unit, production is halted and engineers spend weeks, maybe longer, collaborating on a design fix, creating a workflow that adds unnecessary downtime to the go-to-market schedule, according to Michael Grieves, professor of information systems at the University of Iowa. Grieves is also a consultant to NASA and

author of the book *Product Lifecycle Management: Driving the Next Generation of Lean Thinking*.

Grieves advocates a new workflow, where manufacturers require suppliers to deliver a virtual product weeks ahead of taking delivery of the physical orders. Not only can the manufacturer identify issues involving a single component—related to quality, or noncompliance with environmental regulations, for example—it can also see what the product looks like in the digital world and get a jump on production or compliance concerns that could pop up later.

“Companies have to start to rethink how they procure products, and they have to demand this information from suppliers in advance, before the product shows up,” Grieves explained. “If you have that information well in advance, you can make a determination of whether or not you are being sent a nonconforming product before you actually get it.”

### **Laying the PLM data foundation**

Pathway Medical Technologies Inc., a medical device manufacturer based in Kirkland, Wash., hasn’t gone so far as to request a virtual product from its suppliers, but it has modified its processes to become more proactive. Specifically, the company is moving away from its existing supplier approval system to a more stringent supplier certification system that involves more communication and collaboration about quality management. The new approach gives Pathway greater confidence that its suppliers can consistently meet its standards, said Ken Perino, senior director of quality assurance and regulatory compliance.

As part of the new system, Pathway will perform a more rigorous assessment of suppliers’ capabilities and more continuous monitoring of results. The first stage of the workflow transformation is to create a supplier report card that will track and measure things like percentage of failure rates, specifications and raw materials. Currently, Pathway benchmarks suppliers manually, but the long-term vision is to automate the process through software that will integrate with the company’s core PLM data platform, which is the central repository for all product-, quality- and compliance-related data, Perino said.

"Without the PLM system, we'd be digging through files to build a history and we'd have to start over every time," he explained. "We continually feed information into the PLM system, and it's right at our fingertips when we need it."

PLM also serves at the heart of the quality management system at Instron, a manufacturer of materials testing equipment based in Norwood, Mass. Initially, the company used its PLM system to manage such customer-facing quality processes as tracking complaints and warranty issues, according to Cam Bickel, the company's manager of document control. The next step is to integrate the supplier database housed in the ERP system with the PLM platform so Instron can build supplier-quality profiles and use them to manage supplier certification and quality metrics.

"Over time, this will allow us to build up a history around suppliers so we can make the determination when we're designing a new product whether to use an existing supplier or to move away from a supplier based on past performance," Bickel said. Traditionally, Instron engineers and purchasing managers have worked in silos, which meant they often weren't on the same page when it came to making supplier choices. "This new system [and workflow] will put everything out in the open, so everyone can see what they're getting themselves into," he said.

## Building the global quality control ecosystem

By Beth Stackpole, SearchManufacturingERP.com Contributor

Technologies like cloud computing, social networking and collaborative platforms are emerging as the foundation for manufacturers to build global quality-control ecosystems, allowing them to work with far-flung suppliers as fully integrated organizations.

By leveraging new quality control software technologies, manufacturers can create a next-generation supplier network that delivers the visibility and real-time responsiveness that are lacking in today's siloed systems for plant and quality management.

"Today, products are simply not produced in one factory—components are made in multiple factories, owned by different companies, operating all around the world," explained Pierfrancesco Manenti, research director for manufacturing in Europe, the Middle East and Africa (EMEA) at IDC Manufacturing Insights, based in Framingham, Mass. "A quality system made available over the cloud can be shared by multiple organizations at the same time."

That's not how it works for most manufacturers today. Companies with multiple, geographically dispersed factories typically have separate plant systems at each location, most of which don't talk to each other. Visibility is further hampered because suppliers run their own systems to facilitate production, and any meaningful exchange of information on quality issues and plant snafus occurs through fax and phone or by pushing paper around the globe. Such manual interchange does little to create a real-time environment for addressing problems as they occur, or better still, heading them off at the pass in the design phase.

Enterprise applications, virtualized to run in the cloud, can foster business agility and deliver a level of real-time visibility that's not possible with today's siloed approach. "Leveraging the cloud infrastructure with virtualized applications brings everyone online in the same quality management tool," Manenti explained. "This delivers real-time visibility about what is happening. If you don't have the cloud, you really can't [effectively] collaborate across different businesses."

## **Fostering social engagement**

Another lynchpin in the quality control ecosystem of the future is having a parallel set of systems that are built on social media. Whether it's a public social networking platform or a private one built into an enterprise system, the end game is the same: provide a layer on top of workhorse quality management and core operational systems to facilitate the exchange of information between key business partners.

"By fostering ad hoc, collaborative social engagement in real time, companies can resolve issues as they arrive," said Julie Fraser, principal industry analyst for Boston-based consulting company Cambashi and co-chair of the Metrics Working Groups of MESA International. "With quality management, the idea is to catch something before it goes through the rest of the process or goes out to a customer, avoiding recalls and reducing effort." To push the concept to the next level, Fraser says companies will also tie business process management (BPM) and alert management into a larger global infrastructure to ensure that production doesn't head off track.

These technologies may constitute the future of a global quality control ecosystem, but it's still early on, and the platforms are still emerging. Nevertheless, there are more immediate steps manufacturers can take today.

Take Pathway Medical Technologies Inc., a medical device manufacturer based in Kirkland, Wash. A product lifecycle management (PLM) system serves as the central repository for all product- and supplier-related information, but customer complaints about product quality are handled in a separate database. The company plans to integrate the two databases to facilitate reporting and make it easy to communicate quality issues across the value chain, according to Ken Perino, senior director of quality assurance and regulatory compliance.

At testing equipment maker Instron (Norwood, Mass.), the next steps in its quality management journey call for creating a supplier portal that lets key suppliers tap into the firm's cloud PLM system to check their standing. "It's all about self-service, so they can come in and look up their rating without having to call someone," said Cam Bickel, Instron's manager of document control. "It just allows open exchange of information without the extra effort to make it happen."

In the end, creating the global quality control ecosystem of the future isn't just about the technology. It's about fostering the cultural changes necessary for making quality control and compliance a top priority across partners. "Manufacturers don't necessarily realize what the new capabilities are," said Michael Grieves, professor of information systems at the University of Iowa, a consultant to NASA and the author of *Product Lifecycle Management: Driving the Next Generation of Lean Thinking*. "Purchasing departments are still using those paper-driven inspection sheets when they get a product. They don't know they can demand something different than that."

## Resources from Apriso



[Closed Loop Quality Management - Improving Customer Focus from Design to Delivery](#)

[MES: Achieving Real Quality through Virtual Products](#)

[FlexNet and FDA 21 CFR Part 11](#)

## About Apriso

Apriso is a software company dedicated to transforming global manufacturing operations. It does so by enabling manufacturers to achieve and sustain manufacturing excellence while adapting quickly and easily to market changes. Apriso's FlexNet is a BPM platform-based software solution that helps manufacturers to increase efficiency, agility and quality while reducing costs and idle inventory. Apriso supports global continuous improvement by delivering visibility into, control over and synchronization across global manufacturing operations and the product supply network. Apriso serves 200+ customers in 40+ countries across the Americas, Europe and Asia. Customers include GM, Volvo CE, Honeywell, L'Oréal, Trixell, Lockheed Martin, Bombardier, Textron Systems, MBDA, Saint-Gobain and Essilor. Learn more at: [www.aprison.com](http://www.aprison.com).