WHITE PAPER

A Quality Medical Device Begins with Supplier Quality Management

Honeywell

Sparta Systems

Table of Contents

INTRODUCTION

Medical device manufacturers must pay closer attention to quality management than ever before. An increase in federal regulations along with consumer awareness and greater expectations on the part of the healthcare industry for better products are just some of the factors that have driven medical device companies to invest in better quality management strategies.

At the same time, though, medical device companies are becoming more global to offset production costs and meet customer demand. Federal regulations mandate that manufacturers are responsible for ensuring the quality of their suppliers, which means they must develop an effective supplier quality management system to address supplier selection and ongoing evaluation, nonconformances, risk, and any product deviations.

Those companies that do not adhere to the regulations are subject to penalties levied from the FDA in addition to any scrutiny from the public that develops from a recall or other bad press. It cannot be overstated that medical devices prevent and treat diseases and other conditions. A faulty product can have disastrous consequences so building strong supplier relationships through technology can help reduce quality related risks.

The Rise of Outsourcing in the US Medical Device Industry

The medical device industry in the United States is at a crossroads where it must ensure better quality and reduce costs at the same time. On January 1, 2013, a 2.3% excise tax on all medical devices, a provision of the Affordable Healthcare Act, went into effect. This combined with spending cutbacks by major medical establishments has forced many medical device companies to outsource their suppliers in order to reduce their price point and overall costs.

The medical device outsourcing industry is currently valued at $23.56 billion and is expected to grow at a CAGR of 11.5% by 2020. It's estimated that outsourcing drives production costs down by 15%, which is crucial as 80% of medical supply companies in the United States have less than 50 employees with many having very little to no sales revenue. Therefore, medical device companies are becoming more global, sourcing more and more in raw materials and components from countries all over the world.

The need to manage the complex supply chain is a crucial component to a company's business strategy. A major challenge is not the lack of supply, delivery, inventory or critical supply data, but rather the visibility of critical information to perform proactive tasks or to make impactful decisions. Companies use multiple suppliers that are "out-of-the–four walls" of their own IT environment, so it is imperative to provide near real-time access to a common system so there is no delay when using data to make both minor and major product decisions.

An Increase in the FDA's Attention towards Medical Device Quality Management

Recently, the FDA announced that it is cracking down on medical device quality management and supplier quality management in particular. From 2003 to 2012, medical device recalls increased by 97%. The main causes for the recall issues included design concerns, software problems, or issues with materials and components.

In addition to that, the Center for Device and Radiological Health (CDRH) inspections have accounted for 10%-12% of all FDA inspections since 2005, but these inspections have increased each year. For example, there were 3,369 CDRH inspections in 2011 as opposed to 2,304 in 2005. Form 483s and warning letters have been issued in increased numbers as well.

The FDA has made a concerted effort to reduce recalls by active enforcement of industry regulations, including FDA Quality System Regulation Part 820 and ISO 13485 and ISO 9001. Part 820 also addresses concerns about supplier quality and who is responsible for ensuring that all suppliers and partners in a supply chain are acting under FDA regulations.

Therefore, it is up to the manufacturer to maintain quality procedures as it is the one that will be held accountable by the FDA as well as the consumer if there is an issue with the product. Manufacturers must not only find partners that can provide the materials and components necessary for production; they must also find partners who are trustworthy, and pose as little risk as possible to the final product.

Managing Risk in the Supply Chain

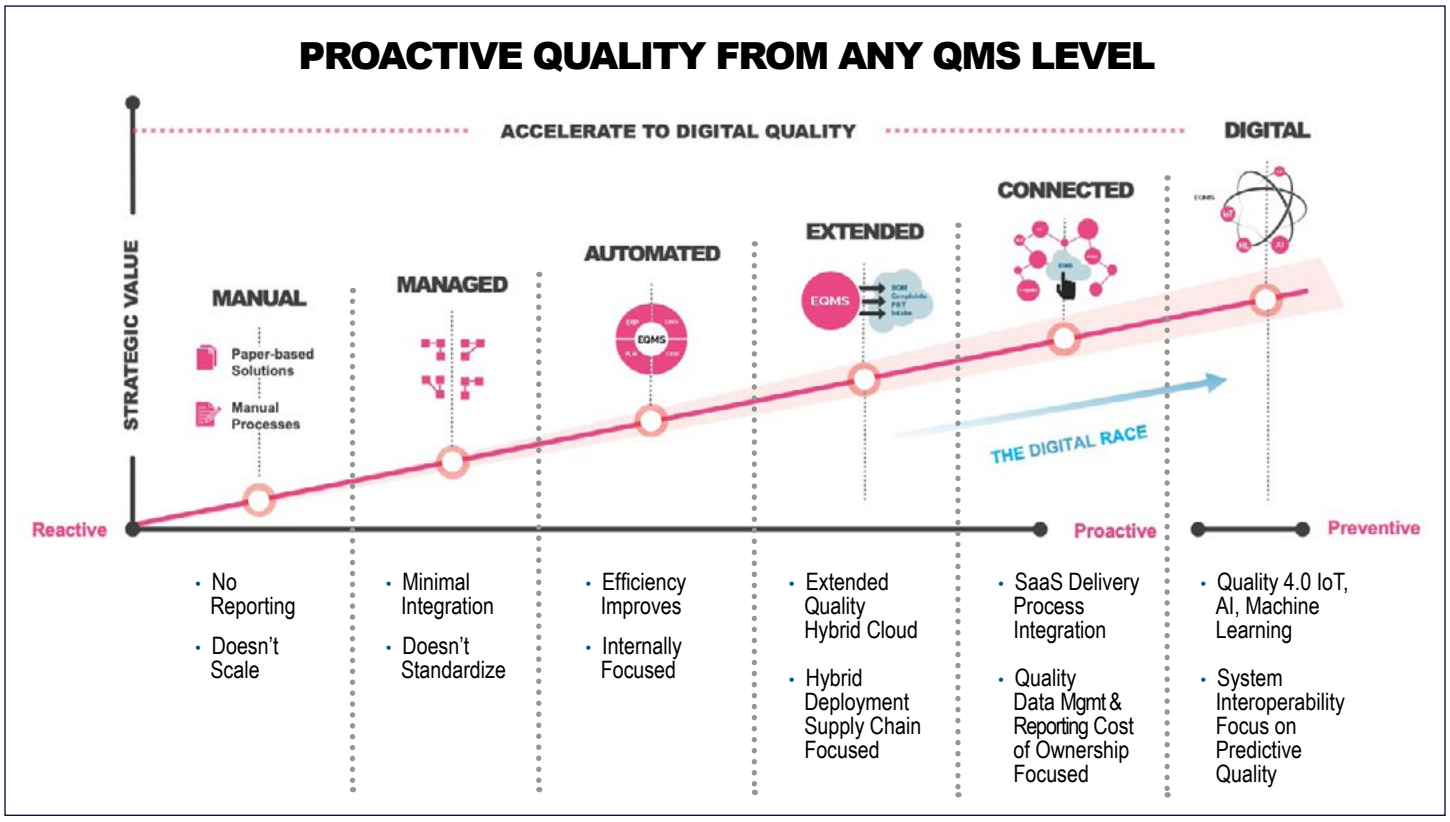
With many suppliers both in the U.S. and abroad working under different regulatory bodies or requirements, having access to the same set of real time data can be very challenging. 52% of the recalls are caused by supplier related issues, whether they are non-conforming material or process used as part of the supplier delivered parts. Considering the cost and resources it takes to remediate, replace, repair and recall a product, it is critical that proactive measures of supplier quality metrics are in place to mitigate as much risk as possible.

> "Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements."

The FDA's recent Unique Device Identification (UDI) legislation and the creation of the Global Unique Device Identification database (GUDID) compliance database requires a more consistent and standardized communication across the medical device supply chain. Prior to creation of the UDI system, various links in the medical device value chain — manufacturers, distributors, suppliers, hospitals, and insurance companies — each had their own codes for the same products. As a result, a given device may have three or four different codes that each link in the supply chain uses to refer to the same product. This lack of uniformity made for flawed and/or delayed reporting and patient notification in the event of a recall.

As part of the FDA's UDI mandate, all manufacturers of Class III medical devices needed to comply with the uniform coding of all products by September 24th, 2014. By establishing a uniform coding system, apps and push notifications can be configured to notify in a timely fashion all parties of a recall or product problem before a tragedy occurs.

Eventually, UDI will be linked to Complaints and eMDR, which would help identify issues before adverse trends materialize. From a supplier management perspective, this could help alleviate serious issues before they become adverse events and recalls, in a proactive manner.

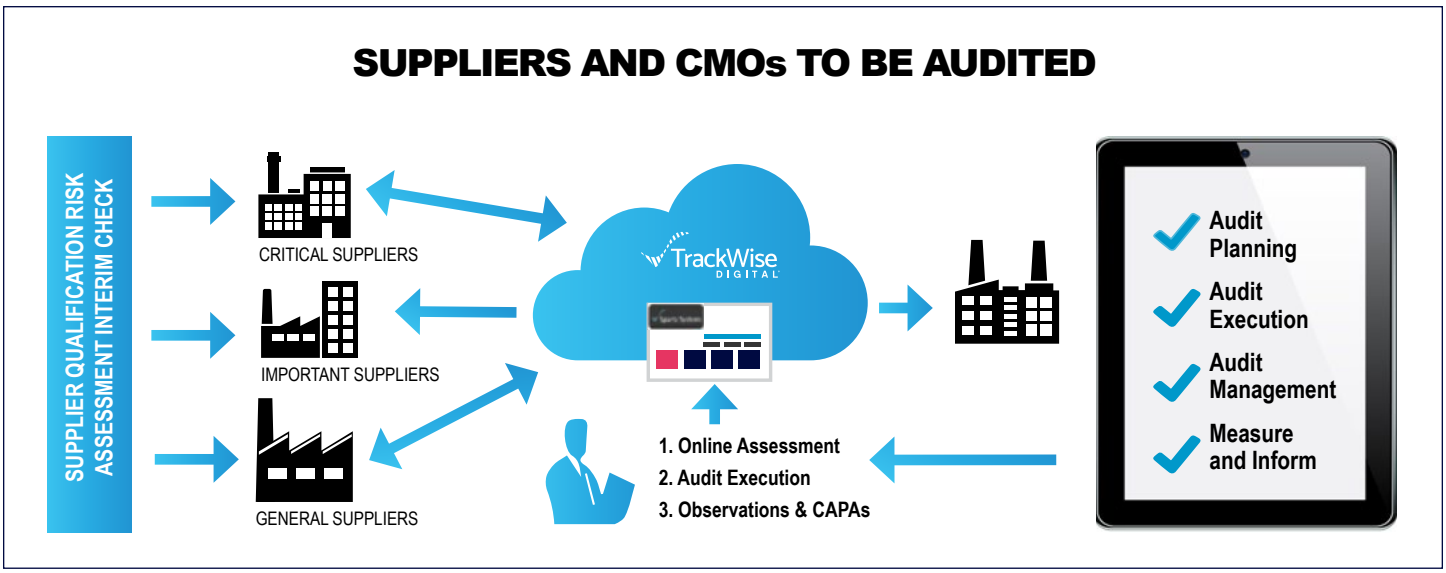


How Do Manufacturers Improve Supplier Quality?

Ultimately, the manufacturer will have to keep accurate records of every aspect of its relationships with suppliers, including transactions and communications. It must also implement best practices. These include a comprehensive selection and evaluation process, supplier audits, supplier scorecards, and supplier risk files.

Supplier Quality Management Best Practices

- **Selection and Evaluation Process:** Manufacturers must forge relationships with suppliers that are trustworthy and can deliver materials and components. Suppliers will be selected and evaluated through industry-standard criteria.
- **Supplier Audits**: Identify any non-conformances before the finished product is affected and work with supplier on corrective actions.
- **Supplier Scorecards:** Evaluate suppliers on metrics to determine supplier's quality and performance over time.
- **Supplier Risk Files:** Determine the impact of a supplier's materials on the quality of the finished product. Those that are more heavily influential should be more closely monitored, and there should be mitigation actions in place to offset these risks.



Most of the time, these best practices are already being done by the manufacturer to ensure FDA compliance and quality assurance. However, the documentation that contains all of the data measured in relation to supplier quality and specifications is often spread out in a manual system through different file systems and spreadsheets, which can lead to greater inaccuracies, duplicate evaluation processes, ineffective or slow communications, and lost reporting.

Benefits for a medical device company to build a supplier audit process include the opportunity to create a consistent format. This is valuable when different auditing groups such as accounting, IT systems, HR, engineering, or materials, need to provide input and have access to the shared supplier information. This streamlines all audits with multiple suppliers by eliminating duplication of effort and variability of outcome. Audit steps and reporting formats require a uniform and consistent appearance, making the audit process easier, faster, and more efficient. Audits help identify and correct minor issues before major issues develop, leading to proactive resolution.

It's for this reason why a software-based integrated supplier management system is crucial to ensure that there is a closed-loop supplier process in place.

Superior Supplier Quality Management with a Quality Management System

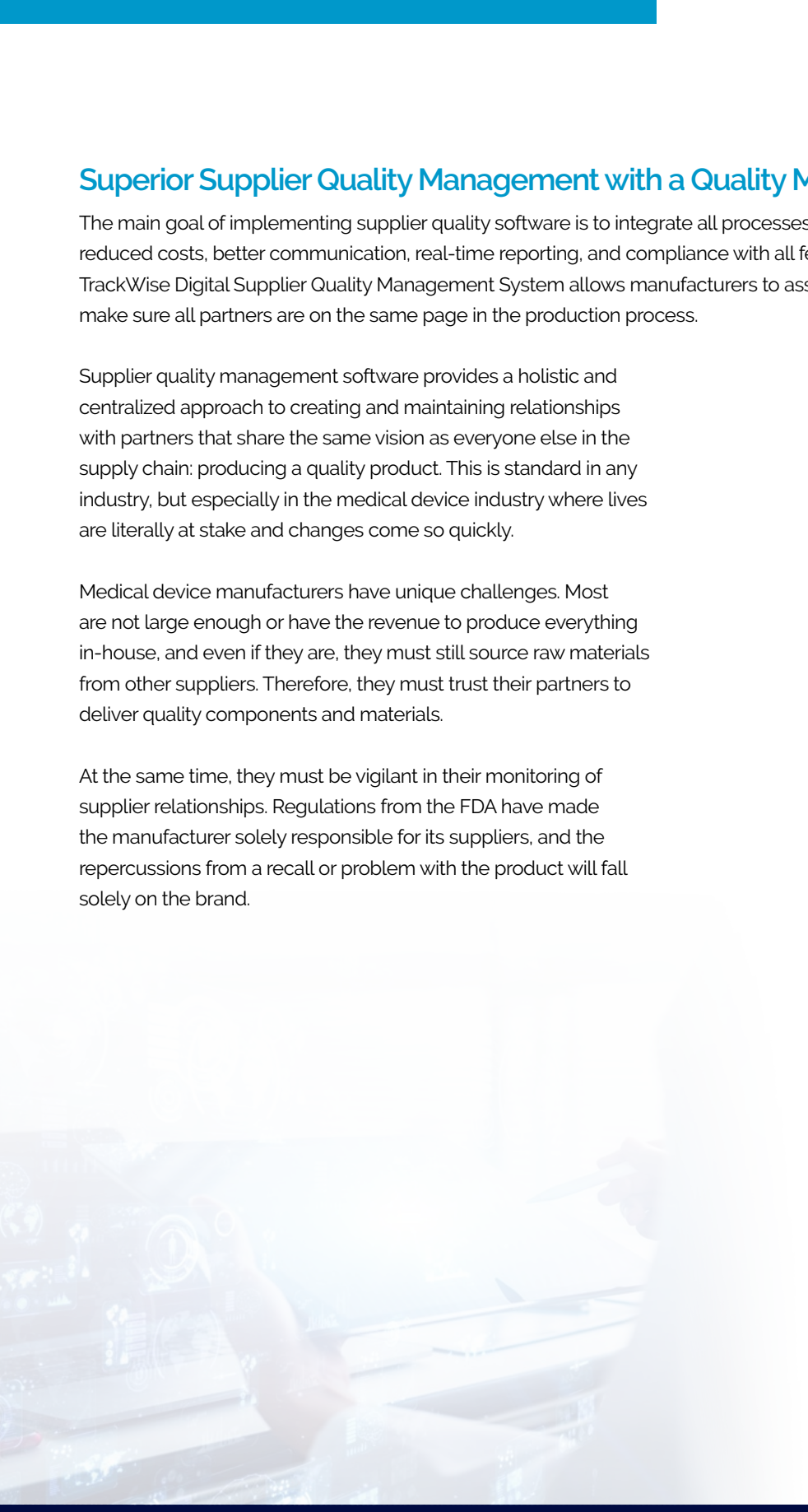
The main goal of implementing supplier quality software is to integrate all processes on one platform to ensure increased efficiency, reduced costs, better communication, real-time reporting, and compliance with all federal and industry regulations. Sparta Systems' TrackWise Digital Supplier Quality Management System allows manufacturers to assess and evaluate new and current suppliers and make sure all partners are on the same page in the production process.

Supplier quality management software provides a holistic and centralized approach to creating and maintaining relationships with partners that share the same vision as everyone else in the supply chain: producing a quality product. This is standard in any industry, but especially in the medical device industry where lives are literally at stake and changes come so quickly.

Medical device manufacturers have unique challenges. Most are not large enough or have the revenue to produce everything in-house, and even if they are, they must still source raw materials from other suppliers. Therefore, they must trust their partners to deliver quality components and materials.

At the same time, they must be vigilant in their monitoring of supplier relationships. Regulations from the FDA have made the manufacturer solely responsible for its suppliers, and the repercussions from a recall or problem with the product will fall solely on the brand.

A supplier quality system that incorporates best practices and technology to integrate those processes is the best way to address and overcome these challenges.



Get in Touch

1.888.261.5948 • sales@spartasystems.com
www.spartasystems.com

REV1:210806

Honeywell
Sparta Systems

Sparta Systems, a Honeywell Company, is the world's premier provider of cloud and on-premises quality management software. For nearly three decades, companies in the life sciences have relied on Sparta for the innovative tools, analytics and expertise that speed up quality and compliance.

Sparta Systems | 2000 Water View Drive | Suite 300 | Hamilton, NJ 08691 | USA | www.spartasystems.com