Objective; This paper is intended to set the bar for establishing Oracle Manufacturing and Supply Chain as an integrated solution by ERTechnologies; designed and built in a modular cloudbase EQMS for the Medical Device manufacturing space. The market is intended to be California (many device manufacturers exist)

Issues in Medical Device Manufacturing, Supply Chain - **Managing Medical Device Quality Issues within a Complex Supply Chain**

An in-depth look at supplier management, quality, and warning signs to prevent problems.

Overview

Today's modern medical device manufacturing is a complex global ecosystem consisting of original equipment manufacturers, strategic partners, and multiple tiers of small and medium sized partners. This strategy allows manufacturers to work with the best suppliers regardless of their locations. However, with geographically dispersed functions it is less likely that quality is will be managed internally by one organization. With so many partners and suppliers providing multiple or inconsistent sources of information, it ca be difficult for consistency and coordination throughout the supply chain. This can lead to myriad of severe quality defects that could impact patient safety. It's bad enough that these defects are often only found when a faulty device makes it into the market and has been implanted into patients.

The Dark Side of Supplier Management

Although using suppliers from around the world is essential to reducing the cost of a manufactured medical device, this strategy creates opportunities for more risk: Ask yourself how many suppliers are making the materials that are shipped and turned into various components by other suppliers? Do you know where these suppliers are based? How many people touch some part of the finished device? Do they uphold and promote appropriate ethical quality standards?

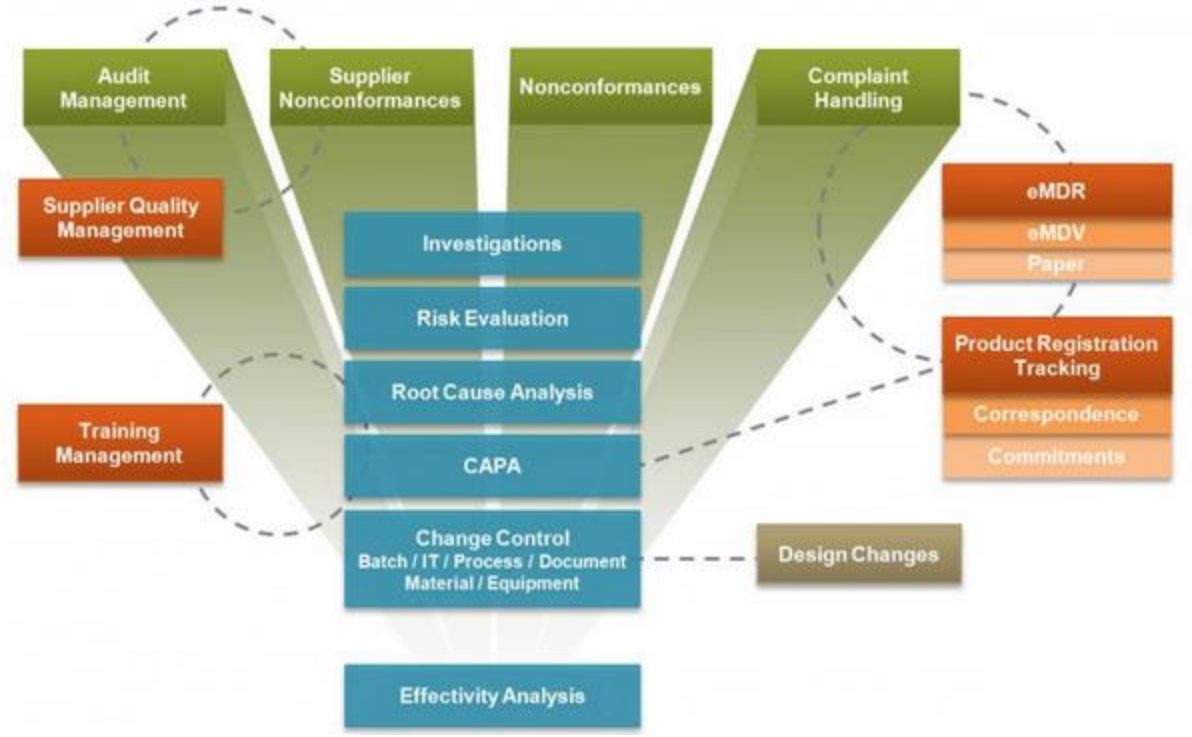
In a complex supply chain where contract manufacturers have their own suppliers, who in turn have their own sub-tier suppliers, and so on, there is always the chance that one "trusted partner" may be looking to cut corners in order to provide a component at the lowest cost for the highest profit. This not only poses a threat to patients by increasing the

chance of a device defect, but also the reputation of the original equipment manufacturer (OEM) and its partners.

Manufacturers and suppliers are constantly looking for ways to reduce costs and another way is by rationalizing Information Technology spending. This often cause users to struggle with ineffective processes, disparate systems and increased risks in regulatory compliance requirements. Rather than settling for an inferior system, organizations should learn how investing in an enterprise quality management software (EQMS) system can save money overall while increasing compliance and ensuring quality is upheld throughout a medical device's entire lifecycle.

Ensure Quality by Leveraging EQMS

In the relentlessly fast paced medical device manufacturing environment, manufacturers face countless unique challenges; to reduce product lifecycles, meet increasing and complex global regulatory compliance, and to manage strategic partnerships across the supply chain. These ever growing mandates demand greater focus on safety and traceability and are aggressive in driving the growing global regulatory landscape. This relentless regulatory landscape demands a well-implemented supplier evaluation process for manufacturers to produce, manage, and track products effectively in order to deliver safe, reliable, and high-quality medical devices to the end user. The solution in a holistic EQMS system enables companies to obtain a global view of all quality issues and supplier information.



An EQMS helps with supplier quality management, risk management and more.

A holistic EQMS offers greater analytical insight into quality process details, work flows, streamline supplier audits, manage product design changes and can trigger early warnings on the manufacturing processes as they occur in real time should they go wrong. By leveraging an EQMS to coordinate various internal departments and suppliers, OEMs can achieve greater traceability and accountability. The right EQMS can also track and analyze data through predictive analytics and leading indicators, turning issues or mistakes into valuable lessons for continuous improvement.

Supplier Quality Warning Signs

With built in structured, automated workflows and quality processes inherently designed throughout your supply chain can help to ensure that medical devices meet the documented internal, quality standards. This is especially important in today's highly regulated global business environment. With increasingly more and stringent regulations being imposed by government bodies, medical device manufacturers are under extreme pressure to ensure quality is maintained.

However, mistakes unfortunately do happen. When those quality standards are not being met, either internally or by a supplier, a corrective and preventative action (CAPA) or a

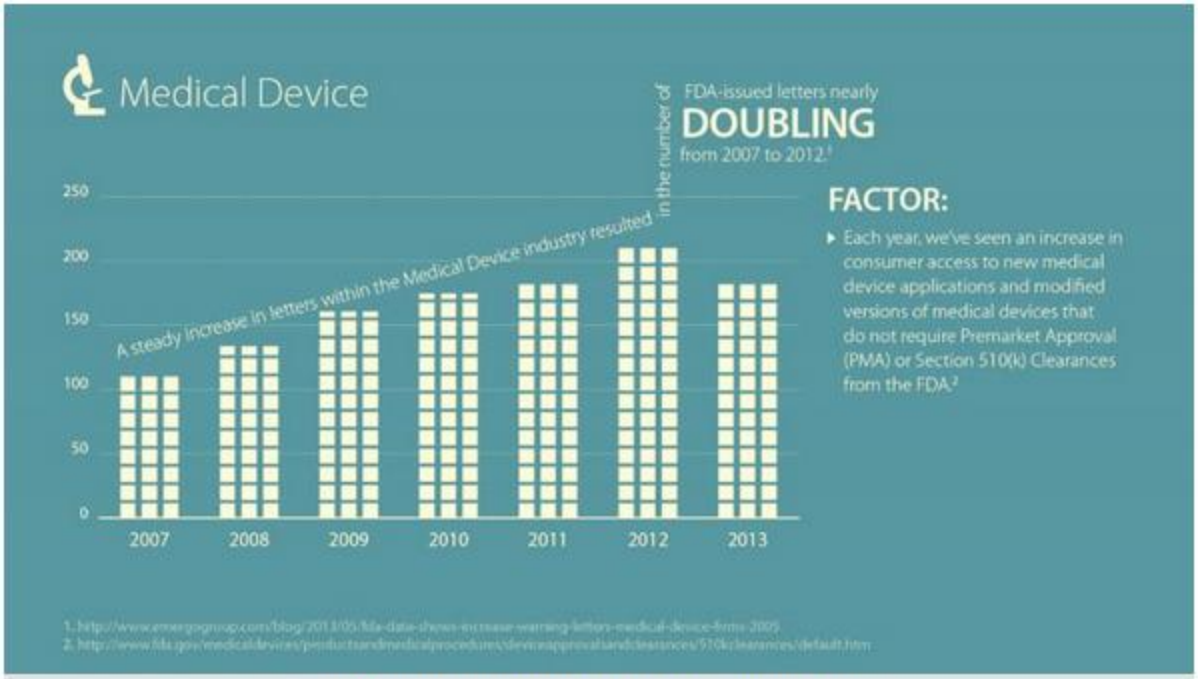
supplier correction action request (SCAR) should be established and addressed. Becoming aware of the common warning signs that trigger the need for remediation helps to ensure issues are addressed quickly. The warning signs would include:

1. Non-conforming materials. For example, should an audit reveal that a supplier is using a conflict mineral (tungsten, tin, tantalum and/or gold mined from war-torn areas such as the Democratic Republic of Congo) to produce a specific device component, that supplier – and, in turn, the OEM – is not in compliance with the Dodd-Frank Act.
2. Changes that have not been approved. Change control is crucial for all manufacturers, but doubly so for makers of medical devices. Should a supplier decide it's more cost effective to use latex instead of neoprene, a supplement to the medical devices UDI must be filed.
3. Changes that have been made without informing pertinent members/departments of a supply chain. A lack of transparency between internal departments and external suppliers means a lack of control over quality, which increases the chance of an uncaught error and potential recall.
4. Incomplete incoming materials. There are some instances where incomplete materials — such as integrated chips without heat-sink mounting — can pose an issue to the final medical device.
5. Excessive field failures as a result of a supplier component. Should some suppliers use an outdated assembly process or material, too many of the non-conforming products could make it to market, resulting in greater-than-forecasted field failures and product returns.

A holistic EQMS will streamline the warning signals and trigger corrective action processes developed for repeatable, compliant, and closed-loop CAPA and SCAR processes that track and manages quality issues originating from any source. This system should be capable of accessing all of your suppliers initiate faster assignment and completion of CAPAs and SCARs, to ensure quality is maintained without slowing down the manufacturing process.

Proactive Management of Quality Issues

Between 2007 and 2012, the number of FDA warning letters issued increased by 104 percent. For the medical device manufacturing industry the number nearly doubled.



FDA warning letters for medical devices are on the rise.

Instead of waiting for a warning letter from the FDA – or worse, a device recall – medical device manufacturers should take a more proactive approach to preventing quality issues rather than reacting to them. If a medical device manufacturer is spending too much time and resources on corrective actions, this is a leading indicator that they are in reactionary mode instead of taking preventative measures to invest in the proper resources, tools and processes necessary to maintain quality.

Along with an effective employee training program an EQMS should be used to prevent quality issues. An automated tracking and management for employee training can help to ensure relevant activities are scheduled and tracked through to completion. Additionally the EQMS can provide a seamless environment to ensure compliance with government and industry regulations and to maintain a standard of excellence to control and monitor the training requirements. A centralized, comprehensive training should be managed and integrated with an EQMS and allow the verification of proof of compliance and maintenance that reflects accurate updated training requirements.

Recently there is a slight trend in final assembly re-shoring, but should not expect global supply chains to be discontinued within the near future. There are many advantages to working with contracted partners and suppliers globally, including decreased costs and the ability to join forces with the best and the brightest other countries offer. An EQMS can help to streamline and manage various initiatives, medical device manufacturers help ensure

quality is backed and managed throughout a medical devices' entire lifecycle, no matter which site the devices were manufacture.

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Quality procedures and documentation—from IQ/OQ/PC (installation qualification/operational qualification/performance qualification) to adherence to ISO 13485 quality management standards, to compliance with FDA good manufacturing practices—must pervade throughout the entire organization.

ISO 13485 certification

An important aspect of the medical device quality support story is the ISO 13485 medical device standard, "Quality management systems—Requirements for regulatory purposes," which outlines a comprehensive quality management system for the design and manufacture of medical devices. Subcontract manufacturers that achieve this certification can demonstrate that they are processing parts to the same rigorous standards as are major medical device manufacturers.

FDA requirements

According to the FDA's *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices,* "Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications." Quality systems for FDA-regulated medical devices are known as current good manufacturing practices (CGMPs). Over the years, CGMPs for medical devices have been revised to include design controls, becoming more closely aligned with the international standards found in ISO 9001 and ISO 13485.

In 1997, FDA revised the CGMP requirements for medical devices and incorporated them into a quality system (QS) regulation called "Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation," found in 21 CFR Parts 808, 812, and 820. While not regulating exactly how a manufacturer should produce specific devices, the QS regulation sets out a framework to be followed, requiring manufacturers to use "good judgment" when developing their quality system and applying the QS sections that are specific to their products and operations.