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Total Product Lifecycle Management: Lowering Costs while Increasing Quality

Executive Summary

In Conjunction with

FDANEWS

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Executive Summary

Medical Device Manufacturers have always focused on bringing innovative high quality products to market. Yet shifting financial, regulatory and globalization landscapes call for closed-loop product management strategies that can keep up with the increasing innovation tempo and complexity of medical devices while at the same time, lower cost, increase quality, and facilitate compliance with regulatory requirements. Total product lifecycle (TPLC) is aimed at enabling accelerated innovation, improved product characteristics and better company performance.

CDRH Vision:

"Ensure the health of the public throughout the Total Product Life Cycle (TPLC)."

This approach has come from an unexpected source, the Food and Drug Administration's (FDA) Center for Device and Radiological Health (CDRH). According to the Agency, in a TPLC environment decisions rely on information from the entire product lifecycle. The TPLC effect is best achieved by leveraging appropriate information technology to share and communicate information across all stages of the lifecycle, enabling internal and external collaboration for improved decision-making.

TPLC provides regulators assurance of:

- Efficient, effective, and predictable product development
- Enabling technology and innovation
- Ensuring the safety of marketed medical devices

From the industry's perspective, TPLC management is a collaborative and concurrent approach that allows medical device manufacturers to leverage information for better decision-making, thus yielding more effective, higher quality, and safer medical devices. Better product outcomes are accomplished while simultaneously supporting shorter innovation cycles that are driven by information that is more complete.

Based on findings from this study, the need for TPLC is clear. The majority of medical device companies represented in this study

- Offer intricate products with numerous components, features and options
- Sell products around the world
- Outsource some of their manufacturing and product design and engineering

Most respondents believe that product innovation is central to their current and future success. Most of the professionals who participated in this research expect new product introduction (NPI) rates to increase dramatically in the next few years, even in the current economic environment.

While the vast majority of organizations participating in this study report having key initiatives aimed at supporting TPLC, most have not taken all of the steps required to

achieve a true TPLC environment. For example, most respondents still use sequential design processes, make product to stock, and assign superficial fixes to corrective and preventative actions (CAPAs) rather than identifying and addressing the true root causes for non-conformances. As a result, most organizations experience the recurrence of issues over time.

The vast majority of respondents also use paper or home-grown information systems for both official regulatory records as well as internal systems of record. Across the spectrum of organizations surveyed, less than half use software applications such as product lifecycle management, manufacturing execution systems, or quality management systems. While larger companies are much more likely to use software, a significant portion still does not use software systems in a collaborative manner.

In this study panel, most companies have not seen improvements in the time needed to complete a recall, cost of regulatory action due to poor quality, reportable adverse events, customer reject rate, time to market, or new product introduction times. We expect that collaborative processes and integrated systems would help medical device manufacturers solve these issues.

Another troubling finding is that while a minority of companies reported a decrease in product costs, CAPAs, and engineering changes, over a third reported increases. These persistent cost, engineering, and quality challenges may be due to the fact that most companies in the study cannot aggregate data from multiple sites effectively.

Disconnected information is also reflected in an inability by most companies to perform product recalls in just one stage. Those who can complete a product recall in one stage are significantly more likely to use packaged software applications.

Based on the results of this study, it is clear that companies will need to embrace collaborative processes and the supporting information systems to make better decisions throughout the medical device value chain. To gain maximum benefits from their TPLC initiatives, we recommend that companies close the loop by effective collaboration through the lifecycle. Specifically, companies must improve root cause analysis, prevention, quality processes, value chain visibility, and consistency of information.

These provide a strong foundation for managing every stage of a product's lifecycle more effectively, as well as across product platforms and succeeding generations. Executing TPLC would result in accelerated time-to-market, at lower costs and higher quality. Regulatory compliance would be a natural outcome of that improved and well documented lifecycle collaboration process.

To download a complete copy of this report, visit the TPLC Home Page at:

http://lsp.axendia.com/managing-the-tplc/?utm_source=Exec-Sum&utm_medium=PDF&utm_campaign=TPLC

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