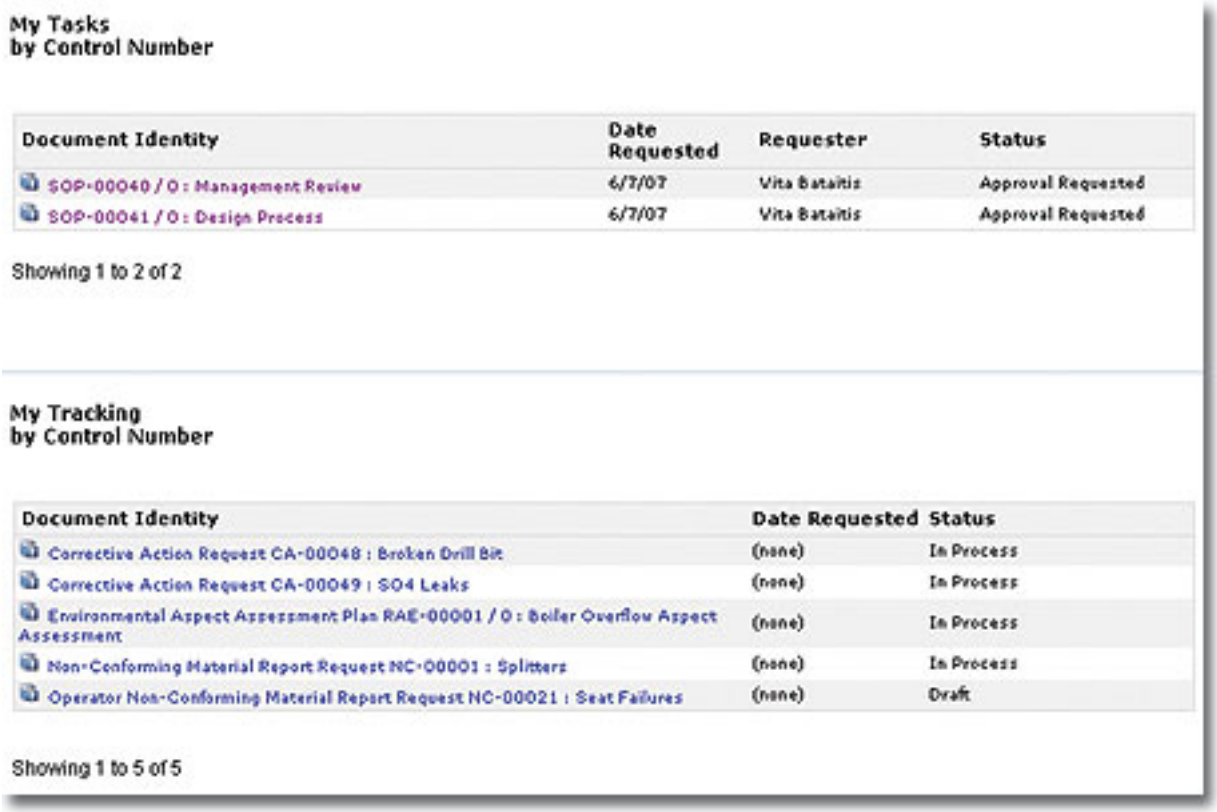
Integrating Compliance and Quality Electronically

Managing compliance systems such as those designed to handle product complaints can be a significant burden if a company is still relying primarily on traditional paper-based methods. While electronic software-based offerings may represent a significant investment upfront, the savings can often be realized within months of the purchase. This article examines how an electronic solution could ultimately enhance a company's product.

By Dan Riordan
Electronic compliance management empowers manufacturers to develop, protect, and access information and simplify quality initiatives. Yet many manufacturers balk at the high upfront costs of automated systems and decide to make do with homegrown systems or manual methods. But they fail to realize that electronic systems should be viewed as an investment in efficient, sustainable quality processes.

Customer complaints offer an excellent example of how electronic compliance management can streamline processes and still improve quality down the line. This article will first examine how customer complaints can be streamlined, and then explore how they can be turned into an asset.

If a company relies on a paper-based system or stand-alone electronic systems that are not linked, the company can face a prolonged and often time-consuming process for managing complaints. When a customer complaint comes in, the recipient first has to make note of the complaint and then determine who needs to be informed. Without clearly defined procedures for complaint management, the responsibility of moving the complaint up the ladder falls on the call recipient. Determining who to inform and what information to pass along can slow the process down. An electronic compliance management system can help link processes and streamline information.



IBS America's CompliantPro solutions provide sophisticated features with an easy-to-use interface to help medical device manufacturers build comprehensive quality systems.

Assuming that the customer complaint is moved to the right people, the next step is to assess the problem and determine its cause(s), scope, and severity. Without an electronic system that stores information and allows it to be retrieved easily, it can take many man hours to look for documentation of product parts, manufacturing records, and suppliers, to name a few. This presents challenges in establishing the root cause of the issue and tracking who received defective products.

Some electronic compliance systems have assessment capabilities that enable users to determine the severity of the issue. Once they have assessed the situation, users can take advantage of predetermined workflows that carry out the company's standard operating procedures, so that they can easily determine whether to launch a corrective action, preventative action, or some other counteractive measure. This way, they can address each complaint quickly, effectively, and appropriately. After the action is completed, an electronic compliance management solution will enable users to assess whether the actions they took were appropriate and effective, and whether they resolved the product or process issues. This information will enable them to develop more effective processes and controls in the future.

Perhaps the largest benefit of an electronic compliance management system is that it enables companies to track each of these steps, connects them to one another, and provides a way to prove they were taken. In the case of an audit, this ability to quickly and easily trace actions is critical. Auditors do not want to sift through piles of documentation in order to understand a company's procedures. With an electronic system, the company can easily demonstrate compliant processes.

But how can customer complaints be turned into competitive advantage? A series of complaints may indicate a flaw in the product. This flaw could be an issue with the design of the product, with how the product was produced, or with the materials used to produce the product. Unfortunately, with a paper based system, documenting every step in design and in production, along with every supplier, the supplier's products, and the testing of products once produced, can result in an overwhelming number of documents that have to be developed, reviewed, approved, revised, and then stored. Often, it is difficult to determine which revision is actually the "correct" one and who the true "owners" of the documents are.

With an electronic system in place, manufacturers can more easily identify and examine flaws in a product. This allows them to quickly spot trends and take actions against chronic product issues. Such customer complaints can ultimately result in a superior product if there is an ongoing initiative to manage complaints more effectively and then act on them to improve quality. This is proactive compliance and electronic compliance management at its most powerful.

A smart organization will then act on that data to create the best possible products every time. The end result is a higher level of quality, a more desirable product, and, ultimately, a level of consumer confidence that can be a huge boost to a brand.

Selecting the Right Software Solution

To determine if electronic compliance management is appropriate, organizations should calculate what they are spending on managing quality documentation and records. For most organizations, the payback period for an electronic compliance management system can be measured in months when the costs associated with managing a paper-based system and lost sales due to quality problems are taken into consideration.

Another important factor to consider is the level of flexibility realized once the product has been installed. There is no standard, out-of-the-box system that can accommodate every company's requirements. Each organization's needs are unique. However, today, there are software solutions available that offer users the capability to match the system's configuration with users' processes. Previously, a software developer was required to make modifications to the software, which more often than not caused upgrade problems. Today, however, some manufacturers offer products that are easily reconfigured and eliminate any issues with future upgrades.

Many of today's compliance management software systems offer a broad set of capabilities that meet most of the requirements spelled out in the FDA's 21 CFR Part 820. These include not only basic quality systems requirements like document control, employee training, CAPA, and assessments, but also additional requirements spelled out in the QSR such as risk assessment, advanced product quality planning, and environmental, health, and safety management. A system's ability to address most of the QSR's requirements should be a prime consideration. In most cases, systems that are put together in a piecemeal fashion ultimately cost

more than an integrated, fully featured system.

Another important element in choosing software is the level of security the product offers. Many of today's products offer the ability to control access to any document, type of document, or organization in the system by role, name, or group, an important consideration when dealing with proprietary specifications or when managing access to the system by external parties like suppliers. Some systems even offer the ability to control access to just specific sections of a document. This can be useful when reporting various types of occupational incidents. Another security consideration not to be overlooked is the ability of the system to comply with the requirements of the FDA's 21 CFR Part 11.

Conclusion

For medical device manufacturers, not adhering to compliance requirements is simply not an option. But rather than seeing compliance and the related documentation requirements as obstacles in bringing a product to market, manufacturers should view them as valuable tools in continuous product improvement. Being able to look back on how a product was developed step-by-step from start to finish is a way to improve quality, ensure fewer problems, and ultimately, result in a better product. And with electronic documentation in the mix, medical device manufacturers can be proactive in compliance and gain an even greater advantage over competitors.

ONLINE

For additional information on the technologies and products discussed in this article, visit IBS America Inc. at www.ibs-us.com [1].

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