How Medical Device Manufacturers Prove Compliance with CMMS

Benefits of Implementing a CMMS, Blog, Blog Article, Healthcare
February 14, 2017 Scott Lasher

Every day, healthcare professionals rely on medical devices that diagnose, treat, prevent and cure medical conditions and diseases. Hospital managers and medical device manufacturers partner to ensure that each part is compliant with regulatory standards.

For medical device manufacturers, using a computerized maintenance management software (CMMS) is a must. Those with complete systems in place see decreased medical device-related accidents and improved efficiencies.

Read on for three ways a CMMS benefits medical device manufacturers, which includes capturing electronic signatures, recording audit trails and ensuring compliance with regulatory standards.

1. Streamline operations with electronic signature capture.

To ensure safety and efficacy, medical devices are manufactured using strict guidelines and regulations. Because a medical device is often used to save human lives, defects during the manufacturing process are unacceptable.

CGMP, or Current Good Manufacturing Practice, is a system enforced by the U.S. Food and Drug Administration (FDA) to ensure that products are consistently produced and controlled according to quality standards. CGMPs assure proper design, monitoring and control of manufacturing processes and facilities. Because detailed, written procedures are essential for

every step of the manufacturing process, electronic signature capture is a great way to reduce paper waste and streamline operations with CMMS.

CMMS helps medical device manufacturers better track documents and business processes. Not only does this comply with government regulatory requirements, but it also saves time, money and error.

2. Complete the audit trail of changes in system records.

Healthcare manufacturers and facilities must track a variety of assets, ranging from heavy machinery to automation systems. This means proper maintenance records are imperative to ensure compliance with regulations and standards.

In the past, recordkeeping was almost entirely a paper-based process. Because of this, the chance that information is misplaced and improperly filed increases. As a result, liability issues may arise.

Luckily, CMMS provides medical device manufacturers with digital recordkeeping procedures and policies. Features within the software help medical device manufacturers complete an audit trail of any changes to records in the system at the touch of their fingertips. A complete audit trail not only reduces liability associated with lost documents, but also, it improves document integrity.

3. Demonstrate compliance with regulatory standards.

There are strict guidelines defining the medical device industry and proper procedures that must be followed when manufacturing devices. FDA standards, such as 21 CFR Part 11, set forth criteria for regulatory compliance. The code references any persons who create, modify, maintain or transmit electronic records to ensure the authenticity, integrity and confidentiality of records.

Fortunately, CMMS supplies manufacturers with canned reports to demonstrate compliance. These reports provide manufacturers with metrics to analyze and improve equipment as needed. The tool is designed to increase operational efficiencies by distributing records to multiple people across an entire organization.

Want to learn more about how a CMMS can improve organization and efficiency for your healthcare facility or hospital? Download our ebook, *How Hospitals and Healthcare Systems Gain a Competitive Advantage Through Better Maintenance*, for more information.