Top medical device industry regulations—and why they matter

Keep up with compliance mandates

The US Food and Drug Administration (FDA) keeps a close watch on the medical device industry. As with all government regulations, being proactive about audit and litigation readiness is safer and generally less costly than being reactive. The lives of your patients and the reputation of your company can damaged if your devices are involved in an accident.

Here are the most significant FDA quality regulatory programs to pay attention to, as well as some tips on how you can steer clear of fines and court action for non-compliance.

Case for Quality (CFQ)—The FDA's Case for Quality regulations focus on data transparency. From design to manufacturing to customer delivery, manufacturers are subject to inspections to ensure quality control is a high priority—CFQ aims to help regulate these processes. The FDA has found that medical device manufacturers that implement quality control systems and other practices that adhere to these program regulations can reduce quality related costs by 20% to 30%, while improving profitability by 4%.

FDA CFR 21 Part 820—FDA CFR 21 Part 820 is a quality systems regulation the FDA uses to ensure that there are controls and documentation systems for a medical device's entire product lifecycle—from design, engineering, and manufacturing, to shipment and aftersales service.

Quality System Regulation (QSR)—The FDA developed Quality System Regulation (QSR) standards to regulate good manufacturing processes (GMP) for medical device manufacturing. QSR standards speak specifically to having a quality plan for your products, a system of record for recording, and a series of controls for functions that include: controls for document management design, management, labeling, and production and planning, as well as standard operating procedures. QSR standards also requires a quality implementation team led by a senior manager and a documented quality policy with metrics and objectives.

ISO9001, ISO9002, and ISO13485—ISO9001, ISO9002, and ISO13485 are standard quality regulations that medical device manufacturers must meet. These standards are designed to help medical device manufacturers ensure their products meet customer and stakeholder expectations, as well as regulatory requirements. Implementing and following quality practices compliant with ISO9001 and ISO9002 is required for most manufacturers worldwide. ISO13485 follows closely behind.

After you have been certified for ISO compliance, you must follow the standards as if an audit could happen any day. Many large and successful manufacturers have "let their guard down" temporarily and were consequently charged with failing to meet quality standards. Regulators are not very forgiving in these situations, especially when malfunctioning devices have hurt patients.

EN46001—EN46001 is the European standard for medical device industries that all European medical devices must fulfill. These standards go beyond ISO 9001 requirements, which need to be met by the quality management systems of suppliers. To market your products under your company's brand in Europe, you must comply with EN 46001 standards. Having a quality management system certified for ISO9001, ISO13485, and EN46001 is essential for companies that want to export their products to the global market. Companies that must be in compliance with these regulations include:

- Companies that currently manufacture private label medical devices, but want to eventually place these devices under their name on the market in the European Union
- Companies and consulting shops that design, manufacture, and assemble medical and in vitro diagnostic devices (IVDs), as well as medical component manufacturers
- Manufacturers of in vitro diagnostic devices that want to prepare for future IVD regulatory obligations and enter the EU

21 CFR Part 11—Because the pharmaceutical, healthcare, and medical device industries involve so many documents—and are under such high scrutiny from federal government agencies—21 CFR Part 11 has been put in place to help eliminate many physical records, while preserving the integrity of the electronic records for auditability. 21 CFR Part 11 helps companies demonstrate that electronic records are verified, controlled, and generally certified as audit worthy by means of electronic signatures.

Avoid penalties and recalls

When there are medical device recalls or patients are harmed or die as a result of a device failure, ripple effects are felt across the entire industry. Some device recalls happen for usability reasons, others for product failures. Having a purpose-built solution for managing data related to medical device quality governance is vital to passing through regulatory audits without fines or penalties.

An extension of Infor CloudSuite Industrial, the FDA Extended ERP Solution from The Copley Consulting Group provides the functionality you need to comply with all of these regulations and more. The total ERP solution gives you the tools you need to store scanned documents with appropriate version control, and deliver them to the appropriate operational transaction. In the event of an FDA audit, these documents can provide evidence of good record keeping practice and assist in meeting compliance standards.

For over 30 years, The Copley Consulting Group has delivered Infor® implementation success to more than 400 enterprises. As one of Infor's leading Gold Level Channel Partners, The Copley Consulting Group has assembled a team of dedicated professionals with years of medical device industry experience and a track record of success.

For more information about keeping up with regulations, visit The Copley Consulting Group.

641 Avenue of the Americas
New York, NY 10011
800-260-2640
infor.com

About Infor

Infor builds beautiful business applications with last mile functionality and scientific insights delivered as a cloud service. With 14,000 employees and customers in more than 200 countries and territories, Infor automates critical processes and helps eliminate the need for customization through embedded industry domain expertise. To learn more, visit www.infor.com.

INF-1505618-EN-US-0616-1