

In the United States, the FDA establishes medical device regulations for medical device companies that wish to sell and market their products, including those for medical device quality management.

When a medical device manufacturer creates a medical device, it must be approved for sale by the FDA before it can be marketed or sold in the United States. The FDA establishes medical device regulations to ensure that medical devices available in the United States are both safe and effective for the end user. These regulations are a critical aspect of patient and consumer safety, but they can also benefit medical device companies. The FDA quality system requirements (QSR), for example, help manufacturers ensure that they built a device that consumers will want to purchase and that can therefore succeed in the marketplace.

Medical Device Regulations Exist in the United States

If your medical device company is developing a new product to be sold in the United States, you must be aware of the most important regulations established by the FDA. These regulations are published in Chapter 21 of the Code of Federal Regulations (CFR) and can be viewed in their entirety on the FDA website.

21 CFR Part 820 - FDA Quality System Regulations

Medical device companies who wish to market their products in the United States must be fully aware of and in compliance with the FDA Quality System Requirements found in 21 CFR Part 820, which sets forth the full requirements for medical device quality systems. In Part 820, the FDA provides guidelines for manufacturers to establish and maintain documented processes that control product design and development, product realization, corrective and preventive actions (CAPA), risk management activities, supplier controls and more.

The FDA conducts compliance audits of medical device companies, reviewing their policies and procedures, as well as technical documentation to ensure that the implemented quality system is effective and that the medical device regulations are being followed.

21 CFR Part 11 - Electronic Records; Electronic Signatures

In the past, medical device companies used rooms full of filing cabinets to manage quality documentation (many still do to this day). In today's digital age,

an increasing number of medical device companies have adopted electronic quality management systems (eQMS) with automated, built-in document control and management features. In 21 CFR Part 11, the FDA supports this transition by establishing regulations for medical device companies that choose to manage and approve quality records in an electronic format.

The purpose of 21 CFR Part 11 is to establish equivalency between paper-based quality systems and electronic record systems, in order to ensure that medical device companies can guarantee the authenticity and security of quality data.

21 CFR Part 803 - FDA Medical Device Reporting

In addition to the medical device regulations for quality management, the FDA has created a mandate for reporting on medical device adverse events or malfunctions. Under 21 CFR Part 803, medical device manufacturers, importers and device user facilities are legally required to report to the FDA when they become aware of any adverse event involving a medical device that they brought to market. Medical device reporting regulations ensure that manufacturers are performing adequate follow-up measures when adverse events occur. The reporting regulations also allow the FDA to issue warnings to the public about potentially dangerous devices.

A corrective and preventive action form is used to initiate the CAPA process for a nonconformance event or to document a preventive action that is being implemented as the result of information or analysis from a qualified source.

Medical device companies are required to establish and maintain a corrective and preventive actions procedure and policies in accordance with the guidance and regulations set out by the FDA and ISO for medical devices sold in the United States and around the world. The corrective and preventive action form - or CAPA form - is one of the most important tools of the CAPA process.

When a medical device company identifies a non-conformance issue, it must invoke its non-conformance management plan, which requires it to identify the problem, document it, evaluate it, segregate instances of nonconforming product and dispose of it in the most appropriate way. If the evaluation signals to a quality manager that a corrective action could be possible, the issue is escalated using a CAPA form. The CAPA form is the mechanism by which nonconformance issues are initiated into the CAPA process so they can turn into business process improvements.

A Corrective and Preventive Action Form

If done correctly, a single CAPA form can be used to track a nonconformance issue from its initiation into the CAPA process until its resolution. This ensures that all data pertaining to this specific CAPA issue can be accessed and viewed together. The important components of a CAPA form are:

1. **Problem Description** - The form should have space for a detailed description of the problem. This section is filled out by the person who initiates the CAPA. They should include their name, the date, a detailed description of the issue or a link to the accident or incident report that does the same, a space for rating the urgency or severity of the perceived problem and how the event was discovered.
2. **Root Cause Analysis and Action Plan** - This section should be completed by the person who conducts the analysis. They should describe what immediate action was taken to prevent recurrence of the issue, as well as their methodology and results in using root cause analysis to determine the source of the nonconformance issue along with other factors that could have contributed to the problem. Finally, a plan for corrective or preventive actions to prevent the non-conformance from recurring should be outlined here.
3. **Verification** - A major part of CAPA is the verification that the solution worked. Once the action plan has been implemented, follow-up is required to determine whether the issue was adequately addressed. The date of verification and the name of the person who conducted the verification test should be documented here.
4. **Signatures**: To comply with document control guidelines set forth by the FDA, medical device manufacturers must include space on CAPA forms for the signatures of the person who initiated the CAPA and the person who analysed the CAPA and implemented the solution. These steps help to ensure accountability and traceability throughout the CAPA process.

The FDA and authorities that regulate medical device companies around the world require the establishment and maintenance of a CAPA process within a medical device quality management system (QMS). Medical device companies must document all CAPA events, maintaining policies and procedures for implementing CAPA plans and following document control procedures in accordance with international standards and FDA guidelines.