USING CAPA

TO COMPLY WITH FSMA CAN IMPROVE

SAFETY + PROFITS

The implementation of the Food Safety Modernization Act of 2011 (FSMA) has forced food and beverage manufacturers to face some of the most sweeping safety laws since Congress passed the Federal Food, Drug and Cosmetic Act of 1938. Although compliance with FSMA's stringent new requirements can seem especially daunting to many food and beverage companies, other industries such as life sciences have been subject to similar or even tougher federal regulations for years. Now, under FSMA, food and beverage companies are bound by some of the same standards.

At the heart of pharmaceutical and medical device regulations is the requirement to create corrective and preventative actions (CAPA) to address product quality issues, manufacturability problems, and customer complaints. The CAPA process focuses on two areas: short-term solutions that solve immediate problems (corrective action), and longer-term strategies to investigate and eliminate the sources of product issues, reducing the likelihood of a problem occurring (preventative action). Assessing risk at each step of the CAPA process enables decision makers to take practical measures to more quickly resolve issues.

CAPA serves as an "early-warning system" for businesses by collecting valuable metrics and information to spot trends in product quality. A CAPA "system" can be as simple as an Excel spreadsheet or SharePoint list, or complex enough to warrant dedicated technology solutions.

Although food and beverage companies may initially develop CAPA plans only to meet FSMA rules, the benefits go far beyond compliance. CAPA can help businesses become more cost efficient and produce a higher-quality product, thus strengthening their competitiveness. More than just minimizing the chances of a recall (and the disastrous fallout associated with it), CAPA can help businesses gear up for future opportunities as well. The CAPA process also aligns well with Six Sigma methodologies for product manufacturing improvement.

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CAPA AND THE PHARMA BUSINESS

CAPA is a well-established standard in the pharmaceutical industry. In 2009, the FDA adopted the International Conference on Harmonization (ICH) Q10 Pharmaceutical Quality System guidelines, which makes company management responsible for developing and implementing an effective quality management system (QMS). Pharma companies use CAPA-type processes as a risk reduction tool to help identify and troubleshoot potential issues before they become major problems.

Global pharmaceutical companies with dozens of products can have scores of CAPA plans in play at a given time. For example, a medical device manufacturer's drug infusion pump, used in hospitals to administer drugs through a patient's IV, could malfunction during use. The manufacturer opens a CAPA to track the investigation of malfunction to find the root cause (Is it a software problem? A battery problem? A manufacturing flaw?), and establish a process to fix it. Once the resolution has been implemented, the CAPA is closed out and documented in a locked database (this is not yet a requirement under FSMA).

FDA involvement consists of auditing companies' CAPA plans, so documentation is an essential step in compliance. If a product repeatedly has a serious problem, and pinpointing the cause and developing a solution takes too long, the FDA could shut down production of the product.

CONTROLLING YOUR PROCESSES

The FDA looks at CAPA as a tool designed to:

Collect and analyze information to identify product performance and quality problems

Investigate product performance and quality problems and develop effective corrective or preventive actions

Help verify the effectiveness of corrective and preventive actions

Communicate corrective and preventive actions to the appropriate people

Provide information for management review

Document quality activities for trending and further improvements

Food and beverage production problems can arise from a variety of issues, including cross-contamination, equipment malfunction, and human error. When properly implemented, a CAPA system provides companies with a process to anticipate the cause of potential problems and mitigate them when they arise.

The key to product quality focuses on the production process—from raw material sourcing to production processing, shipping, storage, and shipping to the point of sale. CAPA processes help food and beverage companies monitor their entire supply chain, another FSMA requirement. CAPA plans can also help companies respond quickly to consumer questions or complaints and inquiries from the FDA.

Just as in the pharma industry, if the FDA determines that a food and beverage company's quality processes are inadequate, it will issue a warning letter, requiring the company to find a way to close the gaps. Failure to comply can result in the FDA shutting down a production line, stopping product shipments (until the company addresses the underlying problem), and possibly forcing a recall. The FDA has the authority to require a company to conduct a recall in Class I situations—involving products that have a reasonable probability of causing serious injury, illness, or death.

See next page for tips on developing a CAPA process

Here are some steps to consider when developing a CAPA process that will satisfy the FSMA requirements of the FDA.

- Map out your current quality control system.
- Determine who is responsible for the system and make sure they are trained and objective enough to conduct an unbiased root cause analysis of quality issues.
- Develop a process to capture and collect product issues, customer complaints, product returns, and other quality issues. These issues need to be reviewed regularly and escalated to senior/executive management when warranted.
- Initiate a tracking system to document and track all CAPA plans.
- Ensure responsibilities are assigned to run and monitor the process.
- Ensure routine communication of CAPA outputs to the executives.
- Provide the necessary resources to fully investigate, document, resolve, and close corrective and preventative actions.

Implementing an effective CAPA system not only helps keep food and beverage companies in compliance with the rollout of FSMA, but can help improve the quality and cost of producing their products. It is an investment that pays significant benefits, greatly exceeding program costs.

CAPA SERVES AS AN "EARLY-WARNING SYSTEM" FOR BUSINESSES BY COLLECTING VALUABLE METRICS AND INFORMATION TO SPOT TRENDS IN QUALITY.

Integrated Project Management Company, Inc.

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