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CAPA: A Review of 21 C.F.R. §820.100 and FDA Warning Letter Trends

Introduction

SPK and Associates routinely review warning letters to help our clients stay in step with FDA trends. One of the problem areas most often cited in company audits continue to be the CAPA system/program. In this article we will take a look at some of the latest data, review some of the essentials of a well-designed CAPA system, and list some of the tools available on the market to help your organization establish a solid CAPA program.

What Is CAPA?

CAPA stands for "Corrective Action, Preventative Action." It is a current good manufacturing practice (cGMP) in which the FDA requires companies to investigate, understand, and then correct discrepancies while putting measures in place to prevent their recurrence.

The FDA formally outlines their CAPA expectations in 21 C.F.R. §820.100 with parts (a) & (b):

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

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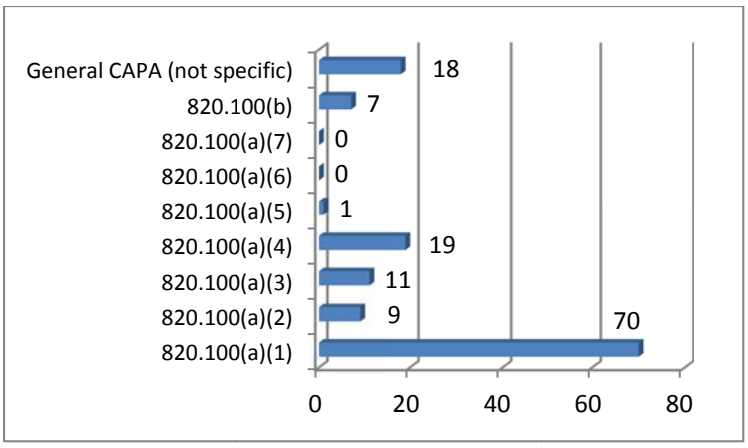
(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented

What is the Latest Compliance Data from the FDA relative to CAPA? How are companies doing?

There has been 746 FDA warning letters generated in year 2010 up to April 10, 2011. Of those, 194 were filed by the Center for Devices and Radiological Health Office (CDRH) or were tagged as "Medical Device" oriented by an FDA district office. Breaking those numbers down further, we have 50% of those (97 warning letters) calling out one or more CAPA issues. That's a significant percentage!

Within those 97 Warning letters, 135 CAPA citations were noted (with some companies with multiple violations). Those 135 citations decomposed further into the following distribution:



Companies are having the most issues with section 820.100(a)(1), which has to do with discovering the issues.

Establishing a Well-Designed CAPA System

Developing your ability to discover an issue is an important first step to avoiding warning letters. Companies need to build a comprehensive review program which goes beyond customer complaints. Analysis and consistent monitoring of business processes should also include data from MDRs (Medical Device Reports), Risk Assessments, Management & Employee Reviews, QA inspections, Failure Mode Analysis, Service Requests, Process Performance Monitoring, Calibration and Maintenance records, and Trending Analysis. Make sure all the data is available in a safe/secure location, easily accessible by auditors.

Understand what caused your issue. An investigative process utilizing "Root Cause Analysis" techniques is recommended. Look at all possible sources of the issue and document your findings into a clear investigation plan.

Fix your issue and develop preventive measures. Once you've fully understood what went wrong, implement and document a *corrective action*. In addition, develop a process which will *prevent* the issue from resurfacing. Make sure your actions are proportional to the severity/impact of the issue discovered.

Test to see if both corrective actions and preventive actions are working. Perform thorough testing of your solution for effectiveness and put monitoring systems in place. Adjust your SOPs. Document everything.

Communicate all updates to your management and individual contributors, ensuring they completely understand the new procedures & processes. Your senior management should sign-off on all Corrective Action Requests (CARs) and/or Preventive Action Requests (PARs). Create objective evidence of these reviews.

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Some Tools To Help Organize and Manage Your CAPA Process.

There are companies which use simple spreadsheets or leverage existing defect tracking systems to manage their CAPA systems (ClearQuest, Bugzilla etc). There are also companies which are leveraging their PLM solutions (Oracle/Agile's PQM), (PTC/NetRegulus). Additionally, there are several vendors with CAPA solutions on the market. Here are few for you to checkout.

Software	Company	URL to its CAPA Software Description
MasterControl CAPA™	MasterControl	http://www.mastercontrol.com/capa-software/corrective-action-capa-software.html
AssurX CAPA	Assurx	http://www.assurx.com/CAPA.html
adWATCH-CAPA	Winchester Business Systems	http://www.wbsnet.com/WBS/WBSHome.nsf/UNIDs/8FA989C932BE90008525 70AB006C8C47
CompliantPro	IBS software	http://www.ibs-us.com/en/products/compliantpro/index.html
TrackWise	Sparta Systems	http://www.spartasystems.com/trackwise-eqms/
CAPA Management	Pilgrim Software	http://www.pilgrimsoftware.com/quality/capa-management-global-deviation-and-nonconformance-management
CEBOS MQ1™ Corrective Action Software	Cebos	http://www.cebos.com/Problem-Solver-System.html
caWeb4	Harrington	http://www.harrington-group.com/products/web-based-corrective-action/
Ready-CAPA™	Interphase Systems	http://www.ready-capa.com/corrective.html
QCBD™	Cama Software	http://www.camasoftware.com/CAPA.htm
EtQ's Corrective Action and Preventive Action (CAPA)	EtQ	http://www.etq.com/capa/
MetricStream CAPA/Remediation Management software module	Metric Stream	http://www.metricstream.com/products/capa.htm

SPK and Associates would like to hear from you. We invite you to share your CAPA questions, experiences, and advice. What CAPA tools are you using and which techniques work best in your company? We are also available to help deliver a CSV of your CAPA system.

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