‘fsma SaaS’ introduces free FSMA corrective action app

...electronically formatting the mandatory FSMA corrective action 117.150 clause with other clauses.

SARASOTA, FL, UNITED STATES, November 12, 2020 /EINPresswire.com/ -- Documentation on the FDA website – stated as current as of 01/04/2018 informs ‘My name is Joe Tartal and I'm the Postmarket and Consumer branch chief in the Division of Industry and Consumer Education. The topic of corrective and preventive action (CAPA) is an important one. Know the purpose of corrective and preventive action; have the ability to distinguish between each of the defined terms; understand the requirements in CFR 8120 - the quality systems regulation’.

> I'm the Postmarket and Consumer branch chief in the Division of Industry and Consumer Education. The topic of corrective and preventive action is an important one (CAPA)”
>
> *Joe Tartal*

Preventive actions are no longer relevant to managing in a risk-based management system. The PA in CAPA is now unrelated to corrective actions. The truth is, preventive controls, instead of preventive actions, are applied because the risk of nonconformity is evaluated to determine the ‘control’, to avoid non-conformities. Preventive actions are not addressed in the law. FSMA is described as a risk-based regulation as stated in the law per 117.3

According to 117.3 definitions ‘Preventive controls means those risk□based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis’ No mention of Preventive Action.

The Corrective Action FSMA Clause is seemingly a standalone clause. The clause in FSMA defines the reasons to conduct corrective actions. FSMA does not indicate HOW the activity is to be conducted. The corrective action FSMA clause must work in conjunction with other clauses because the other clauses call out the Corrective Action clause. However, the methodology is not defined within the regulation. ‘fsma SaaS’ takes the opportunity to facilitate the methodology to avoid FDA citations.

This discourse is intended to connect the respective FSMA related clauses. Corrective Actions follow a specific method to drive improvement through a permanent solution to meet the intended requirements or objectives. The purpose here is to demonstrate how the different FSMA clauses connect as a distinct workflow when a non-conformity occurs.

1. Corrective Actions 117.150 2 are triggered when
(b) Corrective action in the event of an unanticipated food safety problem or A preventive control is not properly implemented or incomplete food safety plans or incomplete records
The non-conformity is stated against the requirement to indicate the condition(s) was not met, as it related to (b)
2. Correction 117.150 c
A risk-based preventive control exercise is likely to correct issues that may result in an isolated problem that results in non-conformities. In the event of a non-conformity, a short term or temporary solution is needed sometimes. Correction is sometimes referred to as 'containment' For example, for a recall. Say a lot number is recalled. The correction is preventing any unshipped product of the same lot numbers in stock, to be purged to ensure likely defects from storage are not inadvertently shipped.
3. Root cause 117.150 2 i
More than one method exists to determine the root cause – for example, fishbone which is complex, and '5 whys. More common is the five whys; Well, not exactly, although called the five whys, the root cause does not necessarily work out at 'why' number 5. It can be #4 #6 or #7 'why' to reach the root cause. There is no exact count on which is the correct 'why'. How is the correct 'why' identified? Which 'why' response is valid, to determine the root cause of the non-conformity. The applicable 'why' is the one which identifies a missing resource (s) and/or control(s), which resulted in the non-conformity.
4. Corrective Action 117.150 (b) 2 (i)
The Corrective Action is the input of the missing resource(s) and/or control(s) – that caused the issue. It could be either one or more resources or control or both. However, a reanalysis according to 117.(b)2ii is required to determine the least likely risk of reoccurrence.
5. Reanalysis 117.170
(b) You must conduct a reanalysis of the food safety plan or the applicable portion of the food safety plan:
(3) Whenever appropriate after an unanticipated food safety problem in accordance with 117.150(b); and
(4) Whenever you find that a preventive control, a combination of preventive controls, or the food safety plan is ineffective.
One or more corrective action options may exist to choose from. The one to be chosen is typically the one with the least risk of re-occurrence of the non-conformity or given cost consideration. The update of a partial or a full procedure is written to mitigate the decided risk and to modify the food safety plan if required.
6. Validation 117.160 (b) ii or iii if required.
An exercise – carried out to verify the chosen corrective action is effectively reducing the risk of reoccurrence. Applied to the same process or food safety plan under the same conditions. A determination that no further action is necessary because the permanent condition, effectively did not allow a reoccurrence of the non-conformity
7. (re)training 117.180(d)
Training to the changed partial or full procedure or retraining if the root cause is due to lack of competency (resource).

Benefits of Corrective Actions
•Records demonstrate a permanent improvement so that the reoccurring problem is eliminated
•Clauses audited in a single workflow and complements risk-based audits.
•Avoids FDA citations
SHECA is a free Ipad ‘fsma SaaS’ developed app, which follows the described workflow to ensure FSMA corrective action compliance is maintained. Jeffrey Lewis CEO states ‘Our corrective action app provides companies with the tools to manage this mandatory requirement of FSMA. In addition, we will respond to any queries related to corrective actions. SHECA can be downloaded from the App Store'.
Contact jeffrey@fsmafoodsafety.com about our free app and its free use.

Jeffrey Lewis
fsma SaaS
+1 650-269-6506
email us here
Visit us on social media:
LinkedIn
