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Media Contact:

Jeffrey Lewis

650 269 6506

jeffrey@fsmafoodsafety.com

fsmafoodsafety.com

fsma SaaS guarantees on-going FSMA compliance

...through PCQI 'management by exception' technology

SARASOTA, FLORIDA, AUGUST xx, 2020 –

Introduction

The Registrar Corp on December 31 2019 stated, 'FDA's inspection data reported 289 citations to importers without an FSVP, up from 108 the previous year. FDA also cited hundreds of facilities for having issues with their Hazard Analysis and Risk-Based Preventive Controls (HARPC) Food Safety Plans. These citations ranged from failing to have a HARPC Food Safety Plan, not identifying hazards that require a control, or not having a Preventive Controls Qualified Individual (PCQI) write the plan as required. With most of the deadlines having passed, some several years ago, it should be expected that FDA will continue to enforce these rules more heavily'. There were 2300 and 2900 FDA food safety citations in 2018 and 2019, respectively. These occurrences are in spite existing software applications and GFSI programs. A review of the citations suggests that operational tasks were left undone or missed.

It may be argued that the PCQI did not perform their role as a 'back up' to the operations. Seemingly, there is no easy way for the PCQI to maintain the Food Safety Modernization Act though the multiplicity of plans, procedures, and records requirements. "We have an increasingly complex supply chain and regulatory landscape," UNPA president Loren Israelsen said. "Both domestic and foreign suppliers are often not equipped to meet the new Food Safety Modernization Act (FSMA) record-keeping requirements, and the industry as a whole is suffering from certifier audit fatigue'.

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The Specialty Foods Association identifies 20 separate documents the PCQI has responsibility for as prescribed by 117.135 Preventive Controls. It seems inevitable that the FDA will find non-compliances at audited companies. The reinspection fee for foreign facilities increased to \$301/hr and \$258/hr for domestic facilities, an additional financial burden due to the reinspection of the audit findings. The further the time between FDA audits, means there are likely to be more findings – increasing the number of re-inspections hours, which may result in ‘certifier audit fatigue’.

Fulfillment of FSMA compliance towards eliminating FDA citations – requires and an alternative strategy to maintain compliance on an ongoing basis.

The Operations Status Quo

Companies generally operate as silos utilizing more than one function software to manage each of the risks (including other legal requirements) related to food safety compliance, the training, the document control, the maintenance, the quality, the GMP, the corrective action, the OSHA requirements. The different programs or paper checklists /batch sheets requires detailed examination for missed compliance tasks or non-conformities across different departments. In the hustle and bustle of daily operations, out of compliance situations across all functions requires detailed knowledge inspections of completed records across a multiplicity of departments. For example, is there training records available for a specific food preventive control? Or, is the practice of maintenance based on GMP principles Re 117.135 (c) 6. Additionally, the receiving facility has the same task to verify the suppliers’ records. With a multiplicity of ingredients into a single product, it is a significant task to effectively review all the relevant documents and records from different suppliers, especially if the records are to be retrieved in a timely fashion for production.

The legal PCQI role requirements

117.126 Food safety plan.

(a) Requirement for a food safety plan. (1) You must prepare, or have prepared, and implement a written food safety plan.

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(2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals (PCQI).

Beyond (2) ...

b. (7) The written verification procedures as required by §117.165(b).

(c) *Records*. The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§117.165 Verification of implementation and effectiveness.

(a) *Verification activities*. You must verify that the preventive controls (117.135) are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system

The PCQI Role in this regard is two-fold according to FSMA (1) prepare and implement a written food safety plan (2) Conduct of verification activities of the preventive controls.

'fsma SaaS' electronic compliance of the 'prepare and implement'.

The preparation and implementation once set up, offers little opportunity for deviation as, unless product formulation is changed and re-validated, the preventive controls are settled. Some quarters advocate full time PCQIs. However, it is imperative that the PCQI sets up all the parameters for 'prepare and implement' completely.

fsma SaaS electronically enables a minimum of three verifications to ensure that the food safety plan is identified at the application point of use on the tablet. The technology architecture is tiered to enable the multiple verifications of the preventive controls, at training, in prework and the work phase at the point of application in the process. Moreover, the process is cloned, and the only change is the lot code. Apart from the actual input of the data, the other controls are 'wired' into the technology. The preventive controls remain unchanged. **'fsma SaaS'** provides the control for the 'preparation and implementation' by the built-in three verification reviews and the unchanged cloned validated process for each product.

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Management by Exception

The management of the 'conduct of verification activities' is sought because of the operational variables, the availability of skill set knowledge across the various disciplines, and the capability to conduct detailed inspection reviews that are likely to lead to non-compliances and citations. The Internal and Receiving facilities PCQIs, according to FSMA, are intended to verify the respective functions and food safety plans via the supplier records, to safeguard food and reduces the likelihood of FDA findings, determined by auditing records, which is after the fact. The FDA citations review indicate that the internal and receiving facility PCQIs' do not have timely access to the supplier records or misses the non-compliances related to the legal requirements based on the multiplicity of records to be examined. The FDA auditor is trained to find breached areas of non-compliance, which were not verified by the PCQIs. If the organization can provide the PCQI with the tools to automatically support the detailed examination of records, FDA citations can be avoided. The detailed review of documents is supported by the 'fsma SaaS 'Management by Exception' technology.

fsma SaaS controls the delivery of the food safety plan at the point of use and uploads records in real time to the cloud for the internal and external PCQIs inspections. **fsma SaaS** manages the legal requirements to ensure compliance and conformity are maintained. The PCQI responsibilities are managed by exception, identified by the software. In other words, through the technology, knowledge of the legal requirements of FSMA is facilitated, eliminating the review of each individual document for compliance or performance verification. In a word – a remote or part time PCQI to verify the records of the 'prepare and implement' serves the purpose.

fsma SaaS as a technology platform, employing a series of error proofing control techniques with notifications from FSMA digitized records. The software enables the food safety plan with multidiscipline preventive controls, utilizing binary formatted directives. Non-compliance alerts are triggered when the tasks are not completed, or the preventive and other controls are not as stated at the point of use or the measured control levels are at variance to the planned monitoring values. Non-compliance alerts

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are delivered in real time. The supplier receives communication because of the exception to the regulatory requirements. The PCQIs do not have to comb through a multitude of records to find discrepant issues for corrective actions. These are already separated and indicated for the PCQI sign-off. Moreover, fsma SaaS automatically calculates the percentage effectiveness of all delivered procedures, providing the PCQI with management data to satisfy 117.165, verification of implementation and effectiveness. Relative to the operations, the PCQI filters by date period and location or process; the percentage of effectiveness, enabling an opportunity to further minimize the risk.

The Technology Experience

In summary, the **fsma SaaS** technology offers the following in automating the PCQI function

- The two PCQI roles are managed by 'fsma SaaS' technology
- a guarantee on-going FSMA compliance for inputted food safety plan and preventive controls
- a single management system platform that covers all fsma compliance and GFSI conformity requirements.
- Identifiable preventive controls with binary options, control limits, the respective records for real time electronic 'management by exception' notifications
- The elimination of the PCQI riffling through many documents for verification compliance
- The management by exception technology consistently follow the same rules and do not depend on human judgement. For example, when to open a corrective action.
- Without knowledge of the law, the PCQI maintains compliance to the law for the operations.
- The receiving facility assurance on the integrity of their supply chain, without the risk of an FDA ordered shut down or delayed documentation
- Simultaneously see all supplier outcomes for verification on a single platform.
- The simplification / automating of the recordkeeping management for suppliers reducing the level of certifier audit fatigue

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- Reduces the risk of legal consequences which can be triggers by one or more of, Product liability, the whistleblower, insurance liability, FDA findings

fsma SaaS offers an economic advantage for the operating PCQI for managing the compliance requirements,

- reducing the time (cost) spent reviewing multidiscipline records and framing corrective actions
- the subscription or upgrade cost of multiple pieces software or the verification of paper records by only have a single platform
- the cost FDA citation reinspection audits.
- More competitiveness – no need for a full-time cost of a PCQI, who can operate remotely part time to conduct real-time verification on-line, provided the preparation and implementation is locked down in the cloned process.

Supplier are invited to sign up for a free online demo at **fsmafoodsafety.com** The suppliers have the benefit of a further offer of free use into perpetuity if, a citation related to the fsma clauses, is gained when using **fsma SaaS**

- provided their food safety plans are defined in the system for each product and lot cloned.
- Notifications are responded to in a timely fashion

Food suppliers standing on the side lines due to PCQI costs and citation re-inspections, can rejoin the marketplace due to the PCQI 'management by exception' automation

About Safety In Your Hand, Inc

Safety In Your Hand, Inc has developed award winning single management system technology to support ongoing regulatory compliance and management standard conformity. Th founder, Jeffrey Lewis, started the integration of disciplines in his patent 6994258 and in 2006 gained the Best of the Best Award for the Best practice process design by the Quality Assurance Institute. The relevance became obvious with the 2015 Standards and the direction of the 19011:2018 Risk based Auditing Standard. Jeffrey Lewis is a 20-year veteran of compliance and conformity implementation and auditing.