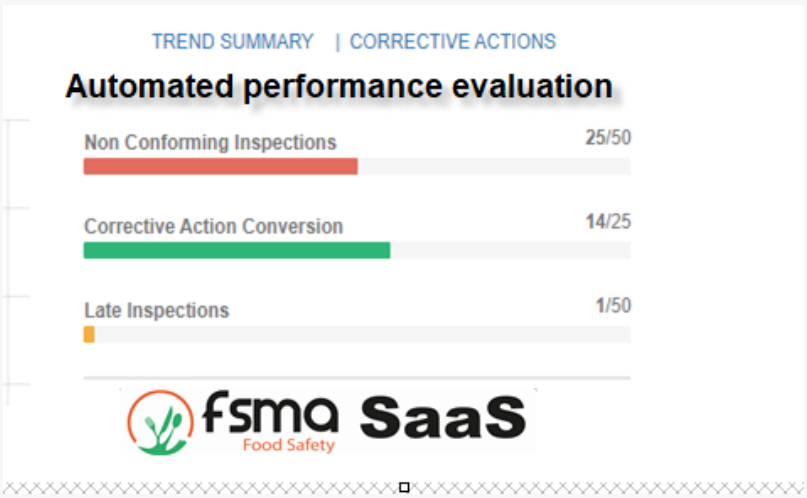
'fsma SaaS' eliminates Supplier, Brand owner and Co-manufacturer supply-chain challenges for the FDA stakeholders

by offering a technology solution with zero costs to brand owners and co-manufacturers



Automated performance evaluation

SARASOTA, FLORIDA, UNITED STATES, October 28, 2020 /EINPresswire.com/ -- On November 6th, 2019, the Guidance on the 'Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry' was due to be FDA enforced. However, because the 'FDA has learned of additional challenges industry is facing in trying to meet the supply-chain requirements; the FDA will continue its enforcement discretion policy while advancing its work with stakeholders to better understand these challenges and to consider possible solutions to address these situations'. The challenges were due to the following guidance:

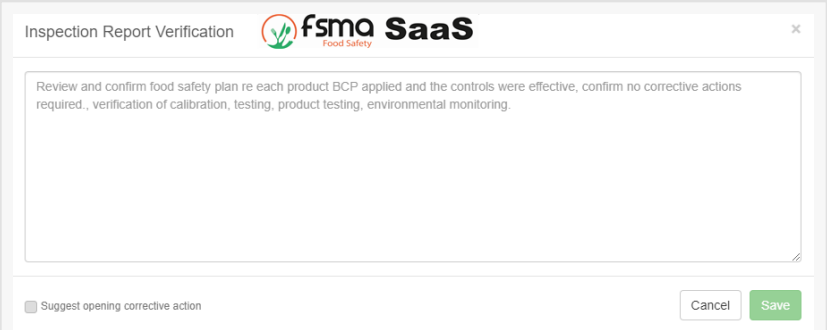
> In support of an extension of enforcement, discretion informed FDA that industry had faced difficulties revising contracts to allow brand owners to share supplier information with co-manufacturers"
>
> *Hogan and Lovell*

1. Supplier Approval FDA does not intend to take enforcement action if:
(1) a brand owner conducts supplier approval activities, (2) the co-manufacturer describes these activities in its food safety plan, and (3) the co-manufacturer conducts any necessary supplier approval activities not conducted by the brand owner

2. Supplier Verification FDA does not intend to take enforcement action if:

1) a brand owner determines and/or conducts supplier verification activities for its co-manufacturer, (2) the co-manufacturer describes these activities in its food safety plan, and (3) the co-manufacturer conducts any necessary supplier verification activities not conducted by the

brand owner



Brandowners or Co-manufacturer -supplier verification

According to Hogan Lovells 'Comments submitted to FDA in support of an extension of enforcement, discretion informed FDA that industry had faced difficulties revising contracts to allow brand owners to share supplier information with co-manufacturers and that the rule presented additional challenges that could not be resolved just through contract revisions. For example, industry comments highlighted the resource burdens on both brand owners and co-manufacturers that would occur if verification needs to take place on the co-manufacturer level. Comments also expressed concern that entities would be required to hire additional personnel or redirect current personnel away from more substantive supply-chain work in order to facilitate compliance, but that these efforts would not add value for food safety.

Collaboration appears to be the approach among the stakeholders to reach an agreement. Technology-enabled collaboration provides a win-win-win for the supply-chain stakeholders. FSPCA directs the operationalization of FSMA. FSPCA mentions 'control' 54 times. Consider how your organization executes 'control'. A system of controls is distinctly different from a checklist of FSMA clauses.
'fsma SaaS' controls are based on the mechanics of error proofing and management by exception techniques, which leads to a resolution of the stakeholder challenges.
The three issues which inhibit contract revisions are

- Sharing of supplier information with co-manufacturers
- Resource burdens on both brand owners and co-manufacturers for verification of records

- Additional staff shifts away from more substantive supply chain work. Such efforts do not add value to food safety

'fsma SaaS' digital application facilitates control through the following

1. Supplier scheduled download of food safety plan / preventive controls to an Ipad and uploaded supplier records in real-time for external access
2. The Brand owner can direct the supplier which information is to be shared with the co-manufacturer electronically at the push of a button, to support the supply chain
3. Standardized formats from all suppliers on a dashboard to enhance efficiency for lower costs
4. A measure of the effectiveness of controls to determine supplier performance
5. Automatically triggered corrective actions when requirements are not met

The brand owner sees all the records for the lot run with the opportunity to be selective to what

is visible to the co-manufacturer. Both parties have a separate dashboard of supplier information. Limited access to supplier records by the co-manufacturer is decided by the brand owner. Similarly, the co-manufacturer enables brand owners to verify their operations in real-time.

Supplier Approval

- Approval

'fsma SaaS' facilitates supplier approval by the brand owner through the fulfillment of the food safety plan and preventive controls. 'fsma SaaS' offers data entry of the parameters so that the brand owner is assured that the legal requirements are met; so that there is no chance of supply interruption due to citations by the FDA. The co-manufacturer has digital access for inputs into their own food safety plans and can be approved on behalf of the brand owner if required.

Supplier verification

Separate verification frameworks are provided by 'fsma SaaS'

- the capability to verify each lot for the full supplier process, by the brand owner which is not seen by the co-manufacturer.
- The co-manufacturer in a separate partitioned section for the same lot verifies only the information that the brand owner wants the co-manufacturer to verify. e.g.
  - food safety plan /preventive controls
  - food testing
  - verification of calibration
  - environmental monitoring
  - Confirmation that no corrective actions are required.

The Supplier and co-manufacturer performances are automatically measured as a percentage variation to the total number of procedures and trended. The brand owner can then assess the actual performance of their individual suppliers or co-manufacturer.

Resource Management

The cost to brand owners and co-manufacturers (as receiving facilities) is zero dollars to utilize 'fsma SaaS' Both these entities access the relevant completed production electronically for the actual point of use records, which can be done prior to shipping in real-time. Enhanced efficiency means lower than current costs to do so – especially since there is no direct charge for receiving facilities to conduct verification. Co-manufacturers receive product documentation in a digital format from the supplier into their own systems or 'fsma SaaS', if they chose to do so.

Only the production entities accrue a subscription cost for utilizing 'fsma SaaS'. The online / Ipad system is more efficient leading to lower costs. Additional or shift of human resources from other areas is unnecessary due to error-proofing and automation control. Access provides real-time original records, 'fsma SaaS' solves the issues associated with supplier/ brand owner /co-manufacturer challenges.

Jeffrey Lewis CEO of ‘fsma SaaS’ states that at the one-year anniversary of the enforcement date, 'fsma SaaS' is pleased to offer a solution of guaranteed FSMA compliance to the stakeholders providing them greater efficiency at a cost lower than their current practices. The brand owner is able to share only necessary information with the co-manufacturer. Contracts can be agreed to!'

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