

ASTA FSMA Inspection Discussion Forum Topics

The ASTA Inspection Forum is being set up to allow ASTA members to share their experiences regarding FSMA inspections. ASTA will host one-hour, quarterly conference calls to allow members to voluntarily discuss inspection related issues like those listed below. These calls are intended to be directed and initiated by the members on the call, and will be monitored by ASTA staff to ensure information shared is in compliance with U.S. anti-trust and competitive practices laws. This forum is intended to allow for discussion of broad aspects of FSMA inspections as all companies get a feel for these new inspections and what to expect. The calls are not intended to discuss issues associated with your companies' specific inspections or the results of those inspections.

Participation in the ASTA Inspection Forum calls is voluntary. All discussion, observations, anecdotes and information shared during the ASTA Inspection Forum calls will be provided by member-company volunteers. As such, the information discussed and shared on the calls will not be verified by ASTA and ASTA makes no warranty, express or implied, for the accuracy of this information. Information provided or shared should not be your only resource for determining preparedness for or compliance with any FDA inspection, including a FSMA related inspection.

Following are several suggestions on the types of information that may be useful to share.

General Inspection Information

- Under which rule did your inspection take place-FSVP, PCHF, Current Good Manufacturing Processes? What type of inspection was conducted: FSMA PC, FSMA FSVP, FSMA Sanitary Transportation?
- Was your company given advance notice for the inspection? How much notice were you given? How were you notified?
- How long did the inspection last? How many inspectors were present?
- Was any follow-up scheduled?
- What agency performed the inspection? Agencies that are performing inspections may include the FDA, a state department of inspection, or others.

Documentation

- What type of information did the inspector focus on such as verification, risk assessment, food safety plan?
- Did the inspector ask questions about validation of microbial reduction processes?
- Did the inspectors focus on following a specific product through the inspection process, as well as the risk assessment documentation for that product?
- Did the inspectors ask for information such as financial information, company size, number of employees, suppliers and customers, and sales volume? Please keep in mind that you should not share your company's actual information, merely an overview of the types of information that was requested.

Swabbing & Photography:

- Did the inspectors ask to take photographs during the inspection? If your company has a written policy regarding photography was it provided to the inspectors and did they adhere to it? Were there any issues related to photography?
- If the inspectors took photographs did your staff take concurrent photographs?
- If the inspectors took photographs, what type of devices were used?
- If there was swabbing during the inspection, how many swabs were taken? What were the organisms of concern? Did the inspectors ask for results of pathogen environmental monitoring?