

FSMA Inspections: Industry Insights

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Top Ten FSMA Inspection Insights

6. Several people needed to accompany the number of inspectors and swabbing
7. Expect a lot of inspectors at your plant; multiple days
8. Inspectors often want to take pictures
9. Inspectors are asking questions of process owners, not just the PCQI or Plant Manager
10. Developing, training, exercising “Regulatory Inspection Guidelines” can help plants prepare



Top Ten FSMA Inspection Insights

1. Contract manufacturing can be a challenge for supply chain program documentation
2. Corrective actions need to be complete—product and process
3. Quickly share FSMA inspection learnings with your other plants
4. Inspectors referencing FDA draft guidance when reviewing your hazard analysis
5. Translation and culture can be a challenge in foreign country inspections



Food Safety Summit 2017

FSMA Inspection Hurdles and Execution Tips

Melanie Neumann-Cherney, J.D., M.S.
President, Neumann Risk Services, LLC
May 10, 2017

Talking Points Today

- FDA “FSMA” Inspections
 - Common Themes
 - Areas of Focus
 - Hurdles
 - Tips

Common Inspection Themes

1

Inspections are
Lasting Longer

2

Two to three
“investigators”

3

Digging
Deeper

Swabs, Swabs and More Swabs!



Four Key areas of Focus:

- Pathogen Control
- Allergen Control
- Sanitation and Cleaning
- Environmental Monitoring

Overcoming Hurdles in Inspections & Execution Tips to Make Sure Your FSMA Plan is **Working** for You!

- Nail that Hazard Analysis!
 - Show your Work!
- Challenge Your Validations
 - Ask “Does Mine Really Work”?
- Simplify & Streamline!
 - Can two monitoring logs be combined to one?
 - Can technology be leveraged vs. paper forms / manual processes?
 - Can information be logged one place vs. three?



Make FSMA Requirements Work for Operations!

Tips During Investigations

- Collaborate With Investigators – They Are Much More Focused On Us Learning And Fixing Proactively / Willingly!
- Have Your Scientific Evidence To Support Decisions!
- Have Your Documentation in Order!
Documentation Review and Requests for Copies of Everything!

Have Your Policies In Order

- FDA Inspection Policy
- Photo Policy
- Swab Policy-
 - Duplicate Swabs?
 - Photos of Swab Areas?
 - Swab and Hold/ Swab and Test?
- Signing or Not?
- Corporate “Playbooks”
- Plant-Level “One Pagers”



Be Prepared ! Test your SOPs and Readiness Levels

Mock FDA
Inspections



investigation

Recall Simulations

What's The
Worst that
Could Happen if
I am Not Ready
for Inspection?



Criminal LIABILITY RISK IN THE UNITED STATES FOR MAKING Contaminated FOOD

Decades in Prison



Criminal misdemeanor / asset forfeiture

Jensen Farms



Home detention/150K restitution

Thank you!

Questions?

Contact info@neumannriskservices.com

For the NRS Newsletter please sign up at our
website at www.neumannriskservices.com

or send an email to the above



NEUMANN RISK SERVICES

FSMA Implementation

FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW

Joann M. Givens, Program Director
Food Safety Summit
May 10, 2017

FSMA Implementation

- Goal of FSMA is to move food safety system from a reactive to a preventive mode.
- FSMA's success depends on bringing about high rates of compliance.
- FDA is committed to educating before and while we regulate.
- FDA will engage and communicate to international community that is consistent with domestic efforts.

What's Next?

- FDA's primary focus will continue to be on education, training and technical assistance to help companies comply with the new requirements.
- FDA recently issued draft guidance documents and will continue collaboration with regulated industry to ensure everyone understands and engages their respective roles in food safety.
- Inspection approach will focus on assessing the progress a company has made towards compliance and whether it is taking appropriate steps necessary to protect public health.
- Work with the food industry to create a culture of food safety, with procedures, processes, and practices that we know will achieve high rates of compliance with the rule and minimize the risk of foodborne illness.

Key Implementation Principles

PC Regulator Training Plan

FDA Food Safety Staff are expected to participate in:

- FSMA Rule Readiness Webinar Series and FSMA Chats
- Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls Course with industry and state counterparts
- PC Regulator Training Curriculum for Human and Animal Food
 - modernized GMP webinar (all)
 - On-the-Job Experience (OJE) for cadre

Key Implementation Principles Inspections

- Not a “One Size Fits All Approach”
- Gain Industry Compliance, Reduce the Risk of Foodborne Illness
- Systems Based Inspections, Not “Observation Focused”
- How facilities are working to comply with the new food-safety standards and protect consumers from unsafe food.

FDA Inspections: Preventive Controls

| | Planned | Accomplished |
|----------------------------------|--|----------------------------|
| Human Food modernized GMP | 250 | 190 |
| Full PC | 240 (domestic) 60 (foreign) | 10* In Progress |
| Animal Food cGMP | 250 | 35 |
| FSVP | 325 | Not initiated |
| Sprout Facilities | 30 | Not initiated |

**Conducted by cadre*

In Summary

- Purpose of new law to create a system that is self-sustaining and encourages the prevention of food safety problems throughout the supply chain.
- New requirements fulfill the paradigm shift toward prevention intended to protect consumers .
- Working together, learning together.