

DRAFT Guide to Handling a Regulatory Inspection

This document was prepared based on the dialogue within round table discussions of the United Fresh Food Safety & Technology Council held January 10, 2017.

Key Common Points:

- Inspections may be “routine” or “for cause”
- Know the law and company policy & GMPs—so that you can push back on inspectors when necessary
 - Know your company policy on photography
 - Have a pre-determined and trained internal team for any inspections
 - Designate inspection team leader and roles (who speaks for the company and who is lead)
 - Usually one team lead/spokesperson is best and that goes all the way from beginning to end interview of inspection
 - Understand inspectors level of knowledge and attempt to educate inspectors accordingly
- Have a prior and ongoing relationship with regional FDA office and staff
 - Set the stage with trust and respect
- Be proactive during and after the inspection in asking for results in writing and stay vigilant
- Be cooperative during an inspection but negotiate with inspectors on their demands if they ask for too much
- There is a need for practical industry guidance on how to handle a regulatory inspection