

How To Live Through An FDA Audit

Citrus Processing Short Course
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Presented by:

Douglas D. Tolen

Senior Consultant

How To Live Through An FDA Audit

- ❖ Pre-audit planning
- ❖ On-site audit mechanics
- ❖ Post-audit management

How To Live Through An FDA Audit

- ❖ Know your rights
- ❖ Know what to expect
- ❖ Have an Inspection Plan
- ❖ Ensure proper response to FDA findings

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❖ FDA's Jurisdictional Authority

- ◆ Enter and inspect at reasonable times and within reasonable limits
- ◆ Access to facilities, equipment, labeling and finished and unfinished products
- ◆ Collection of samples

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- ❖ Section 704 Administrative Requirements
 - ◆ Credentials
 - ◆ FDA-482 Notice of Inspection
 - ◆ FDA-483 List of Observations
 - ◆ FDA-484 Receipt for Samples

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- ❖ Juice HACCP (21CFR120)
 - All records associated with the development, monitoring and corrective actions involving juice HACCP must be made available to FDA for review and copying at reasonable times.

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Pre-audit Planning

- ❖ Develop a written plan for managing the FDA Inspection
 - ◆ Meet and greet
 - ◆ Notify company representative
 - ◆ Advise Counsel of inspection
 - ◆ Taking notes during inspection
 - ◆ Access to employees
 - ◆ Require written report to top management

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Pre-audit Planning

- ◆ Access to records
- ◆ Photographs
- ◆ Signing documents
- ◆ Recordings
- ◆ Training key personnel

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On –site Audit Mechanics

- ❖ Accompany FDA Investigator
- ❖ Obtain duplicates of all FDA samples
- ❖ Keep matching sets of labels or any records
- ❖ Decide on proprietary information

How To Live Through An FDA Audit On-site Mechanics

- ❖ Make corrections during inspection
 - ◆ Make sure FDA investigator is aware of corrections
- ❖ Daily wrap-ups
 - ◆ Avoid surprises at the end of the inspection

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On-site Audit Mechanics

- ❖ Discussion of FDA-483 observations to ensure:
 - ◆ A complete understanding of objectionable conditions
 - ◆ Correct any misconceptions
 - ◆ Commit to appropriate corrective actions
 - ◆ FDA-483 should reflect corrections

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Post-audit Management

- ◆ Letter to FDA addressing ALL 483 observations
- ◆ Commit to corrective actions immediately, Don't wait for a 483 Letter or Warning Letter
- ◆ Assure that commitments are attainable, FDA will confirm
- ◆ Address the broad scope of the problems identified during the inspection
- ◆ Consider requesting a meeting with FDA management

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- ❖ Field Management Directive 45
- ❖ Freedom of Information Act

How To Live Through An FDA Audit Summary

- ❖ Insure that all policy decisions related to FDA inspections are made and that staff is trained on how to implement those decisions.
- ❖ Be prepared to receive an FDA Investigator at a moments notice and know your on-site inspection strategy.
- ❖ Do not delay responding to FDA inspectional observations at the conclusion of the inspection.