



Experiences Participating in the Preventive Controls Cadre

*Brian Schuettler
Environmental Specialist III
Florida Department of Agriculture and
Consumer Services*

*Jason Holleran
Food Safety Specialist
Ohio Department of Agriculture*



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Objectives

- Discuss becoming a cadre member
- List prerequisites for cadre
- Explain Train the Trainer
- Outline FD254
- Describe the overall experience
- Discuss benefit to the state

Instructor Cadre

- Initially recommendation from Management
- Approval by FDA Office of Training, Education and Development (OTED)
- Recommendation from Course Advisory Group and Instructor Cadre

Prerequisites

- FD8000L 21 CFR Modernized Good Manufacturing Practice (GMP) Inspections or FD8000R 21 CFR 117 GMP/Limited Scope Preventive Controls Inspections.
- Food Safety Preventive Controls Alliance (FSPCA)- Preventive Controls for Human Foods course

Prerequisites

- FD180 or FD150 and FD151 and FD190W101
Current Good Manufacturing Practice,
Application, and Evidence Development
- FD254W100 *“Introduction to Preventive
Controls for Human Food for Regulators”*
online course

FD254 Preventive Controls for Human Foods Regulators course

- Course overview:
- 9 modules
- In class exercises (group and individual)
- Small group discussions
- Final Assessment

FD254 continued

Modules:

- Describe the guiding principles for systems-based inspection process
- Interpret 21 CFR 117

FD254 continued

- Determine the scope of the inspection by asking open-ended questions to verify establishment type and to identify product for coverage
- Gather information for hazard analysis through interview and observation

FD254 continued

- Conduct a hazard analysis based on information gathered
- Evaluate components of the Food Safety Plan for adequacy.

FD254 continued

- Using observation skills and interviewing techniques, formulate open-ended questions to determine if a facility is implementing their food safety plan.

FD254 continued

- Provide the basis for reporting observation of non-compliance of the Preventive Controls for Human Foods regulation.
- Review a firm's FSP plan to determine compliance with the PC rule

FD254T Train the Trainer

- Course structure similar to FD254
 - Assigned mentor
- Pre-course responsibilities and preparation
 - Assigned modules to present to trainers
- Week 1 – run through course, class exercises, and small group exercises
- Week 2 and 3 –Instruct course

FD254T Train the Trainer

- Assessed on module taught and on small group exercises
- All Trainers provide feedback to participants during course
- Post course and time commitment

Training

- Class size- 30 (18 FDA/12 State) 40% to states
- Completed Courses
 - 2 Pilot course –Sep 2016 /Nov 2017
 - 14 regular courses 3-FY17, 8-FY18, 2- FY19
(8 more scheduled)
 - 4 Train the Trainer – 1-FY17, 2/-FY18, 1-FY19
(1 more scheduled late 2019)

Training

Number of participants completing FD254:

- 29-FY16
- 111- FY17
- 229- FY18
- 60-FY19 (more scheduled)

Number of Trainers completing FD254T

- 5-FY17
- 11-FY18
- 6-FY19

Training

- OJE - On the Job Experience (FDA)
 - Purpose
 - Inspection process and documentation
- Joint Inspections (3-5)
- Evaluations
 - Audits and continual training?

Benefits

- State benefits
 - Program structure
 - Enhancements to inspectional process and staff
- Industry benefits
 - FSPCA training
 - Inspections risk-based focused
 - Educate industry while inspecting

Contact Information

Brian Schuettler

Environmental Specialist III

Florida Department of Agriculture and Consumer Services

Brian.Schuettler@Freshfromflorida.com

Jason Holleran

Food Safety Specialist

Ohio Department of Agriculture

Jason.Holleran@Agri.ohio.gov

