Experiences Participating in the Preventive Controls Cadre

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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.
• 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

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