



Training Update: Preventive Controls Regulator Training

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Today's Agenda

- Preventive Controls for Human Food Training
- Future Training Considerations

Preventive Controls for Human Food Regulators Training Course

FD254

OVERVIEW/TOPICS

- Course Description
- Course Goal/Objectives
- Course Outline
- Class Schedule for FY18

Reference: PC CAP Webinar, 12/13/2017

FD254 Course Description

- Learn how to apply a systematic approach to inspect food manufacturing firms based on the Current GMP, Hazard Analysis and Risk-Based Preventive Control Regulation, and to document violations of this regulation observed during the inspection.

FD254 Course Description

- Introduces Current GMP, Hazard Analysis and Risk-Based Preventive Controls (GMP/PC).
- GMP/PC provides an overview of the regulatory requirements for food facilities and how to apply them during an inspection.
- Participants complete mock scenarios perform a final assessment to reinforce their understanding through application of the course material.

FD254 Objectives

1. Describe the guiding principles for systems-based inspection process.
2. Interpret 21 CFR 117.
3. Determine the scope of the inspection by asking open-ended questions to verify establishment type and to identify product for coverage.
4. Gather information for hazard analysis through interview and observation.

FD254 Objectives

5. Conduct a hazard analysis based on information gathered.
6. Evaluate components of the food safety plan for adequacy.
7. Using observation skills and interviewing techniques, formulate open-ended questions to determine if a facility is implementing their food safety plan.

FD254 Objectives

8. Provide the basis for reporting observation of non-compliance of the preventive controls for human foods regulation.
9. Review a firm's Food Safety Plan to determine compliance with the PC rule.

FD254 Course Prerequisites

- ORA's **New Hire Investigator Training Program** or equivalent
- **Level 1 Investigator Certification** or equivalent (**ORA Staff**)
- Successfully Completed **FD180** (OR both FD150 & FD151)
- Watch **FD8000** webinar on Modernized GMPs (live or recorded)
(**available via ORA OTED LMS**)
- Successfully Complete **FSPCA Human Food** Training
- Successfully Complete the **FD254W100** online course

Introduction to PC for Human Foods Web Course FD254W100*

Online Module 1: Course Overview

Online Module 2: Modernized Good Manufacturing Practices (GMPs)

Online Module 3: Modernized Good Manufacturing Practices (GMPs)

**Online Module 4: Subparts D&E Modified Requirements & Withdrawal of
Qualified Facility Exemption**

**Online Module 5: Subpart F: Requirements Applying to Records That Must
be Established & Maintained**

Online Module 6: Subpart G Supply-Chain Program

Online Module 7: Training Requirements

Online Module 8: Microbiological Controls for LACF & Acidified Foods

***Must be completed before take FD254**

FD254 Classroom Course Outline

- Introduction: Systems Thinking
- Module 1: Intro to 21 CFR 117
- Module 2: Initial Interview
- Module 3: Gathering Information for your Hazard Analysis

FD254 Classroom Course Outline

- Module 4: Modified Requirements & Withdrawal of Qualified Facility Exemption
- Module 5: Requirements Applying to Records That Must be Established and Maintained

FD254 Classroom Course Outline

- Module 6: Evaluating the Adequacy of the Food Safety Plan
- Module 7: Assess Food Safety Plan Implementation
- Module 8: Document Inspection Observations
- Final Assessment: Application of all Modules

FD254 FY18 Course Schedule

DATE	LOCATION
January 30 - February 9, 2018	New Orleans, LA
March 6- March 15, 2018	Seattle, WA
April 17 - 25, 2018	Brooklyn, NY
May 15 -23, 2018	Orlando, FL
June 19 – 27, 2018	Minneapolis, MN
July 10 – 18, 2018	Pittsburgh, PA
August 14 – 22, 2018	San Antonio, TX
September 18 – 26, 2018	Long Beach, CA

FY18 CLASS SCHEDULE

- States will receive at minimum 40% course slots.
- OTED/OP has prioritized attendance of those states already committed to complete the work.
- OTED/OP followed established procedure for slot allocations amongst the remaining state in collaboration with ORA's Office of Partnership and the Pre-Registration Workbook.

FY19 CLASS SCHEDULE

- Need to understand the needs of States and their inspection staff.
- AFDO Data call will be used to help determine number of needed slots per FY19 and FY20.

Future Training Considerations

- Training WG on Alternative Options
 - Develop proposals to address:
 - Equivalency Tools
 - Training Course
 - Individuals
 - FDA Course Training Hand Off
 - Same course content
 - Qualified Instructors
 - Train the Trainer Programs

Future Training Considerations

- Training WG on Alternative Options
 - **Next Steps?**
 - Develop and finalize recommendations
 - ORA & FDA Review recommendations
 - Socialize recommendations
 - PFP, CFP, AFDO, AAFCO, NASDA
 - Determine interest by State Ag and Health
 - Impact of scaling up pilot programs
 - Develop Implementation and Communication Plan



Future Training Considerations

- Train the Trainer Programs
 - Interest by States?
 - Availability of State personnel?
 - Process/Procedures
 - Requirements for Consistency

Where can AFDO or MFRP Alliance assist?

Future Training Considerations

- FDA/ORA Training Needs Survey
 - FY19 & Beyond
- MFRPA & One time funding for FD152
 - Collaboration with academia
- IFSS National Curriculum Standard

Where can AFDO or MFRP Alliance assist?

Contact Information

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