Training Update: Preventive Controls Regulator Training

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Director, Office of Training, Education and Development
Food and Drug Administration

1/30/2018
9:00 AM
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

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