A Conversation with FDA Office of Training Education and Development

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Director
FDA/Office of Regulatory Affairs

February 12, 2020
8:45 AM – 9:30 AM
Agenda

• How are FDA training courses & locations selected?
• What is role of OTED and OP in the Pre-Registration Notebook and seat allocations?
• FSMA PC Regulator Training Data
• Update on New Training Initiatives
• Question & Answer
How does OTED determine the F20/21 Training Schedule?

• Manufactured Food Programs
  – Reviewed course offerings over past 5 years including FSMA needs
  – Reviewed OP contract data for trends/changes in inspections

• Cooperative Food Programs
  – Worked with OSCP specialists to determine state needs
How are Training Sites Selected?

• What are the specific training facility requirements?
• Analyze the Requirements.
• Select the Facility or Hotel Location
• Things to Consider?
OTED Role & the Pre-Registration Notebook?

- Develops FY Training Plan of courses
- Determines seat offerings for FDA & State
- Shares plan with OP for Pre-registration notebook
- Participates with OP and States on ‘how to use’ Pre Registration Notebook
- Course Announcements issued address seat allocation needs
OP Role in the Pre-Registration Notebook?

- OP places in Pre-registration Notebook format
- OTED/OP host calls to address ‘how to use’ Notebook
- Sends out Notebook for States to complete
- Makes determination of seats available based on algorithm
What is the Pre-Registration Notebook & Analytics

FDA ORA OFFICE OF PARTNERSHIP
Overview of Coordinating State Attendance at FDA Training
Pre-Registration Workbook Process

What’s our biggest fear?

An Empty Classroom
Pre-Registration Workbook Process

- FD152 – Food Processing
- FD190 – Food Current GMP, Application, & Evidence Development
- FD202 – Conducting Acidified Food Inspections
- FD219 – Juice HACCP
- FD249 – Seafood Inspections
- FD254 – Preventive Controls for Human Food
- FD304 – Low Acid Canned Food
- FD340 – Dietary Supplements
- FD405 – Aseptic Processing & Fill
- FD226 – Produce Inspections for Regulators
- FD326 – Produce & Sprouts Investigations
Pre-Registration Workbook Process

- ER220 – Traceback Investigations
- ER300 – Intermediate Incident Command
- ER400 – Advanced Incident Command
- ER962 – Incident Command System: Planning Section Chief
- ER967 – Incident Command System: Logistics Section Chief
- ER973 – Incident Command System: Finance/Admin Section Chief
- VM102 – GMP for Animal Food Regulators
- VM220 – Preventive Controls for Animal Food
Pre-Registration Workbook Process

States Requests Over 3 Years

- 2018
- 2019
- 2020
Pre-Registration Workbook Process

Preregistration Workbook Screenshot
Just 5 data points per attendee allows OP to nationally analyze
Evaluating Need and Allocating Seats

Algorithmic Formula

- Number of Seats Previously Allocated Over last few years
- Inspectional Contract Participation
  - Commodity Participation
  - Number of Inspections per Commodity
- Grant/Cooperative Agreement Participation
- Firm Inventory

Policy Considerations

- Attempt to avoid a 100% denial of an agency’s requested seats.
- Attempt to approve, at a minimum, 20% of any agency’s requested seats
- If possible, avoid over traveling an agency’s employees
- Agencies without at least 1 trained employee to perform FDA contracted inspections receive priority
- Agencies that are brand new to a commodity area will receive priority over agencies that are more established in the commodity (introductory courses)
Allocation Process
Methods to Register for a Course

1. Preregistration Workbook
2. Wait List
   - All preregistration requests that weren’t allocated seats are automatically placed on WL.
   - Send Waitlist request to MailboxStateTraining@fda.hhs.gov
3. Limited Seating Announcement
   - Course announcement sent out to state point of contact coordinator list
State Points of Contact Communication Network

- Commodity Specific Points of Contact list
  - Manufactured Food (FD)
  - Veterinary Medicine (VM)
  - Emergency Response (ER)
  - Produce
  - Each State Agency is allotted two POC’s, a primary and a secondary per list
  - May update at any time by e-mailing OP’s MailboxStateTraining@fda.hhs.gov
Final Notes on Preregistration

• Select the most appropriate candidate to send to training.

• Preregistration is a commitment to send an individual to a training event.

• Registration is not a guarantee of a seat, but our office will make every effort to fulfill requests.
SAMPLE OF FSMA REGULATORY TRAINING
## FDA & State FSMA Regulator Training Accomplishments

<table>
<thead>
<tr>
<th>Course Name</th>
<th>Seats Per Class</th>
<th>Number of Courses per FY</th>
<th>Total FDA per FY</th>
<th>Total State per FY</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC Human Food Training (FD254)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 local staff)</td>
<td></td>
<td></td>
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</table>
Update on New FDA & ORA Initiatives

• National Curriculum Standard (NCS) General Education Unit Online Modules
• NEHA/AFDO Retail Training on behalf of ORA/OTED
• FDA ORA Telepresence/Training Hubs
• Independent Course Delivery Project
  – NYSDAM, CDPH, AFDO, NASDA, OTED
Question & Answer
Contact Information

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FDA & State Regulatory Training Accomplishments as of December 2019

APPENDIX
Accomplishments as of December 2019

FDA FSMA REGULATORY TRAINING DATA – ADDITIONAL DATA
## FDA & State FSMA Regulator Training Accomplishments

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<tr>
<th>Course Name</th>
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<th>Total State per FY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Produce Safety Training (FD226) (1 local, 7 other staff)</td>
<td>30</td>
<td>FY17: 1, FY18: 6, FY19: 4, FY20: 4</td>
<td>FY17: 10, FY18: 17, FY19: 5, FY20: (5)</td>
<td>FY17: 10, FY18: 140, FY19: 100, FY20: (23)</td>
</tr>
</tbody>
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# FDA & State FSMA Regulator Training Accomplishments

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<tr>
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<th>Total FDA per FY</th>
<th>Total State per FY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sprout Safety Training (FD225) (1 local staff)</td>
<td>24</td>
<td>FY17: 1 FY18: 2 FY19: 1 FY20: 0</td>
<td>FY17: 25 FY18: 15 FY19: 10 FY20: 0</td>
<td>FY17: 0 FY18: 33 FY19: 13 FY20: 0</td>
</tr>
<tr>
<td>PC for Grade A Milk (PMO) (FD378) (2 others staff)</td>
<td>40</td>
<td>FY18: 3 FY19: 3 FY20: 1</td>
<td>FY18: 15 FY19: 7 FY20: (0)</td>
<td>FY18: 90 FY19: 78 FY20: (0)</td>
</tr>
<tr>
<td>Produce Safety Training (FD226) (6 other Feds, 1 local staff)</td>
<td>30</td>
<td>FY17: 1 FY18: 6 FY19: 4 FY20: 4</td>
<td>FY17: 10 FY18: 17 FY19: 5 FY20: (5)</td>
<td>FY17: 10 FY18: 140 FY19: 100 FY20: (23)</td>
</tr>
</tbody>
</table>
## FDA & State FSMA Regulator Training Accomplishments – Train the Trainer

<table>
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<tr>
<th>Course Name</th>
<th>Seats Per Class</th>
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<th>Total FDA per FY</th>
<th>Total State per FY</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC Animal Food Train the Trainer (FD254T)</td>
<td>15</td>
<td>FY17: 1 FY18: 2 FY19: 2 FY20: 2</td>
<td>FY17: 4 FY18: 9 FY19: 8 FY20: (0)</td>
<td>FY17: 1 FY18: 2 FY19: 2 FY20: (0)</td>
</tr>
<tr>
<td>CGMP Animal Food Train the Trainer (VM102T)</td>
<td>10</td>
<td>FY18: 1</td>
<td>FY18: 9</td>
<td>FY18: 1</td>
</tr>
</tbody>
</table>