

FROM: Jody Robinson-Ng, Training Officer, DHRD
SENT: December 19, 2014
To: "ORA HQ DHRD Course Distribution List"
Subject: COURSE ANNOUNCEMENT: FD405 Aseptic Processing and Fill
Pending FY14 FUNDS

FD405 Aseptic Processing and Fill: March 10 – 14, 2014
Raleigh, NC

Begin: Monday, March 10, 2014 at 8:00 a.m.
End: Friday, March 14, 2014 at 11:30 p.m.

AUTHORIZED TRAVEL DATES:

Arrival: Sunday, March 9, 2014
Departure: Friday, March 14, 2014 (schedule flights after 2:00 PM)

Everyone is expected to return on the departure date unless there are extenuating circumstances (see ACCOUNTING AND ADMINISTRATIVE INFORMATION, below).

POINTS OF CONTACT:

Participants seeking information or assistance with this training course should contact in the following order:

- 1) Immediate Supervisor (first source of information and assistance)
- 2) New Hire Training Coordinators (for "new hire" related questions)
- 3) District Administrative Officer (AO) (Gov Trip, travel, and accounting code information)
- 4) Regional Training Officer (RTO) (cancellation, substitutions, hotel issues, pre-requisite waivers, special requests for additional overnight stay)
- 5) Jody Robinson-Ng, Training Officer (final POC if the RTO is unavailable)
FDA/Division of Human Resource Development
Office: 301-796-4525; Fax 301-827-8708
e-mail: Jody.Robinson@fda.hhs.gov

Course Description:

This course focuses on the principles and concepts of aseptic processing. This course will cover the technology and manufacturing techniques applicable to aseptic systems. The course will discuss the three components of aseptic processing systems: *product sterilizers, aseptic tanks, and aseptic fillers/packaging systems*. It will also focus on the thermal process establishment including system validation studies, process delivery, process documentation, packaging technology, and package integrity. This course will enhance participant's ability to evaluate the firm's control and documentation of critical factors ensuring commercial sterility. This course will also provide instruction on conducting inspections of aseptic processing operations and complying with the Food, Drug and Cosmetic Act, 21 CFR 108, 110, 113, 114, and other applicable regulations. In addition to classroom lectures, the students will be required to participate in a series of workshops and exercises designed to reinforce their understanding of the subject matter.

Course Objectives:

Upon completion of this course, participants will be able to:

1. Describe the basic principles of aseptic processing principles, products, packaging and product types, and systems.
2. Describe the basic principles of validation and process design
3. Identify the *product sterilizer* component of an aseptic processing system
4. Identify the *aseptic tank* component of an aseptic processing system
5. Identify the *aseptic filler* (package sterilizer) component of an aseptic processing system
6. Distinguish different product categories (lact/acid/acidified/ESL) produced on aseptic processing systems.

7. Utilize appropriate established regulations (regs. 179, 110, 113, 108, 178, 173, 114) as they relate to aseptic processing systems.

Target Audience

This is an advanced course designed to enhance the knowledge of investigators/ laboratory analysts, compliance officers and supervisors who have an understanding and working knowledge of the FDA LACF regulations, Parts 108, 113, and 114.

CEUS: PENDING

Prerequisites

- Completion of new hire training curriculum prior to attending (FDA: Level I; State: Successfully complete Basic Food Inspection Training curriculum as referenced in Standard 2, Manufactured Food Regulatory Program Standards).
1. Completion of Foods GMPs 110 Course (FD150), Food Inspection Techniques and Evidence Development Course (FD151) or the new FD180 Food Good Manufacturing Practice, Application and Evidence Development Course, and Food Processing and Technology Course (FD152) prior to attending. Or min 2 years previous LACF experience/knowledge, if using this waiver please provide the information on your registration form (Attachment A)
 2. Completion of FD304 Low Acid Canned Food Inspections and 3 LACF inspections or Completion of FD203/FD103/FD1003 and 5 LACF inspections (*Provide name of firm, FEI number and date they conducted the inspections.*)
 3. Must have conducted a minimum of one (1) aseptic processing inspection. *Provide name of firm, FEI number and date they conducted the inspection*
 4. FDA participants must have an active FACTS account.
 5. Read the following documents prior to attending the course:
 - 21 CFR Parts 108 and 113
 - FDA “Guide to Inspections of Low Acid Canned Food Manufacturers, Part 1 – Administrative Procedures” (available at <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074992.htm>)
 - FDA “Guide to Inspections of Low Acid Canned Food Manufacturers, Part 2 – Processes/Procedures”(available at <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074995.htm>)
 - FDA “Guide to Inspections of Low Acid Canned Food Manufacturers, Part 3 – Container/Closures” (available at <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074999.htm>)
 - FDA “ Guide to Inspection of Aseptic Processing and Packaging for the Food Industry (Available at <http://www.fda.gov/downloads/ICECI/Inspections/InspectionGuides/ucm091740.pdf>)
 6. Online content is being developed for this course: information regarding this material will be provided once the participants are selected: please be aware that the online material will be required to be completed prior to attending the course

COURSE COMPLETION REQUIREMENTS:

To successfully complete this course and receive a course certificate with Continuing Education Units* (CEUs), each participant will be required to:

- Be on time and attend the entire course
- Participate in class discussions, exercises, workshops and presentations
- Pass the course assessment(s)

Course Assessments/Exam Policy*

As an authorized provider of Continuing Education Units accredited through the International Association for Continuing Education and Training (IACET), DHRD courses are required to have an assessment(s) component

(knowledge & application) to evaluate the effectiveness of the training presented and the participant's grasp of the material covered. Participants will receive only a pass/fail score. Minimum passing score is 75%.

SLOT ALLOCATIONS:

PAR: 5
CER: 5
SWR: 3

CFSAN: 1
NER: 2
STATE: 5

ORA HQ: 2
SER: 2

Please refer all state inquiries to: **FDA/OP** Nikki Wilson at MailboxStateTraining@fda.hhs.gov

DEADLINES / SPECIAL NOTICES:

Regional Training Officers, IA/International, DFSR, Training Contacts:

1. Please provide a copy of this announcement to each participant as soon as they are identified
2. All participant **registration forms** (Attachment A) must be forwarded via e-mail by **COB Jan 17, 2014** to Jody Robinson-Ng, Training Officer.

Course Participants:

Hotel Reservations by COB Feb 9, 2014, participants and instructors that will be in travel status must confirm their reservation at the **Raleigh Marriott Crabtree Valley**, room block: "FDA Aseptic Processing Course" (See **LODGING INFORMATION** below for additional information.)

Completed **Attachment A's** must be forwarded by **COB Jan 15, 2014**, via e-mail, as a Word attachment (Word Doc) to:

FDA: Your Regional Training Officer (RTO)

FDA/Centers: Your Center Training Contact

State: FDA/OP
Nikki Wilson at MailboxStateTraining@fda.hhs.gov for approval. All travel requests for this training course including cost estimates must be submitted via e-mail to Nikki Wilson and your assigned Contract Officer (OAGS). Travel is not authorized unless funds are approved and added to the contract via modification.

TRANSPORTATION:

Participants should fly into Raleigh/Durham International Airport (RDU) which is about 10 miles from the hotel

Airport Transportation

The hotel will a complimentary provide a shuttle to and from the airport. Additional details will be provided

- o Alternate transportation: SuperShuttle; fee: 20 USD (one way) ;reservation required
- o Estimated taxi fare: 25 USD (one way)

LODGING & COURSE LOCATION INFORMATION:

Raleigh Marriott Crabtree Valley(FEMA ID: NC0171)

4500 Marriott Drive

Raleigh, North Carolina 27612

Marriott Reservations at 1-800-228-9290, and ask the hotel by name, and the FDA Aseptic Processing Course Room Block group rate.

Check-in time: **3 PM** Checkout: **11 AM**

Lodging: \$96 + tax

M&IE: \$66

Reservations By: Feb 9, 2014

Your web page address is: [Book your group rate: FDA Aseptic Processing Course Room Block >>](#)

FDA participants **do not** make lodging reservations through GOV Trip. Please indicate the “FDA Aseptic Processing” room block code in your Gov Trip travel information.

Hotel Cancellation Policy: No later than 24 hours prior to your intended arrival date to avoid cancellation charges. If you cancel, please obtain a cancellation number from the hotel.

Internet Fee for Official Duties:

OFS requires preapproval for Internet Fee and must be included in the traveler’s Travel Authorization (TA). Internet Fee no longer can be claimed thru a local voucher.

DHRD will **not** reimburse Internet Fee for those travelers required to perform official duties for their office while attending a DHRD Training. The traveler’s office is responsible for this expense. A second line of accounting codes must be entered into the TA using the traveler’s office funding.

COURSE LOCATION:

NC State University
Department of Food Science-Schaub Hall
400 Dan Allen Dr.
Raleigh, NC 27607

Transportation to the University: University shuttles will transport attendees each morning from the hotel to the Department of Food Science and will return them to the hotel each afternoon. Specific information about this will be provided to the course attendees.

ACCOUNTING AND ADMINISTRATIVE INFORMATION

1. PLEASE NOTE: When a participant fails to confirm a hotel reservation by the deadline and cannot obtain lodging at the negotiated rate, any additional cost must be paid by the nominee’s district, unless the district obtains prior approval from DHRD. Approval requests should be forwarded to the Training Officer for a case by case review by DHRD management.
2. When accounting codes are released, the training officer will send a Travel Authorization Memo to ORA participants and FDA instructors.
3. Tax exempt forms can be found at <https://smartpay.gsa.gov/about-gsa-smartpay/tax-information/state-response-letter>
4. Rental cars are not authorized
5. Civilian dress is business casual as defined by your district.
6. Commissioned Corps Officers are required to be in uniform while attending training.
7. Temperature may vary in the conference room - please bring layers of appropriate clothing.
8. **Request & justification to stay an additional night** (if applicable): Requests need to be **submitted to your Regional Training Officer (RTO)** in advance via email **by the student’s supervisor**. One request can be provided for all students listed from the same District/Lab. Approval must be granted **prior** to the student traveling to the course and DHRD is unable to assist in reimbursement for “after the fact”. The RTO will forward requests to the DHRD Training Officer for review/approval.

The request is to include:

- (a) Reason/justification for request to address factors such as:
 - District policy indicating what is an “unreasonable hour” for travel (if citing undue hardship to the employee)
 - Available flight times (contract and non-contract)
 - Airports researched (if more than one in the area)
 - Any related cost comparison (non-contract fare vs. staying the extra night)

(b) Statement of supervisory concurrence

- If approved, your voucher needs to include a copy of the e-mail granting approval to stay the extra night

9. After the course, FDA participants should report their actual course time in the “Miscellaneous Operations Accomplishment Hours” screen in FACTS following all applicable guidance. The data entered should include the appropriate Operation Code {84 for participants} {83 for instructors} and PAC 03R800.

SPECIAL NEEDS:

FDA provides reasonable accommodations to employees with disabilities. If you need a reasonable accommodation for any part of the training process - due to medical conditions, physical limitations or particular learning challenges - please notify the Training Officer prior to the course. Reasonable accommodations will be granted on a case-by-case basis. For Voice TTY or other interpreting needs, please contact Interpreting Services at the following e-mail address: interpreting.services@oc.fda.gov.

/s/

Jody Robinson-Ng,
Training Officer, DHRD

Attachment for Participant Registration Information

Please submit the information as listed in the format and order below as a Word attachment (Word Doc) no later than **COB January 15, 2014** via e-mail to:

FDA/ORA: Your Regional Training Officer (RTO).

State: FDA/OP Nikki Wilson at MailboxStateTraining@fda.hhs.gov

List State/Local Agency: _____

**FD405 Aseptic Processing and Fill
Raleigh, NC
March 10 – 14, 2014**

Participant Registration Information
Participant's Legal Name:
Position/Title:
GS Series and Grade:
Agency/Organization/Division:
Duty Station (Complete Address with Mail Code):
Business Phone Number and Extension:
Fax Number:
E-mail address:
Supervisor's Name:
Supervisor's Phone Number:
Supervisor's Email:
Arrangements needed to accommodate special needs (if any):
Name and Phone Number to contact in case of emergency (optional):
Course Prerequisites;
1. Completion date of your new hire training curriculum FDA, Level I _____ State, Standard 2, Manufactured Food Regulatory Program Standards _____
2. FDA: Completion dates: Food and Drug Law: Evidence Development: Personal Safety, Verbal Judo or Investigative Interviewing:
3. Completion of FD150 and FD151 or FD180(please provide date and location):
4. Completion of FD152(Please provide date of training):
5. Completion of FD304 or FD203/FD103/FD1003
5. FEI numbers for required LACF Firms and dates of Inspection:
6. Name of Firm, FEI number and Date of Inspection for Aseptic Inspection: