DHRD Course Announcement v5 (25 APRIL 2013)

FROM: Constantine J. Markos, B.S., Pharm.D., R.Ph.
SENT: April 30, 2014
To: "ORA HQ DHRD Course Distribution List"

Subject: COURSE ANNOUNCEMENT: DG230 and DG330—ORA DHRD Drug Investigator Training Program—2 Face-to-Face courses

Please note: Participants register once for both face-to-face sessions (DG230 and DG330) and agree to complete all required web modules and field experience requirements as outlined in this course announcement. Please bring your FDA laptops with you to both sessions:

DATE: April 30, 2014

FROM: Constantine J. Markos, B.S., Pharm.D., R.Ph.
Training Officer, Division of Human Resource Development (HFC-60)

SUBJECT: COURSE ANNOUNCEMENT:

DG230--Systems-Based Drug Inspections
DHRD/ORA U
ROOM 110
11919 Rockville Pike
Rockville, MD. 20852
Begin: Monday, July 14, 2014 at 08:00 A.M.
End: Friday, July 25, 2014 at 12:00 P.M. NOON

DG330—Active Pharmaceutical, Pre-Approval and Sterile Drug Inspections
DHRD/ORA U
ROOM 110
11919 Rockville Pike
Rockville, MD. 20852
Begin: Monday, September 15, 2014 at 08:00 A.M.
End: Friday, September 26, 2014 at 12:00 P.M. NOON

Note: For participants who have completed a portion of the drug program prior to FY2013 see section in this course announcement titled "Transitioning from the previous drug training program."

About the new Drug Investigator Training Program

In response to the ACRA and ORA senior management requests to meet the needs of efficient spending, decreased travel time, streamlined training, and blended learning, we redesigned our Drug Investigator Training Program as outlined below.

The new ORA/DHRD Drug Investigator Training Program (Level II curriculum) would be completed after the new hire completes the basic New Hire training curriculum.

The new Drug Investigator Training Program provides new drug investigators with foundational knowledge, expert advice, and opportunities for practical experience. The blended-learning approach of the new Drug Investigator Training Program is designed to streamline learning, reduce time away on travel, and focus on performance-based training.

The list below provides a brief overview of program changes:

On-line learning – 31 foundational lessons in the areas of Systems inspections, API, Pre-Approval, Sterile drug inspections and risk management. Participants complete all lessons at their district prior to attending the face-to-face sessions.

Field experience – During the course of the program, participants observe 2 inspections led by an experienced investigator.

DG230--Systems-Based Drug Inspections – Face-to-Face classroom instruction. Combines topics in the old DG201-Basic Drug School and DG307-Process Validation, to introduce new investigators to the Systems-based approach to drug GMP inspections.

DG330--API, PAI, and Sterile Drug Inspections – Face-to-Face classroom instruction. Combines and streamlines topics from the old DG303-Active Pharmaceutical Ingredient Inspections, DG301-Pre-Approval Inspections, and MP302-Industrial Sterilization.

AUTHORIZED TRAVEL DATES:

DG230:
Arrival: Sunday, July 13, 2014
Departure: Friday, July 25, 2014 (schedule return flights **after 02:00 p.m.)**

DG330:
Arrival: Sunday, September 14, 2014
Departure: Friday, September 26, 2014 (schedule return flights **after 02:00 p.m.)**

Everyone is expected to return on the departure date unless there are extenuating circumstances (See Accounting & Admin. Info.)

PLEASE NOTE: The ORA DHRD Drug Investigator Training Program consists of 4 stages. All web module requirements and field experiences must be completed as listed below prior to each classroom session. Below is a summary of the program sequence.

DG230 – Systems-Based Drug Inspections		**DG330 – Active Pharmaceutical, Pre-Approval and Sterile Drug Inspections**	
Stage 1 **Web modules and field experience** Completed at participant's district prior to attending classroom instruction	**Stage 2** **Classroom instruction**	**Stage 3** **Web modules and field experience** Completed at participant's district prior to attending classroom instruction	**Stage 4** **Classroom instruction**
Web modules (22 total) For a list of web module titles, please go to the "Required Web Modules" section of this course announcement	DG230-Systems-Based Drug Inspections: face-to-face classroom instruction (2 weeks) Location and travel details provided in this course announcement	Web modules (9 total) For a list of web module titles, please go to the "Required Web Modules" section of this course announcement	DG330-Active Pharmaceutical, Pre-Approval, and Sterile Drug Inspections: face-to-face classroom instruction (2 weeks) Location and travel details provided in this course announcement
Field experience: Please go to "Program Completion Requirements" for a description of the field experience requirements.		Field experience: Please go to "Program Completion Requirements" for a description of the field experience requirements.	

Please review the "Program Completion Requirements" section of this course announcement carefully for detailed information on each stage of the program. Participants who register for the ORA DHRD Drug Investigator Training Program agree to complete all requirements as described in this course announcement.

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) (GovTrip, travel, and accounting code information)
4) Regional Training Officer (RTO) (cancellation, substitutions, hotel issues, pre-requisite waivers, special requests for additional overnight stay(s))
5) Constantine J. Markos, Training Officer (final POC if the RTO is unavailable)
   FDA/Division of Human Resource Development (DHRD)
   (301) 796-1475 Fax (301) 827-8708 E-mail:Constantine.Markos@FDA.HHS.GOV

COURSE DESCRIPTION/OBJECTIVES:
The Drug Investigator Training Program is designed to provide new drug investigators with a combination of foundational knowledge and practical experience in drug cGMP inspections. Participants complete a number of requirements that include web modules, face-to-face instruction, and participation in pharmaceutical inspections.

Objectives: Upon completion, participants will be able to:

1. Outline regulatory requirements, guidance and procedures associated with Systems-Based drug GMP inspections
2. Discuss how to conduct a Quality System inspection
3. Discuss how to conduct a Facilities and Equipment System inspection
4. Discuss how to conduct a Materials System inspection
5. Discuss how to conduct a Production System inspection
6. Discuss how to conduct a Packaging and Labeling inspection
7. Discuss how to conduct a Laboratory Controls System inspection
8. Discuss regulations, resources, and approaches associated with systems-based inspections, including automated systems, electronic data, and risk management
9. Explain how to prepare for an API inspection
10. Discuss regulatory expectations specific to API production and how they differ from finished dosage production
11. Describe common API production processes and equipment and how they may differ from finished dosage production
12. Outline an API inspectional approach
13. Identify possible deficiencies and other concerns associated with API production
14. Identify the critical elements of the Pre-Approval inspection process

15. Recognize the roles and responsibilities of field personnel and centers in the pre-approval inspection process

16. Recognize the significance of inspectional findings and how they relate to field recommendations of withhold or approve

17. Outline the principles of industrial sterilization, lyophilization, aseptic processes, removal of bacterial endotoxins, and supporting utilities

18. Identify equipment and applications of industrial sterilization processes, methods and validation

19. Apply the scientific principles of the processes of industrial sterilization, lyophilization, aseptic processes, removal of bacterial endotoxins, and the supporting utilities to an inspectional approach

Target Audience: This program is designed for FDA personnel who conduct or are planning to conduct pharmaceutical manufacturing inspections.

CEU: 7.1

PREREQUISITES:
Participants must have successfully completed the New Hire training prior to attending this program.

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

1. Complete all web modules and field experience requirements prior to the completion of each of the face-to-face sessions
2. Be on-time and attend all face-to-face sessions of the course
3. Participate in class discussions, exercises, workshops, presentations and assessments
4. Please bring your FDA laptops with you to both sessions

Please read all requirements carefully. By registering for the ORA DHRD Drug Investigator Training Program, participants agree to complete all requirements for each stage as listed below:

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

1. **Stage 1:**
   - Complete required web modules associated with DG230-Systems-Based Drug Inspections on ComplianceWire and HHS LMS (go to the "Required Web Modules" section of this course announcement for a list of all required web modules).

   - Observe 1 drug inspection (field experience). You may observe a drug inspection of any type. Complete and submit the Field experience worksheet form for DG230, available in the ORA DHRD Drug Training Curriculum on ComplianceWire.

2. **Stage 2:**
   - Attend DG230 – Systems-Based Drug Inspections (first of 2 face-to-face sessions)
   - Observe a second drug inspection (field experience). You may observe a drug inspection of any type. Complete and submit the Field experience worksheet form for DG330, available in the ORA DHRD Drug Training Curriculum on ComplianceWire.

   Please note: Please submit the completed field experience worksheet for DG330 (through ComplianceWire) no later than 2 weeks prior to the start of Stage 3, DG330. Participants who fail to complete all Stage 2 requirements will not receive travel accounting codes and will not be authorized to attend DG330.

3. **Stage 3:**
   - Complete required web modules associated with DG330-Active Pharmaceutical, Pre-Approval and Sterile Drug Inspections as listed on ComplianceWire (go to the "Required Web Modules" section of this course announcement for a list of all required web modules).

   - Submit drug inspection (field experience) worksheet for DG330. You may observe a drug inspection of any type. Complete and submit the Field experience worksheet form for DG330, available in the ORA DHRD Drug Training Curriculum on ComplianceWire.

4. **Stage 4:**
   - Attend DG330 - Active Pharmaceutical, Pre-Approval, and Sterile Drug Inspections (second of 2 face-to-face sessions).

   Please note: All Stage 1 requirements must be completed prior to completing the DG230 – Systems-Based Drug Inspections face-to-face session (Stage 2).

Required Web Modules
For your reference, below is a list of required web modules available on ComplianceWire and HHS LMS:

DG230
The following web modules should be completed prior to completing the face-to-face session of DG230-Systems-Based Drug Inspections. Web modules are located in ComplianceWire and HHS LMS (see instructions below the table on how to access ComplianceWire and the HHS LMS):

ComplianceWire

Knowledge Area	Course Title	Course Number
Introduction to Systems-Based Drug Inspections	*Systems-Based Drug Inspections*	FDA55
	Introduction to GMPs	PHA38
	Orientation to GMP Compliance	PHDV73
Quality System	*GMP Principles for Batch Records*	PHA60
	Batch Record Reviews	PHA53
	Change Control	PHA35
	Meeting GMP Training Requirements	PHDV76
Facilities and Equipment System	*Understanding GMPs for Facilities and Equipment*	PHDV63
	Maintenance and Cleaning of Drug Manufacturing Equipment	PHA44
	Implementing and Equipment Qualification Program	PHDV88
Materials System	*High Purity Water Systems*	PHDV82
	Care and Handling of Drug Product Components Containers and Closures	PHA41
	Principles of Cleaning Validation	PHA37
	Collecting Samples and Establishing Limits for Cleaning Validation	PHA54
Production System	*Understanding the Principles and Practices of Process Controls*	PHA47
	Computerized Systems Inspections in the Pharmaceutical Industry	ISPE03

	Requirements for Computer Systems Validation and Compliance	ISPE01
Packaging and Labeling System	*Packaging and Labeling of Finished Pharmaceuticals*	PHA39
Laboratory Controls System	*How to Meet Drug Retention and Stability Testing Requirements*	PHA43
	Application of GMPs to Microbiology Requirements	PHDV72
Investigational Approach /Regulatory	*Failure Investigations for Pharmaceutical Manufacturers*	PHA59

HHS LMS

Knowledge Area	Course Title	Course Number
GDUFA	*An Introduction to the Generic Drug Program and Generic Drug User Fee Amendments (GDUFA)*	DG110

DG330
Please complete the following web modules no later than September 1, 2014--at least 2 weeks prior to attending DG330-Active Pharmaceutical, Pre-Approval and Sterile Drug Inspections:

Knowledge Area	Course Title	Course Number
Active Pharmaceutical Ingredient Inspections	*GMPs for API Bulk Manufacturers*	PHA52
	ICH Q7A: Introduction and Quality Management	ISPE05
	ICH Q7A: Resources and Materials Management	ISPE06
Pre-Approval Inspections	*Pre- and Post-Approval Inspections*	PHDV66
	Understanding Post-Approval Changes	PHA49
Sterile Drug Inspections	*Principles of Sterilization*	PHDV81
	Principles of Aseptic Processing	PHDV71
Risk Management	*Risk Management 1: Key Concepts and Definitions*	FDA29
	Risk Management 2: Pharmaceutical GMPs for the 21st Century	FDA62

How to access the on-line curriculum and field experience worksheets on ComplianceWire:
To access the DHRD ORA U Drug Investigator On-line Training Program and field experience worksheets, please follow the instructions below:

1. Go to https://www.compliancewire.com/Secure/logon-cwire.asp
2. Sign in using your user name, password, and company code (please contact La'Wanda Giles for questions regarding your account).
3. On the left column, click "Catalog."
4. Scroll down and on the left column, click the plus sign to the right of "Curriculum."

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5. For DG230, click "Drug Training Program Curriculum for DG230" The content area will show the list of required on-line activities (22 web modules and 1 field experience worksheet).
6. For DG330, click "Drug Training Program Curriculum for DG330" The content area will show the list of required on-line activities (9 web modules and 1 field experience worksheet).
7. Click the on-line lesson or worksheet you wish to complete and follow the instructions as shown in the activity.

How to access HHS LMS:
The on-line module, An Introduction to the Generic Drug Program and Generic Drug User Fee Amendments (GDUFA) has been posted in the HHS LMS – FDA Commons and is ready for use.
Here is the deep link to the course. It will take the learner directly to the launch page (after AMS login):

https://lms.learning.hhs.gov/Saba/Web/Main/goto/GuestOfferingDetails?offeringId=dowbt00000000000020713

Transitioning from the previous Drug Training program
Participants who have completed a portion of the drug training program prior to FY2013 may complete requirements for the ORA DHRD Drug Investigator Training Program if they meet the criteria as follows:

If you completed:	**Your new requirements are:**
DG201-*Basic Drug School* AND DG307-*Process Validation for Drug Manufacturing Operations* BUT **Did *not* complete ALL of the following:** *DG301-Pre-Approval Inspections* *DG303-Active Pharmaceutical Ingredient Manufacturing Inspections* *MP302-Manufacturing Principles for Processing Sterile Medical Products (formerly titled Industrial Sterilization for Drugs and Devices)*	**Stage 3**: Web modules listed under DG330 and 2 field experiences as described under the "Program Completion Requirements" section of this course announcement **Stage 4:** DG330 - API, PAI and Sterile Drug Inspections face-to-face session (This means you do not need to attend Stage 2: DG230-*Systems-Based Drug Inspections* face-to-face session or complete the Stage 1 web modules associated with DG230). Please use the space provided in the Attachment A to document the dates you completed DG201 and DG307. Only participants who meet the criteria via transcript verification will be considered for this exception.

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 participants' grasp of the material covered. Participants are required to complete all required assignments and formative assessments, and participate fully in all activities to receive credit for the course. Participants will receive only a Pass/Fail score.

SLOT ALLOCATIONS:
RTOs will allocate slots to the Districts utilizing the ORA survey data:

NER- 9
CER- 8
SER- 7
SWR- 8
PAR- 9
HQ- 2
CDER-3
CVM- 1
States*- 3 (DFSR)

***NOTE**: Due to internal demand, 3 slots are allocated for state participants for this session. Please refer all state inquiries to:

FDA/ORA Regional Training Officer (RTO)
Regional and/or District Offices will refer any states contacting them about this training course to the Regional Training Officer. Regions and Districts cannot assign slots for these courses to a specific state without the approval of the Training Officer and concurrence of the RTO and/or DFSR (Wendy Campbell and Nikki Wilson). Funding for state employees to attend this course is to be provided by their state agency.

DEADLINES/SPECIAL NOTICES:
Regional Training Officers, { DFSR and Center *if appropriate* } Training Contacts:

1. Please provide a copy of this announcement to each participant as soon as they are identified.
2. **By COB June 6, 2014,** forward all participant names and registration information via e-mail to Constantine J. Markos**.**

Course Participants:

DG230-Systems-Based Drug Inspections	**DG330–Active Pharmaceutical, Pre-Approval and Sterile Drug Inspections**
1. **Hotel Reservations by COB June 16, 2014;** participants and instructors that will be in travel status must confirm their reservation at: Marriott Residence Inn Bethesda (301) 718-0200 Room block: "FDA Systems-Based Drug Inspections—DG230 July 2014"	2. **Hotel Reservations by COB August 18, 2014;** participants and instructors that will be in travel status must confirm their reservation at: Marriott Residence Inn Bethesda (301) 718-0200 Room block: "FDA Active Pharmaceutical, Pre-Approval, and Sterile Drug Inspections—DG330 September 2014"

Registration

Please note: For your convenience only 1 registration form (Attachment A) is required for both DG230 and DG330.

3. **By COB May 30, 2014,** complete the Attachment "A" and forward it via e-mail, **as a Word attachment** (Word Doc) to:

   FDA: Your Regional Training Officer (RTO) {*RTOs will forward info. to the Training Officer*}

   FDA/Centers: Your Center Training Contact {*CTCs will forward info. to the Training Officer*}

State: FDA/ORA Regional Training Officer (RTO)
Regional and/or District Offices will refer any states contacting them about this training course to the Regional Training Officer. Regions and Districts cannot assign slots for these courses to a specific state without the approval of the Training Officer and concurrence of the RTO and/or DFSR (Wendy Campbell or Nikki Wilson). Funding for state employees to attend this course is to be provided by their state agency.

(See LODGING INFORMATION below for additional information.)

TRANSPORTATION:

- Travelers must select an airport and flight that is most cost effective to the Government, in accordance with the Federal Travel Regulations.
  - Reagan Washington National (DCA)
  - Baltimore Washington International (BWI)
  - Dulles International Airport (IAD)

- Rental cars are **NOT authorized**.
- DC Metro: http://www.wmata.com/rail/
- Shuttles (need 24 hours notice):
  - Burki Limo 1-877-665-3292
  - Super Shuttle 1-800-258-3826
  - Barwood Taxi (301) 984-1900

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LODGING INFORMATION:

DG230 – Systems-Based Drug Inspections	**DG330 - Active Pharmaceutical, Pre-Approval and Sterile Drug Inspections**
The Residence Inn **Bethesda Downtown** Marriott Residence Inn Bethesda 7335 Wisconsin Avenue Bethesda, MD. 20814 **(301) 718-0200** **Room Block**: FDA Systems-Based Drug Inspections—DG230 July 2014 **Arrival:** Sunday, July 13, 2014 **Departure:** Friday, July 25, 2014 **Lodging:** $167.00 + tax **M&IE:** $71.00 **Reservations By:** June 16, 2014 **Check-in time**: 03:00 p.m. **Check-out time:** 12:00 p.m. noon	**The Residence Inn** **Bethesda Downtown** Marriott Residence Inn Bethesda 7335 Wisconsin Avenue Bethesda, MD. 20814 **(301) 718-0200** **Room Block**: FDA Active Pharmaceutical, Pre-Approval, and Sterile Drug Inspections—DG330 September 2014 **Arrival:** Sunday, September 14, 2014 **Departure:** Friday, September 26, 2014 **Lodging:** $219.00 + tax **M&IE:** $71.00 **Reservations By:** August 18, 2014 **Check-in time**: 03:00 p.m. **Check-out time:** 12:00 p.m. noon

FEMA ID #: MD0066

Hotel Cancellation Policy: No later than 72 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 pre-approval for Internet Fees and must be included in the traveler's Travel Authorization (TA). Internet Fees no longer can be claimed through a local voucher.

DHRD will **not** reimburse Internet Fees 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: You will need your Government ID to enter the building. Please allow enough time to get from the hotel to the building and through security prior to the start of class.

ORA U, Room 110
11919 Rockville Pike
Rockville, MD. 20852
(301) 796-4550

Metro: From the Bethesda Metro station, across the street from the hotel, take the red line train towards Shady Grove. Get off at White Flint Metro station and walk 2 city blocks north on Rockville Pike.

Parking at ORA U: Local participants and instructors are strongly encouraged to ride Metro, carpool, or use public transit since parking at ORA U is limited. Those commuting locally need to voucher parking expenses with their office (local voucher) except for ORA staff.

Instructors, CAG (Content Advisory Group) members, and those employees who car pool (2 or more) to ORA U may be granted permission to park at ORA U on a case-by-case basis pending availability and providing arrangements are made 2 weeks in advance with the DHRD course Training Officer. Please contact the Training Officer 2 weeks in advance to confirm arrangements and receive further instructions for parking.

Possible parking options for local participants and instructors who must drive to ORA U:

1. White Flint Metro station and use the pay-to-park lot. Reference the following link for more information: http://www.wmata.com/rail/parking/

2. Metrorail daily parking is available at the parking lot east of Rockville Pike on Marinelli Road.

ACCOUNTING AND ADMINISTRATIVE INFORMATION

- 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.
- Employees should stay at the designated hotel with the negotiated room block. Travelers must indicate in the "Trip Detail" section of the Travel Authorization that there is a "Hotel Reservation made through a Room Block detailed within the ORA U Course Announcement." If the employee chooses to stay at a different hotel, the employee will be responsible for any costs incurred above and beyond what the expenses would have been if the employee stayed at the hotel with the negotiated room block. Reimbursement will be made at the negotiated rate. If the employee does not use the room block, the employee must use GovTrip to book the hotel.
- When accounting codes are released approximately 4 weeks prior to the course, the Training Officer will send a Travel Authorization Memo to ORA participants and FDA instructors. *When we are* in a continuing resolution, the release of accounting codes may be as short as 2 weeks.
- Tax exempt forms can be found at (*OPM web link when forms are accepted in the state*)
- Rental cars are **NOT authorized.**
- Civilian dress is business casual as defined by your district.
- Commissioned Corps Officers are required to be in uniform while attending training.

- Prior to attending the course, the commissioned officer should contact CAPT Diann Shaffer (ORA Commissioned Corps Liaison) if unsure which uniform to wear on a scheduled plant tour. Temperature may vary in the conference room - please bring layers of appropriate clothing.
- Bring your FDA or other official Government issued identification for identity verification.
  - **Please note: Due to budget constraints, DHRD will no longer pay for UPS return shipment of student manuals, etc.**
- **Request & justification to stay an additional night** (if applicable): Requests need to be **submitted to your Regional Training Officer** (RTO) in advance via e-mail **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 then forward requests to the DHRD Training Officer for review/approval.

  The request is to include:
  1. 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 1 in the area)
     - Any related cost comparison (non-contract fare vs. staying the extra night)
  2. Statement of supervisory concurrence

  If approved, your voucher needs to include a copy of the e-mail granting approval to stay the extra night.
- 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 (see below):

  Op 83 – Training Given (for use by FDA course instructors)
  Op 84 – Training Received (for use by FDA participants)
  46R800 – NDA Pre-Approval courses
  56R800 – Drug courses (other than pre-approval)

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/
Constantine J. Markos, B.S., Pharm.D., R.Ph.
National Drug ProgramTraining Officer, DHRD
(301) 796-1475

Attachment A

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 May 30, 2014,** via e-mail to:

FDA/ORA: Your Regional Training Officer (RTO) {*RTOs will forward info. to the Training Officer*}
FDA/Centers: Your Center Training Contact {*CTCs will forward info. to the Training Officer*}

State:
FDA/ORA Regional Training Officer (RTO)
Regional and/or District Offices will refer any states contacting them about this training course to the Regional Training Officer. Regions and Districts cannot assign slots for these courses to a specific state without the approval of the Training Officer and concurrence of the RTO and/or DFSR (Wendy Campbell and Nikki Wilson). Funding for state employees to attend this course is to be provided by their state agency.

List State/Local Agency:_____
{*DFSR will forward selected state participant info. to the Training Officer and copy the RTOs*}

For your convenience, only 1 Attachment A is required for both face-to-face sessions:

DG230--Systems-Based Drug Inspections
ORA U, Rockville, MD. 20852
July 14, 2014—July 25, 2014

DG330--Active Pharmaceutical, Pre-Approval and Sterile Drug Inspections
ORA U, Rockville, MD. 20852
September 15, 2014—September 26, 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:
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 (including the audit) or 6-month district training program if hired prior to January 1, 2002 and not Level I_____ State: Basic Food Inspection Training Curriculum in Standard 2, Manufactured Food Regulatory Program Standards_____
2. Request for partial program attendance (only for participants who meet the criteria as described in the "Transitioning from the previous drug training program" portion of this course announcement.") Please list the drug program courses you attended prior to FY2013, as well as the dates of attendance, in the space provided below. Upon transcript verification, you will be notified if your request is approved.