Working Together: Learn How You Can Participate in FDA/Industry Training Partnerships

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Disclaimer

Information Disclaimer:

The information provided is only intended to be general summary information. It is not intended to take the place of either the written law or regulations.

Opinion Disclaimer:

The comments and opinions expressed are those solely of the presenter. They are not intended to take the place of either the written law or regulations

Where We have been and
What We have learned

CAPT Jane Marie Kreis, R.Ph., MBA

Training Officer

Getting Started

Pharmacist

Lessons Learned:

Communication

Critical Thinking

United States Public Health Service

Lessons Learned:

Clinical care

Scientific Research

Regulatory Service Tasks

Indian Health Service

Lessons Learned:

Clinical Care

Quality

Adult Learning

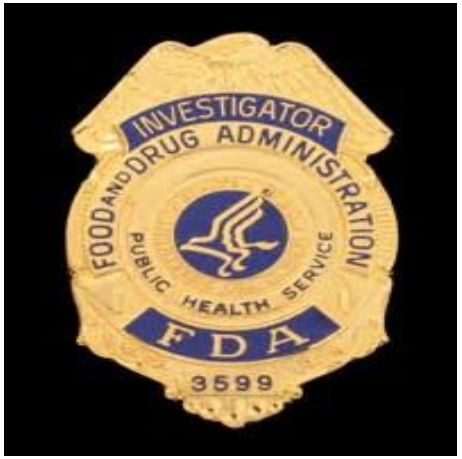
United States Food and Drug Association Office of Regulatory Affairs

Lessons Learned:

Regulatory

Protect the Public Health

Communication



Agenda

FDA/Industry Partnership Training

Future Partnerships

Question

True or False

Office of Regulatory Affairs (ORA) no longer has District Offices?

Answer: **False**

Reference

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ucm557997.htm

ORA Program Divisions

Effective May 15, 2017

Under ORA's new program-based management model, there are seven key programs for operations (Biological Products, Bioresearch Monitoring, Human and Animal Food, Medical Devices and Radiological Health, Pharmaceutical Quality, Tobacco and Imports).

Each program has a unique number of program divisions for a total of 28 operational divisions.

ORA Program Divisions

ORA's laboratories will also specialize and align into Human and Animal Food labs or Medical Product, Tobacco, and Specialty labs.

ORA's 20 districts are being retained and our district directors will continue to lead and manage the district overall, but are also aligned operationally within a single program.

ORA Program Divisions

The Fact Sheets will provide you with an overview of each office's responsibilities and functions.

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ucm557997.htm

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

A critical part of the commitment by CDER to make safe and effective high- quality drugs available to the American public is gaining an understanding of all aspects of a drug's development and commercial life cycle, including the variety of drug manufacturing operations.

To support this commitment, CDER has initiated various training and development programs including the FY2019 Experiential Learning Site Visit program.

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

This site visit program is designed to offer experiential and firsthand learning opportunities that will provide OPQ staff with a better understanding of the pharmaceutical industry and its operations, as well as the challenges that impact a drug's developmental program and commercial life cycle. The goal of these visits is to enhance OPQ staff exposure to the drug development and manufacturing processes in industry; therefore, a tour of pharmaceutical company facilities including manufacturing and laboratory operations, is an integral part of the experience.

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

In this site visit program, groups on average of 15 to 20 OPQ staff—who have experience in a variety of backgrounds, including science, medicine, statistics, manufacturing, engineering, testing, and project management—will observe operations of commercial manufacturing, pilot plants (if applicable), and testing over a 1- to 2- day period.

To facilitate the learning process for OPQ staff, overview presentations by industry related to drug development, manufacturing and testing may be included.

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

OPQ encourages companies engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to respond.

Please note that this site visit program is not intended to supplement or replace a regulatory inspection, *e.g.,* a preapproval inspection, prelicense inspection, or a surveillance inspection.

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

OPQ staff participating in this program will benefit by gaining a better understanding of current industry practices, processes, and procedures.

Participating sites will have an opportunity to showcase their technologies and their actual manufacturing and testing facilities.

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

Although observation of all aspects of drug development and production would be beneficial to OPQ staff, OPQ has identified a number of areas of particular interest to its staff.

The following list identifies some examples of these areas but is not intended to be exhaustive, mutually exclusive, or to limit industry response:

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

Drug products

- Solutions, suspensions, emulsions, and semisolids
- Modified- and immediate-release formulations
- Drug-device combination products (*e.g.,* inhalation products, transdermal systems, implants intended for drug delivery, and prefilled syringes)

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

Active pharmaceutical ingredients manufactured by

- Chemical synthesis
- Fermentation
- Biotechnology

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

Design, development, manufacturing and controls

- Engineering controls for aseptic processes
- Novel delivery technologies
- Hot melt extrusion
- Soft-gel encapsulation
- Lyophilization
- Blow-Fill-Seal and isolators
- Spray-drying
- Process analytical technology, measurement systems, and real-time release testing

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

Emerging technologies

- Continuous manufacturing
- 3-dimensional printing
- Nanotechnology

Site Visit Training Program for Office of Pharmaceutical Quality (OPQ) Staff

All travel expenses associated with this program will be the responsibility of OPQ; therefore, selection will be based on the availability of funds and resources for the fiscal year.

OPQ will not provide financial compensation to the pharmaceutical site as part of this program.

Site Visit Training Program for Office of Pharmaceutical Quality Staff

Federal Register Notice: 83 FR 18305, August 24, 2018

https://www.gpo.gov/fdsys/pkg/FR-2018-08-24/pdf/2018-18305.pdf

Center for Devices and Radiological Health: Experiential Learning Program

This training is intended to provide CDRH and other FDA staff with an opportunity to understand laboratory practices, quality system management, patient perspective/input, and challenges that impact the medical device development life cycle.

The purpose of the FR document is to invite medical device industry, academia, and health care facilities, and others to participate in this formal training program for CDRH and other FDA staff, or to contact CDRH for more information regarding the ELP.

Center for Devices and Radiological Health: Experiential Learning Program

In the ELP training program, groups of CDRH and other FDA staff will observe operations in the areas of research, device development, Digital Health, incorporating patient information and reimbursement, manufacturing, quality management principles, and health care facilities.

The areas of interest for visits include various topics identified by managers at CDRH and other areas within FDA.

These areas of interest are listed on the ELP website and are intended to be updated quarterly.

Center for Devices and Radiological Health: Experiential Learning Program

https://www.fda.gov/science-research/fda-science-jobs-and-scientific-professional-development/cdrhs-experiential-learning-program

Program Specifics

FDA staff (experienced in science, statistics, manufacturing, engineering, and testing) will observe operations of commercial manufacturing, pilot plants, and testing

Visit will last 1-2 days

Industry can showcase their technology by explaining the drug development and manufacturing processes for drug products and drug substances

Caveat

These formal training visits are not intended for FDA to inspect, assess, judge, or perform a regulatory function (*e.g.,* compliance inspection), but rather, they are an opportunity to provide FDA review and inspectional staff a better understanding of the products they review, how they are developed, the voice of the patient, challenges related to quality systems development and management in the product life cycle, and how these products fit into the larger health care system

Areas of Interest

Drug products and active pharmaceutical ingredients

Solutions, suspensions, emulsions, and semisolids

Sustained, modified, and immediate release formulations

Areas of Interest

- Drug-device combination products, particularly inhalation, transdermal, iontophoretic, and implant formulations
- Biotechnology products
- Design, development, manufacturing, and controls
- Engineering controls for aseptic formulations
- Unique delivery technologies
- Hot melt extrusion processes
- Soft-gel encapsulation processes

Areas of Interest

- Lyophilization processes
- Blow-Fill-Seal and isolator
- Spray-drying processes
- Process analytical technology
- Real time release testing
- Emerging technologies
- Continuous manufacturing
- 3-dimensional printing
- Nanotechnology

Procedure

Companies interested in offering a site visit or learning more about this site visit program should respond by submitting a proposal

To aid in site selection, your proposal should include the following information:

- A contact person
- Site visit location(s)
- Facility Establishment Identifier and DUNS numbers, as applicable
- Maximum number of FDA staff that can be accommodated during a site visit, and
- A sample agenda outlining the proposed learning objectives and associated activities for the site visit

Site Visit Training Program for Office of Regulatory Affairs (ORA)

Active Pharmaceutical Biotechnology

Tour of

- Manufacturing
- Production
- Facilities
- Warehouse
- Laboratory

Site Visit Training Program for Office of Regulatory Affairs (ORA)

Personalized Immunotherapy

Tour of

- Manufacturing
- Production
- Facilities
- Warehouse
- Laboratory

Site Visit Training Program for Office of Regulatory Affairs (ORA)

Active Pharmaceutical Ingredient Powder

Tour of

- Manufacturing
- Production
- Warehousing
- Laboratory
- Facilities

Site Visit Training Program for Office of Regulatory Affairs (ORA)

Drug Substance Biotechnology

Tour of

- Manufacturing
- Production
- Warehousing
- Laboratory
- Facilities

Site Visit Training Program for Office of Regulatory Affairs (ORA)

Sterile Biotechnology

Tour of

- Manufacturing
- Production
- Warehousing
- Laboratory
- Facilities

Site Visit Training Program for Office of Regulatory Affairs (ORA)

Solid Dosage Forms

Tour of

- Liquid manufacturing
- Solid dose manufacturing
- Packaging
- High containment area for highly toxic/potent drugs
- Laboratory operations

Site Visit Training Program for Office of Regulatory Affairs (ORA)

Lessons Learned:

- New equipment/technology design and capabilities presented
- Observation of firm's high quality culture
- Review of various visual management tools throughout the facility
- Q&A opportunities
  - FDA Subject Matter Experts
  - Firm's management

Task

Form groups of 5 people

Briefly introduce yourself:

- State your name, title, and number of years at your organization
- Role as it relaters to training – state all that apply (trainer, trainee, specifications developer for training)

Task

Form groups of 5 people

Roles

- Person whose last name is closest to A is the chair
- Person whose last name is closest to Z is the scribe

Interactive Activity

Discuss advantages of FDA Partnership Training

Discuss disadvantages of FDA Partnership Training

Advantages Industry

Investigators process knowledge can lead to shorter inspection time for voluntary participating companies

Qualified training site-name recognition

Better understanding of compliance expectations

Protect Public Health

Advantages FDA

Provide technical training to investigators, analysts, supervisors and compliance officers

Update on new and novel technologies in food, feed, medical products, cosmetics, and tobacco for investigators, analysts, supervisors and compliance officers

Protect Public Health

Disadvantages Industry

Concern about regulatory actions

Budget

Resource allocation

Production interruption

Disadvantages FDA

Budget

Workplan

Question

True or False

FDA is receptive to partnering with industry and foreign governments to provide training for FDA employees.

Answer: **True**

Reference:

Federal Register Notice: 83 FR 36608, July 30, 2018

https://www.federalregister.gov/documents/2018/07/30/2018-16177/center-for-devices-and-radiological-health-experiential-learning-program

Federal Register Notice: 83 FR 18305, August 24, 2018

https://www.gpo.gov/fdsys/pkg/FR-2018-08-24/pdf/2018-18305.pdf

Answer: **True**

Reference:

GMP Tea

Society of Clinical Research Associates

Import Brokers Association

UC Davis Western Institute for Food Safety and Security

North Carolina State University and Biomanufacturing

Office of Training and Education Courses

Answer: **True**

Reference:

To fulfill its mission to monitor and ensure the safety of the supply chain for food, feed, medical products, cosmetics, and tobacco products that enter the United States from other parts of the world, the FDA engages in partnerships with foreign governments, regulatory coalitions, development organizations, academic institutions, among others.

https://www.fda.gov/internationalprograms/partnerships/default.htm

Question

True or False

FDA has an extensive array of online courses to train industry personnel about how FDA regulates pharmaceuticals and medical devices. Some of these classes are complimentary and for other industry need to pay a fee.

Answer: **False**

References:

CDER World

https://www.accessdata.fda.gov/scripts/cderworld/

Information for Industry (Drugs)

https://www.fda.gov/Drugs/ResourcesForYou/Industry/default.htm

CDERLearn

https://www.fda.gov/Training/ForHealthProfessionals/default.htm

CDRHLearn

https://www.fda.gov/Training/CDRHLearn/default.htm

Investigator Resources

IOM
https://www.fda.gov/iceci/inspections/iom/default.htm

Compliance Program Guidance

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/compliance-program-guidance-manual-cpgm

Discussion- Q & A

Thank You!

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