DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6286]

Site Visit Training Program for Office of Pharmaceutical Quality Staff; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) in the Food and Drug Administration (FDA) is announcing the 2018 CDER Office of Pharmaceutical Quality (OPQ) Staff Experiential Learning Site Visit Program. The purpose of this document is to invite pharmaceutical companies interested in participating in this program to submit a site visit proposal to CDER's OPQ.

DATES: Submit either an electronic or written proposal to participate in this program by February 2, 2018. See section IV of this document for information on what to include in such proposals.

FOR FURTHER INFORMATION CONTACT: Janet Wilson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4642, Silver Spring, MD 20993–0002, 240–402–3969, email: *CDEROPQSiteVisits@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

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 drug development and the drug's commercial life cycle, including the variety of drug manufacturing operations. To support this commitment, CDER has initiated various training and development programs including the 2018 Experiential Learning Site Visit Program. 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 provide OPQ staff exposure to the drug development and manufacturing processes in industry; therefore, a tour of pharmaceutical company facilities in operational status is an integral part of the experience.

II. The Site Visit Program

In this site visit program, groups on average of 15 to 20 OPQ staff—who have experience in a variety of backgrounds, including science, medical, statistics, manufacturing, engineering, and testing—will observe operations of commercial manufacturing, pilot plants, and testing operations over a 1- to 2-day period. To facilitate the learning process for OPQ staff, overview presentations by industry related to drug development and manufacturing may be provided, which may allow the participating sites to benefit by having an opportunity to showcase their technologies and manufacturing processes.

OPQ encourages companies engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to respond. However, please note that this site visit program is not intended to supplement or replace a regulatory inspection, *e.g.,* a preapproval inspection, pre-license inspection, or a surveillance inspection. OPQ staff participating in this program will benefit by gaining a better understanding of current industry practices, processes, and procedures.

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:

- Drug products:
  - Solutions, suspensions, emulsions, and semisolids;
  - modified- and immediate-release formulations; and
  - drug-device combination products (*e.g.,* inhalation products, transdermal products,implants intended for drug delivery, and pre-filled syringes).
- Active pharmaceutical ingredients manufactured by:
  - Chemical synthesis;
  - fermentation; and
  - biotechnology
- 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; and
  - process analytical technology, measurement systems, and real time release testing.
- Emerging technologies:
  - Continuous manufacturing;
  - 3-dimensional printing; and
  - nanotechnology.

III. Site Selection

Selection of potential facilities will be based on the priorities developed for OPQ staff training, the facility's current compliance status with FDA, and consultation with the appropriate FDA district office. 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.

IV. Proposals for Participation

Companies interested in offering a site visit or learning more about this site visit program should respond by submitting a proposal directly to Janet Wilson (see **FOR FURTHER INFORMATION CONTACT**). To aid in OPQ's site selection and planning, your proposal should include the following information:

- A contact person;
- site visit location(s);
- Facility Establishment Identifier and Data Universal Numbering System numbers, as applicable;
- maximum number of FDA staff that can be accommodated during a site visit (maximum of 20);
- a sample agenda outlining the proposed learning objectives and associated activities for the site visit;
- number of visits (no more than two) your site would be willing to host by the close of the government fiscal year, September 30, 2018; and
- months the site is operational that would be ideal for a site visit.

Proposals submitted without this minimum information will not be considered. Based on response rate and type of responses, OPQ may or may not consider alternative pathways to meeting our training goals.

Dated: November 29, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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