DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3030]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) is announcing an invitation for participation in the Fiscal Year (FY) 2020 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 electronic or written proposals for participation in this program by November 18, 2019. See **SUPPLEMENTARY INFORMATION** for information on what to include in such proposals.

ADDRESSES: If your facility is interested in offering a site visit, submit either an electronic proposal to *CDEROPQSiteVisits@fda.hhs.gov* or a written proposal to 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.

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 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 FY2020 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 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.

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, 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.

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, pre-license inspection, or a surveillance inspection.

The 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 actual manufacturing and testing facilities.

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
  - Drug-device combination products (*e.g.,* inhalation products, transdermal systems, implants intended for drug delivery, and pre-filled syringes)
- Active pharmaceutical ingredients
  - Made entirely by chemical synthesis
  - Derived from a biological source (*e.g.,* fermentation, mammalian cell culture)
- 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
- Emerging technologies
  - Continuous manufacturing
  - 3-dimensional printing
  - 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 in 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 **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**). To aid in OPQ's site selection and planning, your proposal should include the following information:

- A contact person
- The site visit location or locations
- A Facility Establishment Identifier (FEI) and any applicable Data Universal Numbering System (DUNS) numbers
- The maximum number of FDA staff that can be accommodated during a site visit (maximum of 20)
- A proposed agenda outlining the learning objectives and associated activities for the site visit
- The maximum number of site visits (no more than two) that your site would be willing to host by the close of the government fiscal year (September 30, 2020)
- The proposed dates for each site visit

Please note that the requested proposed agenda will be reviewed to determine the educational benefit to OPQ in conducting the visit, and selected sites may be asked to refine the

agenda to maximize the educational benefit. After a site is selected, OPQ will communicate with the contact person for the site to determine the actual dates for the 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: October 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0444]

Health Canada and United States Food and Drug Administration Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a regional public meeting entitled ''Health Canada and U.S. Food and Drug Administration Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).'' The purpose of the public meeting is to provide information and solicit public input on the current activities of the ICH, as well as the upcoming ICH Assembly Meeting and the Expert Working Group Meetings in Singapore scheduled for November 16 through November 20, 2019. The topics to be addressed at the public meeting are the current ICH guideline topics under development that will be discussed at the forthcoming ICH Assembly Meeting in Singapore.

DATES: The public meeting will be held on Monday, November 4, 2019, from 1 p.m. to 4 p.m. Submit either electronic or written comments on this public meeting by Friday, November 8, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at Sir Frederick G. Banting Research Centre, 251 Sir Frederick Banting Dr., Ottawa, ON K1Y 0M1, Canada. The meeting will also be broadcast on the web, allowing participants to join in person OR via the web.

You may submit comments as follows. Please note that late, untimely, filed comments will not be considered. Electronic comments must be submitted on or before November 8, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time on November 8, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed in the sections below (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–0444 for ''Health Canada and U.S. Food and Drug Administration Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.