4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1003]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing the 2018 Experiential Learning Program (ELP). 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 this 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.

DATES: Submit electronic proposals for participation in the ELP within the dates provided at the ELP website at:

https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

ADDRESSES: For access to the docket to read background documents, 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.

FOR FURTHER INFORMATION CONTACT: Christian Hussong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5261, Silver Spring, MD 20993-0002, 240-402-2246, Christian.Hussong@fda.hhs.gov or ELP Management, ELP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Additionally, CDRH assures patients and providers have timely and continued access to high-quality, safe, and effective medical devices. Since CDRH has identified Partnering with Patients and Promoting a Culture of Quality and Organizational Excellence as strategic priorities, for the 2018 ELP, our goal is to specifically understand the perspective of our stakeholders and understand implementation of these topics within their institutions. The Center encourages applicants to consider including opportunities to discuss patient perspective and incorporating quality system design and management in their proposals as they contribute to the success of the device development life cycle.

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH and other FDA staff with an opportunity to understand the laboratory and manufacturing practices, quality system management, patient perspective/input, and other challenges and how they impact the medical device development life cycle. ELP is a collaborative effort to enhance communication with our stakeholders to facilitate medical device reviews. The Center is committed to understanding current industry practices,

innovative technologies, regulatory impacts and needs, and how patient perspective and quality systems management advances the development and evaluation of medical devices, and to monitor the performance of marketed devices.

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 CDRH and other FDA 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 medical devices fit into the larger health care system. CDRH is formally requesting participation from industry, academia, and clinical facilities, medical device incubators and accelerators, health technology assessment groups, and those that have previously participated in the ELP or other FDA site visit programs.

Additional information regarding the CDRH ELP, including the table of areas of interest, submission dates, a sample request, and an example of the site visit agenda, is available on CDRH's website at:

https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

II. CDRH ELP

A. Areas of Interest

In the ELP training program, groups of CDRH and other FDA staff will observe operations in the areas of research, device development, in making coverage decisions and assessments, incorporating patient information and reimbursement, manufacturing, 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.

To submit a proposal addressing one of the Center's training needs, visit the link for the table of areas of interest at: https://www.fda.gov/ScienceResearch/ScienceCareerOpportunities/UCM380676.htm. Once you have determined an area of interest to address in your ELP proposal, follow the instructions in section III to complete the site visit request template and agenda provided at: https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf and at: https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM487190.pdf.

Submit all proposals at ELP@fda.hhs.gov within the dates provided at the ELP website at: https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

B. Site Selection

CDRH and FDA will be responsible for its own staff travel expenses associated with the site visits. CDRH and FDA will not provide funds to support the training provided by the site to the ELP. Selection of potential facilities will be based on CDRH and FDA's priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding (if applicable). If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history, and must be listed in the proposal along with a Facility Establishment Identifier number, if applicable.

III. Request to Participate

Information regarding the CDRH ELP, including a sample request and an example of a site visit agenda, and submission dates is available on CDRH's website at:

https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm. Proposals to participate should be submitted to ELP@fda.hhs.gov, within the dates provided, at the ELP website at https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

Date: October 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-22626 Filed: 10/17/2017 8:45 am; Publication Date: 10/18/2017]