4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0338]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing an invitation for participation in its Experiential Learning Program (ELP). The ELP provides a formal training mechanism for regulatory review staff to visit research, clinical, manufacturing, and health care facilities to observe firsthand how medical devices are designed, developed, and utilized. This training is intended to provide CDRH staff with an opportunity to observe the device development life cycle and provide a better understanding of the medical devices they review and the challenges faced throughout development, testing, manufacturing, and clinical use. The purpose of this document is to invite medical device industry, academia, and health care facilities to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the program.

DATES: Submit either an electronic or written request for participation in this program by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The request should include a description of your facility relative to product areas regulated by CDRH. Please include the Area of Interest (see table 1or 2) that the site visit will demonstrate to CDRH staff, a contact person, site visit location, length of site visit, proposed

dates, and maximum number of CDRH staff that can be accommodated during a site visit. Submitted proposals without this information will not be considered. In addition, please include an agenda outlining the proposed training for the site visit. A sample request and agenda are available on the ELP Web site: http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf and http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

ADDRESSES: Submit either electronic requests to http://www.regulations.gov or written requests to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Latonya Powell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4448, Silver Spring, MD 20993-0002, 301-796-6965, FAX: 301-827-3079, Latonya.powell@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH launched the ELP Pilot in 2012 and fully implemented the program (78 FR 19711, April 2, 2013) in 2013. The Center is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to high-quality, safe, and effective medical devices and safe radiation-emitting products. In support of this mission, the Center launched various training and development initiatives to enhance performance of its staff involved in regulatory review and in the premarket review process. 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. This program is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, and regulatory impacts and needs.

These formal training visits are not a mechanism for FDA to inspect, assess, judge, or perform a regulatory function (i.e., compliance inspection), but rather, are an opportunity to provide the CDRH review staff a better understanding of the products they review. Through this notice, CDRH is formally requesting participation from companies; academia; and clinical facilities, including those that have previously participated in the ELP; other FDA site visit programs; and new interested parties.

II. ELP

A. Experiential Learning Program

In this program, groups of CDRH staff will observe operations of medical device establishments, including research, manufacturing, academia, and health care facilities. The areas of focus and specific areas of interest for visits may include the following:

Table 1.--Areas of Interest--Medical Devices/Technology

Focus Area	Specific Areas of Interest
Advanced simulation testing of mechanical ventilators	Performance testing of closed loop controlled ventilators using advanced physiologic simulation and computational modeling of the system (patient, ventilator, and sensor)
Assisted reproductive technology (ART) clinic setting	Structure and organization of an ART clinic; understanding the necessary specifications for ART devices (incubators, microscopes, media, micromanipulation, assisted reproduction lasers, and lab ware); cleaning and disinfection of reprocessed instruments in the ART clinic; aseptic techniques used in ART clinic.
Clinical use of orthopedic bone void filler devices	Observation of surgical procedures (posterolateral spine fusion, foot, ankle) utilizing bone void fillers

Focus Area	Specific Areas of Interest
Clinical use of physical medicine devices	Rehabilitation hospitals and programs; devices for treatment of pain (transcutaneous electrical nerve stimulator, diathermy), devices for muscle rehabilitation (powered muscle stimulators), devices intended to help restore function to patients (prosthetic limbs, functional electrical stimulators, orthoses)
Design and development of ablation devices, including electrosurgical units and accessories, electrosurgical/ultrasonic devices, microwave ablation devices	Tumor ablation devices
Electrophysiology (EP) catheters for diagnostic (mapping) and therapeutic (ablation) indications	Observe manufacturing and testing of EP devices, with inclusion of design verification and returned product testing, as available
Emerging manufacturing methods for orthopedic devices	3D printing, rapid manufacturing
Endosseous implants	Computer Aided Design/Computer Aided Manufacturers produced elements, titanium bases, and various software programs utilized for forming abutments
Hemodialysis devices used in the home environment	Home hemodialysis training program, hemodialysis machines, "wetness" detectors, hemodialysis blood access devices, water treatment
Interface between the brain thought processes and the movement of medical devices to assist mobility	Brain-computer interface manufacturer or laboratory
Intraocular lenses (IOLs) and injectors	Development and manufacture of IOLs and injectors
Manufacturing of polymeric sealants	Vascular surgical sealants
Refractive lasers	Manufacturing; preclinical testing; femtosecond lasers
Robotic surgery	Manufacturing of robotic surgical devices

Table 2.--Areas of Interest--In Vitro Diagnostic and Radiological Devices/Technology

Focus Area	Specific Areas of Interest
Artificial pancreas related devices	Manufacturing of continuous glucose monitoring devices and insulin pumps
Manufacturing of different types of human antibodies for the use of immunoassays	Manufacturing of antibodies (monoclonal and polyclonal) for immunoassay tests
Coagulation point of care and home use devices	Coagulation devices for point of care and home use (COUMADIN self-monitoring) utilizing whole blood and/or citrated plasma
Immunohistochemistry for the diagnostic evaluation for cancer	Immunohistochemistry as an important tool in biomarkers detection and clinical practice
Systems capable of running multiple analytes composed of a specimen collection and processing unit at satellite locations and data transmittal to a central location for analysis and quality control oversight	Systems maintaining quality oversight of data generated at a distant location and transmitted digitally to another location for analysis
Antimicrobial resistance detection and characterization	Observation and hands-on experience with reference methods and assays for phenotypic and non-phenotypic-based methods for determining antimicrobial resistance
Diagnostic x-ray imaging devices	Site visits to user facilities
Next generation sequencing/single-nucleotide polymorphism (SNP) arrays and clinical genomics	Next generation sequencing and/or SNP array devices in the clinical laboratory setting for molecular diagnostics used

B. Site Selection

CDRH will be responsible for all CDRH staff travel expenses associated with the site visits. CDRH cannot provide funds to support the proposed training provided by the applicants to this program. Selection of potential facilities will be based on CDRH'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 a site visit involves a visit to a separate physical location of another firm under contract to the applicant, that firm must agree to participate in the program and must also have a satisfactory compliance history.

III. Request for Participation

Identify requests for participation with the docket number found in the brackets in the heading of this document. Received requests may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-09916 Filed 04/30/2014 at 8:45 am; Publication Date: 05/01/2014]