4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0986]

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 the 2015 Experiential Learning Program (ELP). This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities to apply to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the ELP.

DATES: Submit either an electronic or written request for participation in the ELP by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The proposal should include a description of your facility relative to focus areas described in tables 1or 2). Please include the Area of Interest (see tables 1or 2) that the site visit will demonstrate to CDRH staff, a contact person, site visit location(s), length of site visit, proposed dates, and maximum number of CDRH staff that can be accommodated during a site visit. Proposals

submitted without this minimum 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 at 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 proposals 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. 32, rm. 5232, Silver Spring, MD 20993-0002, 301-796-6965, FAX: 301-827-3079, Latonya.powell@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH 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. 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. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (78 FR 19711). 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 staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. This is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, regulatory impacts, and regulatory needs.

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 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 or other FDA site visit programs.

II. ELP

A. ELP Training Component

In this training program, groups of CDRH staff will observe operations at research, manufacturing, academia, and health care facilities. The focus areas 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
Failure analysis of orthopedic devices	Methods for retrieval and preservation of failed implants for analysis; understanding how retrieved implants may be analyzed; methods for identifying failure modes; understanding how analysis of failed implants influences device design modifications
Radiologic analysis of orthopedic devices	Methods of radiologic analysis and associated data analyses; radiologic imaging core laboratories
Automated external defibrillators (AEDs)	Manufacturing process; incoming component inspection; design verification testing; human factors testing; returned product testing (as available)
Diagnostic imaging catheters for cardiovascular diseases	Manufacturing process; design verification testing; returned product testing (as available); ultrasound, optical coherence tomography (OCT), and near infrared spectroscopy (NIS) catheters

Focus Area	Specific Areas of Interest
Endovascular grafts for treatment of aortic aneurysms	Physician-sponsored clinical studies; observation of endovascular grafting surgical procedure; surgical planning process; factors that influence device modifications (e.g., patient anatomy, patient pathology)
Animal models for evaluation of hemostatic devices	Models of traumatic injury and severe hemorrhage; limitations of the model; understanding the relevance of the data generated from these models in evaluating hemostatic devices
Hyaluronic acid in dermal tissue fillers	Manufacturing process; source materials; performance testing (e.g., material characterization, biocompatibility, residence time)
Minimally invasive glaucoma surgery (MIGS) devices	Observation of a MIGS procedure; surgical planning; surgical challenges
Neurointerventional devices	Stents, flow-diverters, mesh balls, coils, and other related devices; observation of surgical procedures; understanding of clinical decision making for relevant patient populations; manufacturing; performance testing
Implantable functional electrical stimulation devices	Observation of implantation procedure; surgical challenges
Male condoms	Manufacturing process; lot release testing (e.g., airburst, water leak, dimensional analysis)
Solid organ preservation devices	Observation of organ preservation procedures; pulsatile perfusion (for either cold storage or normothermia)
Infusion pumps	Manufacturing process; device design considerations; patch pumps; insulin pumps; implantable infusion pumps; implantable ports
Bone grafting materials for dental applications	Manufacturing process; sourcing process; viral inactivation testing; animal testing

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

Focus Area	Specific Areas of Interest
Manufacturing of glucose test strips and meters	Observation of the manufacturing and in-process and finished device testing of glucose monitoring devices
Manufacturing of continuous glucose monitoring systems and insulin pumps	Observation of the manufacturing and in-process and finished device testing of glucose monitors and insulin pumps
Manufacturing of chemistry devices	Observation of the manufacturing and in-process and finished device testing of point of care chemistry cassettes/cartridges/strips for smaller chemistry analyzers used in clinical and point of care settings
Manufacturing of chemistry reagent, controls and calibrators	Observation of the manufacturing and in-process and finished device testing of chemistry reagents, calibrators, and controls for common chemistry analytes used in a clinical laboratory setting
Manufacturing of urine test strips and readers	Manufacturing and observation of in process or finished device testing for urine test strips and meters in clinical laboratory and point of care testing settings
Manufacturing and development of IHC (immunohistochemistry) devices	Observation of manufacturing, in-process testing, and/or finished device testing of IHC devices (used in the diagnostic evaluation of cancer, classification of tumors, or companion diagnostic testing)
Manufacturing and development of ISH (in situ hybridization) devices	Observation of the manufacturing, in-process testing, or finished device testing of colorimetric in situ hybridization (CISH) and/or fluorescent in situ hybridization (FISH)

Focus Area	Specific Areas of Interest
	assays used in identifying specific nucleic acid sequences within tissue sections (for diagnostic and/or treatment decisions)
Manufacturing and development of NGS (next gen sequencing) platforms and devices	Observation of NGS sequencing platforms, bioinformatic analysis of the resulting sequence information, and types of interpretative software for potential clinical purposes
Manufacturing, development and observation of CTC (circulating tumor cells) devices	Observation of the manufacturing, in-process testing, or finished device testing of CTC devices that assess the prognosis of patients with metastatic breast, colorectal, or prostate cancer (manufacturing site or research site or clinical setting)
Manufacturing, development and/or observation of clinical mass spectrometers and high performance liquid chromatography (HPLC) devices	Observe the manufacturing, development and/or demonstration of clinical mass spectrometers and HPLC as part of laboratory workflow including sample preparation, equipment usage, and data analysis
Manufacturing, development and research of flow cytometry devices and components	Manufacturing, research, and development of in-process testing, or finished device testing of cytometry analyzers and accompanying components
Manufacturing of immunoassays for autoimmune diseases	Manufacturing and development of in-process testing, or finished device testing, for diagnostic evaluation and research
Manufacturing and development of coagulation--point of care devices	Manufacturing and development of in-process or finished device testing for point of care devices such as Prothrombin Time and International Normalized Ratio (PT/INR) meters
Manufacturing and product development of global hemostasis testing devices	Manufacturing of global hemostasis testing for anti-coagulants and anti-platelet drugs for new molecular targets to assess the level of drug-induced inhibition for qualitative and quantitative evaluation
Manufacturing and product development of direct anticoagulants assays/controls/calibrators	Manufacturing and development of assays, controls, and calibrators for the detection of direct anticoagulants
Observation of testing of sequencing technologies in large sequencing centers	Visit a sequencing center where various sequencing methods are used for different applications other than in vitro diagnostic devices (IVD) manufacturing
Manufacturing, and product evaluation of IVDs using next generation sequencing (NGS) technology	Visit a manufacturer of IVD designed for sequencing of microorganisms for identification purposes
Clinical applications-NGS in practice	Visit a clinical laboratory that uses NGS as a diagnostic/screening tool
Antimicrobial susceptibility testing (AST)	Visit to a manufacturer of antimicrobial susceptibility test platforms intended for use in clinical laboratory settings
Antimicrobial susceptibility testing (AST)	Visit to a clinical laboratory that employs various AST methodologies for identification of antibiotic resistance

B. Site Selection

CDRH will be responsible for CDRH staff travel expenses associated with the site visits. CDRH will not provide funds to support the training provided by the site to this ELP. 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 with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history.

III. Request for Participation

Submit proposals 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 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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