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's (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 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 CDRH regulates. Please include the Area of Interest/Medical Device or Technology (identified in table 1or 2) that the visit will demonstrate to CDRH staff.

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:

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SUPPLEMENTARY INFORMATION:

I. Background

CDRH launched the ELP Pilot in 2012 and will fully implement the program 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 safe, effective, high-quality 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 regulatory review staff and other staff involved in the premarket review process. CDRH is driven to advance regulatory science; provide industry with

predictable, consistent, transparent, and efficient regulatory pathways; and assure 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. This request includes those that have previously participated in the ELP or other FDA Site Visit programs, as well as 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
Performance validation and reliability testing of intensive care unit ventilator and anesthesia gas machines	Ventilators, continuous positive airway pressure devices, anesthesia gas machines, and closed-loop ventilators

Focus Area	Specific Areas of Interest
Implantation techniques for spinal devices	Implantation training and assessment using cadavers and direct observation of surgical procedures for spinal implants including, but not limited to, lateral intervertebral body fusion devices, minimally invasive pedicle screw systems, and spinous process plates
Manufacturing of ultra-high molecular weight polyethylene device components	All joint replacement devices
Clinical use of orthopedic bone void filler devices	Observation of surgical procedures (posterolateral spine fusion, foot, ankle) utilizing bone void fillers
Reprocessing methods and techniques in the clinical environment	Cleaning and sterilization methods and techniques for endoscopes (including colonoscopes, duodenoscopes, cystoscopes, etc.) and accessories; automatic endoscope reprocessors
Bariatric surgery	Observation of bariatric surgical techniques, with and without bariatric devices
Manufacturing and assessment of hemodialyzers and filters	Hemodialyzers, hemofilters, hemoconcentrators, ultrafilters, and plasma filters
Sourcing and manufacturing of animal-derived collagen	Surgical meshes, wound dressings
Traumatic wound care, management, and treatment	Observation of clinical uses of wound management/treatment devices and hemostatic products for use on traumatic injuries
Clinical use of plastic and reconstructive devices	Observation of surgical procedures utilizing surgical meshes, dermal fillers, hemostatic agents, and bone waxes
Treatment of acute ischemic stroke	Clot retrieval procedures, clot retrieval devices and ancillary products (medications, angiograms), stroke centers, and acute stroke care programs
Clinical use of neurosurgical monitoring devices	Neuro-evoked response devices that are used for real-time monitoring of patients undergoing a back procedure
Clinical use of rehabilitation devices	Clinical use of physical medicine devices (prostheses, pressure-relieving seat cushions, tilt-in-space wheelchairs, and devices for pain relief) in a rehabilitation center setting for treatment of various conditions (e.g., spinal cord injuries, traumatic brain injuries, and amputations)

Focus Area	Specific Areas of Interest
Clinical use of cardiovascular devices	Endovascular stent grafts and associated delivery systems; Stents and associated delivery systems
Manufacturing of cardiovascular devices	Drug coated devices (e.g., stents and balloons), endovascular stent grafts and associated delivery systems, stents and associated delivery systems, percutaneous heart valves
Animal testing for chronic care cardiovascular devices	Observation of surgical procedures and chronic care maintenance in animal models using chronic care cardiovascular devices, such as heart valves and ventricular assist devices
Manufacturing of contact lenses and care products	All contact lenses and care products
Treatment of severe hearing loss	Surgical implantation of cochlear implants, electro-acoustic stimulation using hybrid cochlear implants, preservation of residual hearing, postoperative evaluation of residual hearing and implant performance
Auditory brainstem implants (ABIs)	Observation of ABI surgical procedures
Management of clinical trials for medical devices	Understanding clinical trial infrastructure, roles/responsibilities of your organization, and relationships with other organizations involved in the management and conduct of clinical trials; institutional review boards; clinical research organizations

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

Focus Area	Specific Areas of Interest
Manufacturing and development of molecular/immunology devices	Molecular diagnostics devices, and companion diagnostics devices
Manufacturing, development, and assessment of cytology/pathology devices	Semiautomated cytology screening devices; cytology collection devices use in human papillomavirus tests; immunohistochemistry tests development in clinical trials
Manufacturing of microbiology devices	Antimicrobial susceptibility devices
Manufacturing of chemistry devices	Clinical Laboratory Improvement Amendments (CLIA) waived devices, blood collection tubes,

Focus Area	Specific Areas of Interest
	fecal occult blood devices
Manufacturing and development of hematology devices	Hematology analyzers (specific interest in new technology)
Manufacturing and development of coagulation devices	Coagulation assays and controls, platelet aggregatometers devices, prothrombin time /international normalized ratio meters and assays, D-Dimer analyzers and assays
Observation of clinical testing in a CLIA high complexity laboratory	Observation of testing in a clinical testing environment.

B. Site Selection

CDRH will be responsible for all travel expenses associated with the site visits. Therefore, selection of potential facilities will be based on the coordination of CDRH's priorities for staff training and the resources available for 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 are available for public examination in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

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