4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1088]

Center for Devices and Radiological Health: Experiential Learning Program; General Training 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 a new component of the Experiential Learning Program (ELP) identified as the ELP General Training Program. 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 General Training Program.

DATES: Submit either an electronic or written request for participation in the ELP General Training Program by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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. 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 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. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (see 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 General Training Program 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. This component 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 a mechanism 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 General Training Program

A. ELP General 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: Office of Device Evaluation

Focus Area	Specific Areas of Interest
Biocompatibility testing	Decisionmaking process for biocompatibility test selection; considerations for use of animal testing vs. in vitro testing; sample preparation of nanoscale, bioabsorbable, and in situ polymerized materials; evaluation of color additives.
Combination products	Devices coated with drug(s); drug delivery products.
Emerging manufacturing methods	3-D printing; additive manufacturing; additional or unique validation and verification activities.
Management of clinical trials for medical devices	Understanding clinical trial infrastructure, roles, responsibilities, and relationships with other organizations involved in the management and conduct of clinical trials; challenges encountered in obtaining regulatory approval and successfully executing a clinical trial; issues related to early feasibility studies; institutional review boards; clinical research organizations.
Reprocessing and sterilization	Reprocessing challenges in the manufacturing or clinical environment; validation of reprocessing or sterilization instructions; simulated use testing; unique sterilization methods (e.g., use of flexible bags, sound waves, ultraviolet light, microwave radiation.)

Table 2.--Areas of Interest: Office of In Vitro Diagnostic Devices and Radiological Health

Focus Area	Specific Areas of Interest
Manufacturing of in vitro diagnostic devices	Preanalytical devices (i.e. blood tubes), pathogen collection devices, micro collection/transport devices; general reagents, manual reagents; general assays, common point-of-care devices.
Instrument training of medical devices (manufacturer or clinical laboratory)	Hands-on instrument and system training; clinical implication of common laboratory testing.
Quality system in manufacturing environments based on 21 CFR part 820	Observation of implemented quality systems practices based on current good manufacturing practices.

B. Site Selection

The Center 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 the ELP General Training 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 with the site, that firm must agree to participate in the ELP General Training program 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, and will be posted to the docket at http://www.regulations.gov.

The proposal should include a description of your facility relative to focus areas described in table 1or 2. 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(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.

Dated: July 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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