



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 2017 Experiential Learning Program (ELP). This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, patient perspective/input, quality system management, and other challenges that impact the 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's employees, or to contact CDRH for more information regarding the ELP.

DATES: Submit either electronic or written requests for participation in the ELP by dates specified in the ELP Web site at:

<http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

ADDRESSES: Submit either electronic requests to <https://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 requests with the docket number found in brackets in the heading of this document.

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.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for helping to ensure 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. For 2016-2017, CDRH has identified Partnering with Patients and Promoting a Culture of Quality and Organizational Excellence as strategic priorities, specifically having the perspective of our stakeholders and understanding implementation of these within their institutions would provide great insight to FDA review staff. The Center encourages applicants to consider including opportunities to discuss patient perspective and meeting the challenges of quality systems design and management 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 staff with an opportunity to understand the policies, laboratory and manufacturing practices, and the challenges addressing patient perspective/input, quality system management, and other challenges that impact the device development life cycle. This component is a collaborative effort to enhance communication and facilitate the premarket review process. 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 innovative devices, and to monitoring 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 review 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 companies, academia, and clinical facilities, medical device incubators and accelerators, health insurers, health technology assessment groups, and others, including those that have previously participated in the ELP or other FDA site visit programs.

CDRH encourages applicants to consider including opportunities to discuss how patient perspective and effective quality systems management contribute to the success of the device development life cycle. Additional information regarding the CDRH ELP, including the table of areas of interest, submission dates and deadlines, a sample request, and an example of the site visit agenda, is available on CDRH's Web site at:

<http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>. The Center encourages applicants to consider including opportunities to discuss patient perspective and meeting the challenges of Quality Systems Design and Management as they contribute to the success of the device development life cycle.

## II. CDRH ELP

### A. Areas of Interest

In this training program, groups of CDRH staff will observe operations in the areas of research, device development, in making coverage decisions and assessments, incorporating patient information and reimbursement, manufacturing, academia, and health care facilities. The areas of interest for visits include various topics identified by managers at CDRH. These areas of interest are listed publicly 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 to be addressed at:

<http://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 properly fill out the site visit request template and agenda provided at:

<http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf>

and at:

<http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM487190.pdf>.

### 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 the 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 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 (FEI #) if applicable.

### III. Request to Participate

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.

Additional information regarding the CDRH ELP, including a sample request and an example of a site visit agenda and submission deadlines, is available on CDRH's Web site at: <http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

Dated: March 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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