4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Medical Devices--Quality Systems Survival: Success Strategies for Production and Process Controls/Corrective and Preventative Action; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Office, in co-sponsorship with the FDA Medical Device Industry Coalition, Inc. (FMDIC), is announcing a public workshop entitled "Medical Devices--Quality Systems Survival: Success Strategies for Production and Process Controls/Corrective and Preventative Action". The public workshop is intended to seek input from representatives of medical device manufacturers and other stakeholders, on best practices, what has worked for them and what FDA can do to inspire quality efforts. This event will also focus on various topics of interest for those industry representatives who are responsible to insure compliance with FDA regulations.

DATES: The meeting will be held on April 15, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at Courtyard and TownePlace Suites by Marriott, DFW Airport North/Grapevine, 2200 Bass Pro Ct., Grapevine, TX 76051. Directions and lodging information are available at the FMDIC, Inc. Web site at http://www.fmdic.org/.

FOR FURTHER INFORMATION CONTACT: Staci McAllister, Consumer Safety Technician, Food and Drug Administration, 4040 N. Central Expressway, Suite 300, Dallas, TX 75204, 214-253-5259, FAX: 214-253-5314, staci.mcallister@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. This workshop helps achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121) as an outreach activity by Government agencies to small businesses.

The goal of the public workshop is to present information that will enable manufacturers and regulated industry to better comply with FDA's medical device requirements. Please visit the http://www.fmdic.org/ Web site for the agenda and for information about the presenters at the workshop.

II. Participation in the Public Workshop

Registration: FMDIC has early registration ($250 for industry /$150 for government with ID/$50 for students) available until March 14, 2016. Registration after March 14, 2016, increases to $300 for industry, $200 for government with ID, with student registration staying the same, at $50. To register online, please visit http://www.fmdic.org/. As an alternative, send the registration information including the registrant's name, title, organization, address, telephone and fax numbers, and email address (for each registrant), along with a check or money order (covering all registration fees) payable to the FMDIC, Inc., to FMDIC Registrar, 4447 N. Central Expressway, Suite 110 PMB197, Dallas, TX 75205. FMDIC, Inc. accepts registrations onsite on the day of the event beginning at 7:30 a.m. at the regular registration fee stated above.

Registration on site will be accepted on a space available basis on the day of the public workshop beginning at 7:30 a.m. Please note that due to popularity, similar past events have reached maximum capacity well before the day of the event. The cost of registration at the site is $300 payable to the FMDIC, Inc. The registration fee will be used to offset expenses of hosting the event, including continental breakfast, lunch, audiovisual equipment, venue, materials, and other logistics associated with this event.

If you need special accommodations due to a disability, please contact Staci McAllister (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop.

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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