

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2009-N-0664]

Medical Device Quality System Regulation Educational Forum on Risk Management Through the Product Life Cycle; Public Workshop**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office (DALDO), in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Medical Device Quality System Regulation Educational Forum on Risk Management through the Product Life Cycle." This public workshop is intended to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses.

Date and Time: The public workshop will be held on April 2, 2010, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the new Cowboy Stadium in Irving, TX. Directions to the facility are available at the FMDIC Web site at <http://www.fmdic.org/>.

Contact Person: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, e-mail: david.arvelo@fda.hhs.gov.

Registration: FMDIC has a \$250 early registration fee. Discounts for full-time students and government employees with valid identification are available. Early registration ends March 19, 2010. Registration is \$300 thereafter. For more information on fees and/or to register online, please visit <http://www.fmdic.org/>. As an alternative, you may send registration information including name, title, firm name, address, telephone and fax numbers, and e-mail, along with a check or money order for the appropriate amount payable to the FMDIC, to William Hyman, Texas A&M University, Department of Biomedical Engineering, 3120 TAMU, College Station, TX 75843-3120. Registration on site will be accepted on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$300 payable to the FMDIC. The registration fee will be

used to offset expenses of hosting the event, including food, venue, and equipment.

If you need special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 21 days in advance.

Transcripts: Transcripts of this event will not be available due to the format of this workshop. Digital event handouts will be posted online at <http://www.fmdic.org/> or may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm.12A-16, Rockville, MD 20857, after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: 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 is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the medical device QSR. The following topics will be discussed at the workshop: (1) Standards and guidance, (2) risk management in design, (3) risk management in execution, and (4) risk management and post market surveillance.

Dated: December 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Statement of Organization, Functions and Delegations of Authority**

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 74 FR 48089-48090 dated September 21, 2009).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice establishes the Office of Special Health Affairs (RA1) and the Office of Planning, Analysis and Evaluation (RA5) within the Office of the Administrator; transfers the functions and renames the Office of Minority Health and Health Disparities (RA9) and the Office of International Health Affairs (RAH) to the Office of Special Health Affairs (RA1); establishes the Office of Strategic Priorities (RA13) within the Office of Special Health Affairs (RA1); renames the Office of Equal Opportunity and Civil Rights (RA2); abolishes the Office of Health Information Technology (RT) and moves the functions to the Office of Planning, Analysis and Evaluation (RA5), the Office of Rural Health Policy (RH) and the Bureau of Primary Health Care (RC); and updates the functional statement for the Healthcare Systems Bureau (RR), the Bureau of Health Professions (RP), and the Office of Operations (RB).

Chapter RA—Office of the Administrator*Section RA-10, Organization*

Delete in its entirety and replace with the following:

The Office of the Administrator (RA) is headed by the Administrator, Health Resources and Services Administration, who reports directly to the Secretary. The OA includes the following components:

- (1) Immediate Office of the Administrator (RA);
- (2) Office of Equal Opportunity, Civil Rights, and Diversity Management (RA2);
- (3) Office of Planning, Analysis, and Evaluation (RA5);
- (4) Office of Communications (RA6);
- (5) Office of Special Health Affairs (RA1); and
- (6) Office of Legislation (RAE).