

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

Quality System Regulation Educational Forum on Design Controls; 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 Region, Dallas District Office, in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Quality System Regulation Educational Forum on Design Controls." 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 4, 2008, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Omni Mandalay Hotel at Las Colinas, 221 East Las Colinas Blvd., Dallas (Irving), TX 75039. 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. Early registration ends March 21, 2008. Registration is \$350 thereafter. 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 Dr. William Hyman, Texas A&M University, Department of Biomedical Engineering, 3120 TAMU, College Station, TX 75843-3120. Registration onsite 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 \$350 payable to the FMDIC. The registration fee will be used to offset expenses of hosting the event, including meals, refreshments, meeting rooms, and materials.

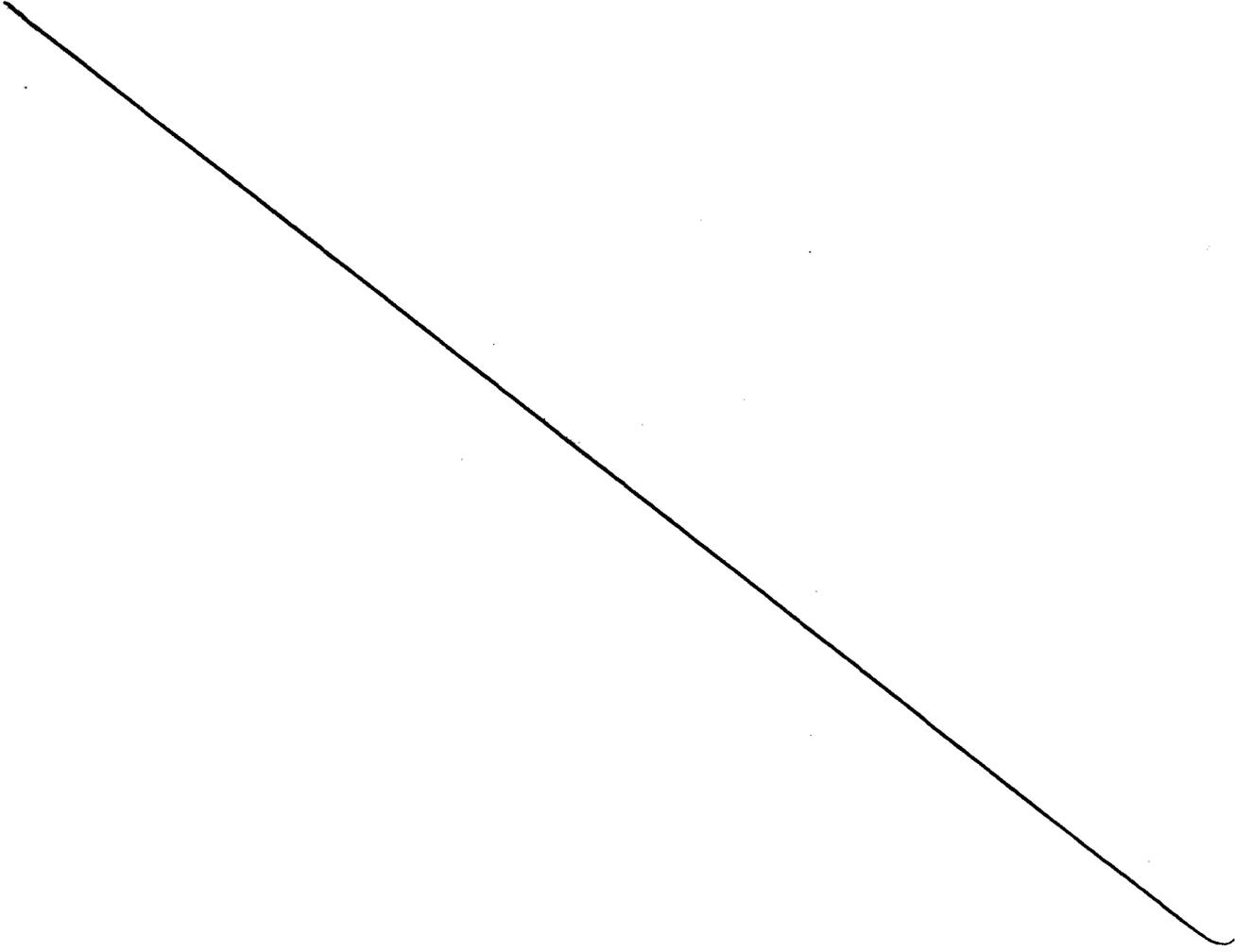
If you need special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 21 days in advance.

Transcripts: Transcripts of this event will not be available due to the format of this workshop. Event handouts may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days 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. FMDIC and FDA present this workshop to help 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) Planning design controls, (2) design inputs and outputs, (3) design validation and verification, (4) design transfer and change, (5) control of suppliers, (6) design history file, and (7) how design controls relate to corrective and preventive action, change control, and risk management.



Dated: OCT 4 2007
October 4, 2007.

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Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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Dawn P. Hawkins