



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Global Quality Systems--An Integrated Approach to Improving Medical Product Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District Office, in cosponsorship with the Association of Food and Drug Officials (AFDO), is announcing a public workshop entitled “Global Quality Systems--An Integrated Approach to Improving Medical Product Safety.” This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

DATES: The public workshop will be held on June 10 and 11, 2013, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Louisville Marriott Downtown, 280 West Jefferson St., Louisville, KY, 502-627-5045 or toll-free 800-533-0127;

<http://www.marriottlouisville.com/>.

Attendees are responsible for their own accommodations. To make reservations at the Louisville Marriott Downtown, at the reduced conference rate, contact the Louisville Marriott Downtown before May 2, 2013, and cite meeting code “AFDO Conference.”

FOR FURTHER INFORMATION CONTACT:

Krystal Reed,

Association of Food and Drug Officials,

2550 Kingston Rd., suite 311,

York, PA 17402,

717-757-2888,

FAX: 717-650-3650,

email: kreed@afdo.org.

SUPPLEMENTARY INFORMATION:

Registration: You are encouraged to register by May 14, 2013. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration is as follows:

Cost of Registration	
Member	\$450.00
Non-Member	\$550.00
To be added to registration fee for registration postmarked after May 14, 2013	\$100.00

If you need special accommodations due to a disability, please contact Krystal Reed (see FOR FURTHER INFORMATION CONTACT) at least 21 days in advance of the workshop.

Registration instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to “AFDO.” Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register online, please visit <http://www.afdo.org/conference>. (FDA has verified the

Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at 717-757-2888, FAX: 717-650-3650, or email: afdo@afdo.org

The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include the following:

- Future of Combination Product Regulation
- Unique Device Identifier Progress
- Health Canada Update
- The Safety of our Drugs and Devices--the Complex Reality
- Nanotechnology
- Drug and Medical Device Trends
- Case for Quality (Center for Devices and Radiological Health) Presented by Steve Silverman
- Working Luncheon Interactive Session--Lessons Learned From the Mistakes of Others
- Complaint Handling--It's Not Just About Compliance--It's an Effective Business Driver
- FDA's Cosmetic Regulatory Agenda
- Challenges With Implementation of U.S.P. 35 on a Global Basis
- Pilot Program for Abbreviated Drug Inspections

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government Agencies to small businesses.

Dated: February 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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