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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration/International Society for Pharmaceutical Engineering Cosponsorship Educational Workshop: Redefining the 'C' in CGMP: Creating, Implementing, and Sustaining a Culture of Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) Center for Drug Evaluation and Research, in cosponsorship with the International Society for Pharmaceutical Engineering (ISPE), is planning a multiday, educational public workshop entitled "Redefining the 'C' in CGMP: Creating, Implementing, and Sustaining a Culture of Compliance."

Date and Time: The public workshop will be held on June 4, 2012, 9 a.m. to 5 p.m. and June 5, 2012, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Renaissance Baltimore Harborplace Hotel, 202 E. Pratt St., Baltimore, MD 21202, 1-800-535-1201.

Contact Persons: FDA Contact: Rhonda Hill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4341, Silver Spring, MD 20993, 301-796-3267, rhonda.hill@fda.hhs.gov.

ISPE Contact: Julianne Rill, Continuing Education Program Manager, 600 N. Westshore Blvd., suite 900, Tampa, FL 33609; Web site: http://www.ispe.org/2012-gmp-conference; email: jrill@ispe.org. (FDA has verified the Web site address in this announcement but we are

not responsible for any subsequent changes to the Web site in this announcement after this document publishes in the Federal Register.)

Accommodations: Attendees are responsible for their own accommodations. Please mention ISPE/FDA Conference to receive the hotel room rate of $195.00 plus applicable taxes (available until May 7, 2012, or until the ISPE room block is filled).

If you need special accommodations due to a disability, please contact ISPE (see Contact Persons) at least 7 days in advance of the meeting.

Registration: The ISPE registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted for the workshop will receive confirmation. Registration will close after the workshop is filled.

Cost of Registration

ISPE member	$1,695
ISPE nonmember (includes membership)	$2,035
Federal Government	$750
FDA Planning Committee members and invited speakers	Fee Waived

Please visit ISPE's Web site to confirm the prevailing registration fees.

To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to "ISPE." To register via the Internet, go to http://www.ispe.org/2012-gmp-conference. The registrar will accept payment by major credit card (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact ISPE (see Contact Persons).

SUPPLEMENTARY INFORMATION: The workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated drug manufacturing operations with information on a number of topics concerning FDA requirements and expectations related to current good manufacturing practice (CGMP). The joint public workshop offers the opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ strategies to manufacture high quality drugs in their daily processes. Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices. Topics for discussion include the following: (1) The Business Case For Change; (2) Quality Risk Management--When, What, and How; (3) Sustaining Compliance Consistency Throughout Your Company and Supplier Network; (4) IT Strategies--Cloud Computing, RFID, and Beyond; (5) The Future of Drug Manufacturing.

To help ensure the quality of FDA regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (Public Law 105-115), 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: May 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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