4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Food and Drug Administration/Xavier University PharmaLink Conference--Quality in a Global Supply Chain

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University PharmaLink Conference." The PharmaLink conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA, and includes presentations from key FDA officials, global regulators, and industry experts. Each presentation challenges the status quo and conventional wisdom of our industry to create synergies focused on finding solutions which make a difference. Every discussion, exploration, and solution is framed by the goal of delivering increased patient health and safety through topics such as a working session with the Office of the Commissioner on the implementation of the FDA Safety and Innovation Act, Business Impact of Outsourcing, Supplier Management Models that Work, Implementing Quality by Design (QbD) Successfully--like other industries, lunch with global regulators (FDA, Medicines and Healthcare products Regulatory Agency (MHRA), Fimea, and Swissmedic), and many more. The experience level of our audience has fostered engaged dialog that has led to innovative initiatives.

DATES: The public conference will be held on March 12, 2013, from 8:30 a.m. to 5 p.m.; March 13, 2013, from 8:30 a.m. to 5 p.m.; and March 14, 2013, from 8:30 a.m. to 12:45 p.m.

ADDRESSES: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice:

Steven Eastham,

Office of Regulatory Affairs,

Food and Drug Administration,

Cincinnati South Office,

36 East 7th Street, suite 1910,

Cincinnati, OH 45202, 513-246-4134,

email: steven.eastham@fda.hhs.gov.

For information regarding the conference and registration:

Marla Phillips,

Xavier University,

3800 Victory Pkwy.,

Cincinnati, OH 45207,

513-745-3073,

email: phillipsm4@xavier.edu.

SUPPLEMENTARY INFORMATION:

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2 1/2

days of the conference. Advanced registration rate ends February 18, 2013. Standard registration rates begin on February 19, 2013. There will also be onsite registration. The cost of registration is as follows:

Table 1.--Registration Fees[1]

Attendee Type	Fee Jan. 23-Feb. 18	Fee After Feb. 18
Industry	$1,295	$1,495
Small Business (<100 employees)	$900	$1,000
Consultants	$600	$700
Startup Manufacturer	$250	$300
Academic	$250	$300
Media	Free	Free
Government	Free	Free

[1]The fourth registration from the same company is free--all four attendees must register at the same time.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the "Registration" link on the conference Web site at http://www.XavierPharmaLink.com. 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.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Susan Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH 45202, 513-421-9100. To make reservations online, please visit the "Venue & Logistics" link at

http://www.XavierPharmaLink.com. The hotel is expected to sell out during this timeframe, so early reservation in the conference room block is encouraged.

If you need special accommodations due to a disability, please contact Marla Phillips (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the conference.

The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will engage those involved in FDA-regulated global supply chain quality and management through the following topics:

- Beyond our Borders--Maximizing the Impact of FDA's Global Interactions
- MHRA, Fimea, and Swissmedic--Driving Safety and Innovation
- Food and Drug Administration Safety and Innovation Act--Be Part of the Solution, and How do we Measure the Effectiveness of the Resulting Change
- Track and Trace in a Global Market
- How do we Gain Greater Supply Chain Visibility?
- Supplier Management Models that Work
- Implementing QbD like Other Industries--Proven Success
- How to Avoid Drug Shortages in your Company
- Pfizer Business Model: Quantitating Culture
- Outsourcing: Business Impact
- FDA, MHRA, and Fimea Inspection Trends and Expectations

The conference includes:

- Lunch with the Regulators--Facilitated, Interactive Session
- Networking by Topic

- Case Studies
- Small Group Discussions
- Innovation Session Engaging the Audience
- Keynote Dinner at the Cincinnati Art Museum with Chairman, CEO, and President of Eli Lilly and Chairman of the Board of PhRMA--John Lechleiter

The most pressing challenges of the global pharmaceutical industry require solutions which are inspired by collaboration to ensure the ongoing health and safety of our patients. These challenges include designing products with the patient in mind, building quality into the product from the onset, selecting the right suppliers, and considering total product life-cycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing our jobs right the first time.

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 conference 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 conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) by providing outreach activities by Government Agencies to small businesses.

Dated: February 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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