4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Food and Drug Administration/Xavier University PharmaLink Conference--Leadership 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: Leadership in a Global Supply Chain." 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 to create synergies focused on finding solutions which make a difference. The experience level of the audience has fostered engaged dialog that has led to innovative initiatives.

Dates and Times: The public conference will be held on March 25, 2015, from 8:30 a.m. to 5 p.m.; March 26, 2015, from 8:30 a.m. to 5 p.m.; and March 27, 2015, from 8:30 a.m. to 12:45 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3020.

Contact Persons: For information regarding this notice: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East 7th Street, 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 45207-5471, 513-745-3073, email: phillipsm4@xavier.edu.

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 ½ days of the conference. There will be onsite registration. The cost of registration is as follows:

Table 1.--Registration Fees[1]

Attendee Type	Early Rate (on or before 1/24/15)	Advanced Rate (1/25/15 to 2/24/15)	Standard Rate (after 2/24/15)
Industry	$1,295	$1,695	$1,895
Small Business (<100 employees)	$995	$1,195	$1,295
Startup Manufacturer	$200	$250	$300
Academic	$200	$250	$300
Media	Free	Free	Free
Government	Free	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: Mason Rick, 3800 Victory Pkwy., Cincinnati, OH 45207-5471. 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 sellout 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 Contact Persons) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: 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:

- Major Changes at FDA Affecting You
- FDA-Driven Initiatives through Food and Drug Administration Safety and Innovation Act Implementation
- Held at the Border? Understand Why
- Toyota Production System--Cultural Requirements
- Barriers to Quality and Supply Chain Excellence
- Establishing Good Supply Practices
- Medicines and Healthcare Products Regulatory Agency Perspective on Global Supply Chain Challenges
- Systematic Approach to Managing Your Global Supply Chain
- Deep Dive Lunch Session--Clinically Relevant Metrics
- Deep Dive Lunch Session--Data Integrity: How to Verify You Are Okay

- Deep Dive Lunch Session--Integrity of Supply Workshop
- Nobel Prize-Based Alignment Optimization
- Quality Metrics Beyond Compliance to Drive Strategic Value
- Risk Categorization of Your Company
- Challenges that Lie Outside U.S. Borders
- Global Supply Chain Risk Management Case Studies
- FDA Investigator Insights

The conference includes:

- Networking by topic
- Case studies
- Small group discussions
- Action plans
- Keynote dinner at the Newport Aquarium

The most pressing challenges of the global pharmaceutical industry require solutions which are inspired by collaboration to ensure the ongoing health and safety of 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 lifecycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing the job 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 (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 (Pub. L. 104-121) by providing outreach activities by Government Agencies to small businesses.

Dated: January 21, 2015.

Leslie Kux,

Associate Comissioner for Policy.

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