

Register Today

Registration

www.XavierGOC.com

or call Sue Bensman, 513-745-3396

Special advanced rates through August 1, 2011

Industry	\$995
Small Business	\$800
Consultants	\$500
Start-Up Manufacturers	\$200
Academic/Government	\$200
Media	Free

Conference Location

Cintas Center
Xavier University
1624 Herald Ave.
Cincinnati, OH 45207

A Look Back at 2010

- FDA's CDER Announced Policy at the Podium
- 4 Countries: Canada, Israel, United Kingdom, United States
- Expertise in:
 - Quality: 64%
 - Regulatory: 12%
 - Operations: 10%
 - Supply Chain: 6%
 - Procurement: 1%
 - Other Disciplines: 6%

Post-Conference Workshops

IPEA EXCIPIENT GMP AUDITING

Oct. 5-7, 2011, 2 1/2 days

A comprehensive workshop in excipient auditing for makers and users. Training will analyze the essential elements of excipient good manufacturing practice for materials intended for use in pharmaceuticals or dietary supplements.

TRAINERS: **Irwin Silverstein** **Sydney Goode,**
IPEA PharmD
Dow Chemical Company

DANGEROUS DOCUMENTS

Oct. 5, 2011, 1/2 day

To teach company employees how to write documents that will reflect the company's commitment to compliance, Nancy Singer, former FDA prosecutor and defense counsel, will lead an interactive workshop. During this high energy session, registrants will not sit back and passively listen to series of lectures. Rather they will be divided into teams to explore case studies, real life examples and exercises.

TRAINERS: **Nancy Singer** **Virginia Connelly**
Compliance Alliance FDA, Cincinnati District, Invited

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GOC

Global Outsourcing Conference

Cincinnati, Ohio
Oct. 2-5, 2011
www.XavierGOC.com

Early
REGISTRATION
Ending Soon!

Join the Conversation

- FDA Inspection Trends and Enforcement
- Global Regulator Expectations for Outsourcing and Supply Chain Integrity
- Supplier Qualification Program – best practices
- And more!

Content Developed For:

- All levels and all roles of the organization
- Pharmaceutical, Biotech, Generics, and OTC Companies
- Contract Organizations
- Government Officials
- Industry Organizations and Associations
- Consultants

Associate Commissioner Steven Niedelman
FDA Deputy
Associate Commissioner



GOC

Global Outsourcing Conference
Oct. 2-5, 2011

engage with the experts.
influence the discussion.
change the industry.

GOC 2011 Co-Chairs



Kathleen Culver
FDA
Cincinnati District
Field Investigator
and Drug Pre-Approval Manager



Hedley Rees
Biotech
Pharmaflow
Managing
Partner



Marla Phillips, PhD
Xavier University
Director

Conference Topics

Sponsored by the FDA and Xavier University, the World-Class pharmaceutical conference GOC 2011 is in direct alignment with the FDA Strategic Priorities 2011-2015 as we address the challenges of global outsourcing head-on.

It's the only conference to intentionally bring pharmaceutical, biotechnology, over-the-counter, and generic companies together collaboratively with their contract partners.

- Strategic Procurement
- Total Cost of Ownership
- Operationalizing QbD Principles
- Establishing Meaningful Metrics – from both sides
- Global Regulatory Expectations for Outsourcing
- Effective Supplier Qualification Program
- How to Manage a Global Complex Supply Chain
- End-to-End Planning
- The Power of Integrated Supply Chains
- FDA and MHRA Inspection Trends and Enforcement Action
- The McNeil Case Study and Living Under Consent Decree
- Due Diligence Audits, On-Going Audits and How to Audit the Supply Chain

...And many more!

Featured Speakers



Steven Niedelman
Former FDA Deputy
Associate Commissioner



Chris Watts
Former FDA Center
for Drug Evaluation
and Research



Robert Coleman
Former FDA national
drug expert



Jair Calixto
Sindusfarma
Association – Brazil



Andrew Cox
World Leader in
Strategic Procurement

We *invite* you to engage with industry experts and regulatory authorities from around the globe.