

**Pharmaceutical Training Workshop  
New Orleans District, U.S. Food and Drug Administration  
March 16, 2017**

**Hosted by: Samford University McWhorter School of Pharmacy  
Location: Samford University College of Health Sciences**

**The purpose of this workshop is two-fold\*:**

- 1)** To provide basic information to industry representatives and state board of pharmacy officials focusing on the system deficiencies most frequently documented during previous inspections of small pharmaceutical firms located within the New Orleans District area (Alabama, Louisiana, Mississippi, and Tennessee).
- 2)** To provide a platform to engage in face-to-face dialogue with FDA and establish contacts in an effort to improve proactive, voluntary compliance with regulatory requirements.

The target audience for this training is the pharmaceutical industry in the District area, which includes Alabama, Louisiana, Mississippi, and Tennessee; however, the training will be open to any participants who register to attend. The objective is to increase voluntary compliance and promote the manufacturing and processing of safe product; thus, enhancing the protection of the public health and use resources wisely.

\*Note: Professional continuing education credits will not be awarded for this workshop event.

**WORKSHOP AGENDA**

<b>March 16, 2017</b> <b>Location: Samford University, College of Health Sciences</b> <b>Birmingham, AL</b>		
7:30 AM - 8:00 AM	<b>REGISTRATION</b>	
8:00 AM - 8:05 AM	<b>Welcome</b>	Ruth Dixon, New Orleans District (NOL DO) Director, FDA
8:05 AM - 8:35 AM	<b>Current &amp; Future State of Affairs</b>	Scott MacIntire, FDA, Office of Regulatory Affairs (ORA), Division of Enforcement
8:35 AM - 9:45 AM	<b>Overview of the Drug Supply Chain Security Act (DSCSA)</b>	Diane Goyette, FDA, ORA, Office of Policy and Risk Management; & Melissa Kim Mannion, FDA, Center for Drug Evaluation and Research (CDER), Office of Compliance
9:45 AM - 10:00 AM	<b>BREAK</b>	
10:00 AM - 10:10 AM	<b>Types of Inspections</b>	Brandon Heitmeier, Investigator, NOL DO, FDA
10:10 AM - 10:20 AM	<b>Collaboration and Information Sharing</b>	Lindsay Bertling, NOL DO Emergency Response Coordinator, FDA
10:20 AM - 10:30 AM	<b>Recalls: When to Report</b>	Cindy Gibson, Supervisory Investigator, NOL DO, FDA
10:30 AM - 11:30 AM	<b>College of Health Sciences Open House</b>	Samford University, College of Health Sciences Faculty

11:30 PM - 1:00 PM	<b>LUNCH*</b>	
1:00 PM - 2:00 PM	<b>Cleanroom Design Considerations</b>	Thomas Arista, National Expert, FDA
2:00 PM - 3:00 PM	<b>Panel Discussion with State Board Officials: AL, LA, MS, and TN</b>	Facilitators - Rebecca Asente, NOL DO Compliance Officer, FDA & JoAnn Pittman, NOL DO Public Affairs Specialist, FDA
3:00 PM - 3:15 PM	<b>BREAK</b>	
3:15 PM - 3:30 PM	<b>Inspection Process Overview</b>	Claire Minden, Investigator, NOL DO, FDA
3:30 PM - 4:30 PM	<b>Validation Principles</b>	Andrew Walsh, Center for Pharmaceutical Cleaning Innovation, LLC
4:30 PM - 5:30 PM	<b>Q &amp; A Discussion Session</b>	Panel of all Speakers with Facilitators
	<b>Closing Remarks</b>	Ruth Dixon, NOL DO Director, FDA

\*Lunch is not provided as part of registration for the workshop. Many dining options are available within a short distance from the Samford University campus.

**How to register:** To register for the event please visit the Samford University McWhorter School of Pharmacy Office of Continuing Pharmacy Education website by clicking [here](#). Follow links to register for the event free of charge. Registration is limited to the first 130 registrants on a first come, first served basis. Demand is expected to be high for this event. If you register and your plans change please notify our office so we may make your seat available to someone who is on a waiting list.

**Lodging and dining options:** Lodging options are listed on the registration form. There are many lodging and dining options less than a 5 minute drive from campus.

**How to find the Samford University College of Health Sciences:** The street address for Samford University is 800 Lakeshore Drive, Birmingham, AL 35229. The map linked [here](#) will indicate where to park and enter the building. Directional signs will be placed on Lakeshore Drive on the day of the event to indicate where to enter the campus.

To learn more about the College of Health Sciences click [here](#).

**Do you have other questions?** Please contact Mrs. Joan Jackson, Manager of CE at 205-726-2722 or [ijmcguir@samford.edu](mailto:ijmcguir@samford.edu)