

**Activity Outline**  
**FDA Grand Rounds:**  
**Metabolomics and Proteomics Biomarkers Discovery and Validation in Toxicity Studies**

**November 10, 2016**  
**12:00 PM-1:00 PM**

**Series Description**

The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

**Session Description**

Metabolomics and proteomics technologies are being used in nonclinical and clinical toxicity studies to discover translational biomarkers in biofluids to diagnose toxicity and predict toxicity before it occurs. Metabolomics and proteomics biomarkers identified have the potential to protect public health by enabling safer drug development and clinical management. The results may also fill gaps at the approval, and possibly change of labeling post-approval in the regulation and monitoring of drugs with potential toxicity liabilities.

**References**

1. Beger, RD., Bhattacharyya, S., Yang, X., Gill, P.S., Schnackenberg, L.K., Sun, J., and James, L.P. Translational Biomarkers of Acetaminophen-Induced Acute Liver Injury. Arch Tox. (2015). DOI 10.1007/s00204-015-1519-4
2. Schnackenberg LK, Pence L, Vijay V, Moland CL, Cao Z, Yu L-R, Fuscoe JC, Beger RD, and Desai VG. Early metabolomics changes in heart and plasma during chronic doxorubicin treatment in B6C3F1 mice. 2016. J Applied Toxicology. 2 MAR 2016. DOI: 10.1002/jat.3307

**Series Objectives:**

1. Discuss the research conducted at the FDA
2. Explain how FDA science impacts public health

**Session Learning Objectives** After completion of this activity, the participant will be able to:

- Discuss metabolomics and proteomics as analytical tools to discover potential translational biomarkers of drug efficacy and toxicity.
- Explain the usage of metabolomics and proteomics in precision medicine to monitor patient responses to drug therapies.

**Target Audience**

This activity is intended for physicians, pharmacists, nurses and other scientists within the agency and external community.

**Schedule**

<b>Date/Time/Place</b>	<b>Lecture Title</b>	<b>Lecturer</b>
Thursday, November 10, 2016 12:00 pm –1:00 pm Bldg 32, Rm 1243	FDA Grand Rounds: Metabolomics and Proteomics Biomarkers Discovery and Validation in Toxicity Studies	Richard Beger, Ph.D.

## **Continuing Education**

The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Food and Drug Administration – Center for Drug Evaluation and Research designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit(s)*<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-16-079-L04-P). This program meets the criteria for 1 contact hour(s) of pharmacy education.



This activity is a knowledge - based activity. These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

This 1 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

### **Requirements for receiving CE credit**

Physicians, pharmacists, nurses and those claiming non-physician CME: attendance is verified by a sign-in sheet and completion of the final activity evaluation. For multi-day activities, participants must sign in every day. Final activity evaluations must be completed within two weeks after the activity.

Pharmacy participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

### **Statements of Credit**

Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

### **Disclosure**

#### **Faculty**

Richard D. Beger, Ph.D., Branch Chief, Biomarkers and Alternative Models Branch, Division of Systems Biology, NCTR has nothing to disclose

### **Planning Committee**

Emmanuel Fadiran, PhD, RPh, Intramural Research Program Director, FDA/OC/OWH, has nothing to disclose

Rokhsareh Shahidzadeh, MSN, RN, Regulatory Health Education Specialist, DLOD/CDER, has nothing to disclose

Eileen Parish, MD, Medical Officer, FDA/OC/OCS/OSPD, has nothing to disclose

Leslie Wheelock, MS, RN, Director OSPD, FDA/OC/OCS/OSPD, has nothing to disclose

### **CE Consultation and Accreditation Team**

Traci Bryant, B.A., M.A., Education Specialist, FDA/CDER/OEP/DLOD, has nothing to disclose

Virginia Giroux, MSN, ARNP, CE Program Administrator, CDER/DLOD, has nothing to disclose

Karen Zawalick, CE Team Leader, FDA/CDER/OEP/DLOD, has nothing to disclose

### **Registration Fees and Refunds**

Registration is complimentary therefore refunds are not applicable.

### **Requirements for Certificate of Completion (Non CE)**

Must attend 80% of the lectures (verified by a sign-in sheet).

**Initial Release Date:** November 10, 2016

### **Remote Access Instructions:**

To register for the webcast, please click the link below and click the link that says “please click here to register.” Then follow the instructions. After you register you must use the same link below to access the live webinar by logging in with your username and password which you create when you register.

### **Access link:**

<https://collaboration.fda.gov/grandroundsregs11102016/event/login.html>

For technical assistance please contact Jeffery Rexrode at [Jeffery.Rexrode@fda.hhs.gov](mailto:Jeffery.Rexrode@fda.hhs.gov).

\*The on-line presentation provides reasonable accommodation for individuals with disabilities.