Activity Outline
CDER SBIA Webinar: How should I measure this? An FDA perspective on the Bioanalytical Method Validation (BMV)
June 17, 2019
Live Webinar

Activity Coordinator
Lisa Misevicz
lisa.misevicz@fda.hhs.gov

Description

The webinar provides an opportunity for FDA/CDER offices (OGD, OCP, and OSIS) to discuss how they use the 2018 BMV guidance and what FDA expects from the regulated industry. Attendees will be able to identify aspects of the FDA guidance on Bioanalytical Method Validation and learn FDA reviewers' perspective on the assessment of bioanalytical data submitted INDs, NDAs, ANDAs, and BLAs

References

- GUIDANCE DOCUMENT FDA Bioanalytical Method Validation Guidance for Industry May 2018 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bioanalytical-method-validation-guidance-industry

Learning Objectives

- Identify important aspects of FDA's guidance on Bioanalytical Method Validation used to evaluate data submitted on INDs, NDAs, ANDAs, and BLAs.
- Identify what FDA bioanalytical site inspections will address.

Target Audience
This activity is intended for physicians, pharmacists, and nurses.

Agenda
Day 1 June 17, 2019

Time	Topic	Speaker
10:00 - 10:45 AM	Bioanalytical Method Validation Overview	Brian Booth
10:45 - 11:25 AM	Bioanalytical Method Validation of ANDAs - What the reviewer looks for (Part 1& Part 2)	Suman Dandamudi, PhD Leah Falade, PhD
11:25 - 11:35 AM	*Break*	
11:35 - 12:15 PM	Bioanalytical Inspections: Overview and Case Studies	Seongeun Cho John Kadavil, PhD
12:15 - 12:55 PM	Accuracy and Precision in Bioanalysis: Review of Case Studies	Charles Bonapace, Pharm.D. Arindam Dasgupta, PhD
12:55 - 1:15 PM	*Break*	
1:15 - 2:00 PM	Panel Discussion and Questions and Answers	Brian Booth Suman Dandamudi, PhD Leah Falade, PhD Charles Bonapace, Pharm.D. Arindam Dasgupta, PhD Seongeun Cho John Kadavil, PhD Sean Kassim, PhD

Continuing Education Accreditation

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 3.50 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 3.50 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-19-053-L04-P for 3.50 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 3.50 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - 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.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Bonapace, Charles, Pharm.D., Director, DNDBE, FDA/CDER/OTS/OSIS - nothing to disclose
- Booth, Brian, Deputy Director, CDER\OTS\OCP\DCP V - nothing to disclose
- Cho, Seongeun, Director, FDA - nothing to disclose
- Dandamudi, Suman, PhD, Staff Fellow, Food and Drug Administration - nothing to disclose
- Dasgupta, Arindam, PhD, Deputy Division Director, CDER/OTS/OSIS/DNDBE - nothing to disclose
- Falade, Leah, PhD, Lead Pharmacologist, CDER/FDA - nothing to disclose
- Kadavil, John, PhD, Deputy Division Director (Supervisory Pharmacologist), USFDA - nothing to disclose
- Kassim, Sean, PhD, Director, CDER/OTS/OSIS - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose

- Kleppinger, Cynthia, MD, Medical Officer, FDA - nothing to disclose
- Stodart, Brenda, PharmD, BCGP, Program Director, FDA - nothing to disclose

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 100% of the activity.