
# Workshop: Bioanalytical Method Validation: The Finalized Guidance

On May 18, 2018, the FDA issued the final version for the Guidance for Industry Bioanalytical Method Validation. What has been incorporated into the Guidance is a new tabular presentation of validation parameters for chromatography and ligand binding assays. The guidance also presents FDA expectations on biomarker assays used during drug development, and updates various bioanalytical practices based on the proceedings of the 2013 AAPS/FDA Collaboration meeting, Crystal City, Va.

The purpose of the workshop is to highlight the new elements of the Guidance and provide a space for regulators to respond to audience questions using an open forum and panel discussion format.

Participants of this event will:

- Understand the new aspects of the finalized FDA Guidance.
- Learn about the non-clinical, clinical, generic, and inspection perspectives on bioanalytical method reviews.
- Discuss and gain insight on the various aspects and implications of the finalized Guidance.

## Presentations

All presentations will be available on the workshop website, no later than 24 hours following the workshop. Presentations will remain online for registered attendees until August 7, 2019.

## AAPS Disclaimer Statement

All scientific presentations at AAPS-sponsored events must adhere to the highest standards of scientific ethics, including acknowledgements or references to sources (both scientific and financial), and the absence of promotional content or endorsement of commercial products. Any conflict of interest must be disclosed prior to the meeting. Authors and speakers are responsible for the content and ideas stated in their oral and written presentations. AAPS is not responsible for, nor do we endorse, the material published in any final program materials or any oral or written statements made by presenters at this meeting.

## Workshop Planning Committee

Brian Booth, Ph.D., U.S. Food and Drug Administration

---

***Thank You AAPS Sustaining Sponsors for Your Support***

---

abbvie

AstraZeneca

MedImmune
A member of the AstraZeneca Group

Biogen

MERCK
INVENTING FOR LIFE

Lilly

EMD SERONO

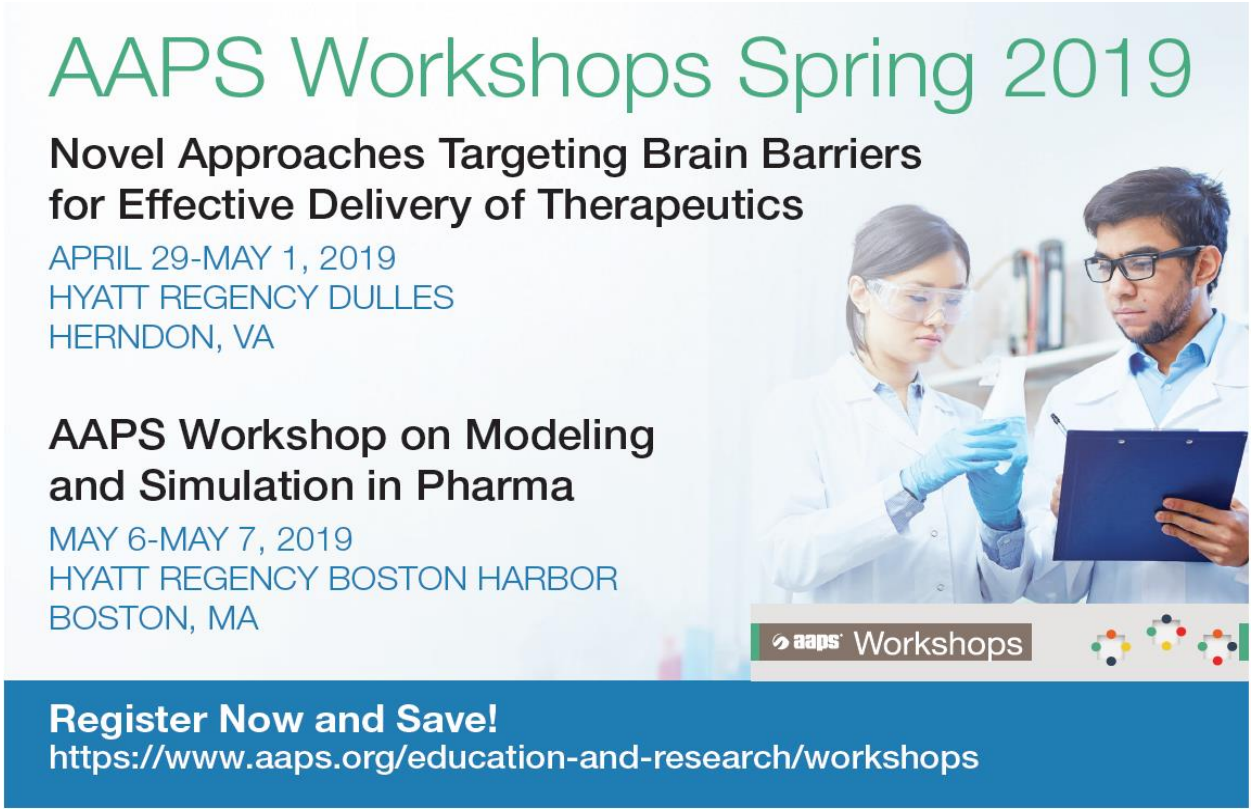
Genentech
A Member of the Roche Group
Roche

SANOFI

Pfizer

Lonza

## Join AAPS at These Future Meetings



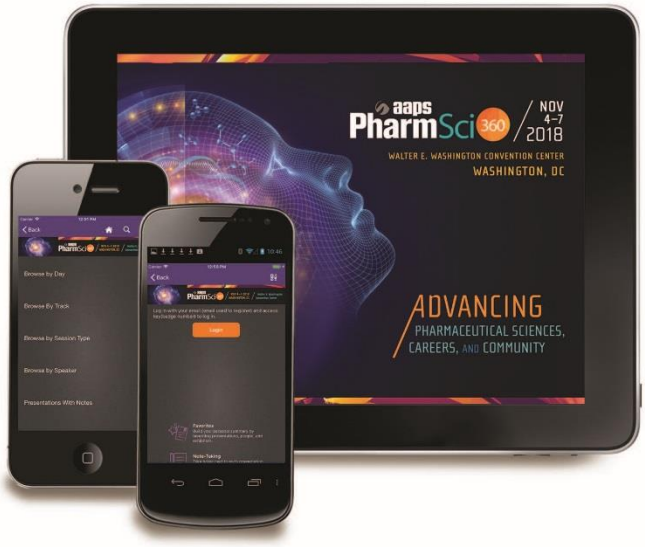


# Need the presentation?

## Get the app!

Download the **"AAPS PharmSci 360"** app from the Apple App Store or Google Play Store before you travel.

Find your event app by searching for **"2018 PharmSci 360"** or find the event icon and click to open the app. Follow the login instructions provided by your event registration to begin using the app.




As long as you have an internet connection, you can access the app through your **laptop** via this link:

**www.eventscribe.net/2018/PharmSci360**

***Download before you go!** On-Site WiFi service can affect the functionality of the app.

aaps PharmSci 360 / NOV 4–7 2018 / Walter E. Washington Convention Center

# Workshop Agenda

*Sessions will take place in the Washington Convention Center, room 146 C*

| **Sunday, November 4, 2018** | |
|---|---|
| 9:00 am – 9:35 am | **Highlights of the BMV Guidance**<br>Brian Booth, Ph.D., U.S. Food and Drug Administration |
| 9:30 am – 10:05 am | **Bioanalytical Method Validation of LC/MS assays-what the clinical reviewer looks for**<br>Sriram Subrmaniam, Ph.D., U.S. Food and Drug Administration |
| 10:05 am – 10:45 am | **Bioanalytical Method Validation of LBAs—what the clinical reviewer looks for**<br>Thiengi Thway, Ph.D., U.S. Food and Drug Administration |
| 10:45 am – 11:00 am | Coffee Break |
| 11:00 am – 11:30 am | **Bioanalytical Method Validation of ANDAs-what the reviewer looks for**<br>Nilfuer Tampal, Ph.D., U.S. Food and Drug Administration |
| 11:30 am – 12:00 pm | **Bioanalytical Method Validation-OSIS inspections**<br>Sean Kassim, Ph.D., U.S. Food and Drug Administration |
| 12:00 pm – 1:00 pm | **Panel Session**<br>All Speakers |
| 1:00 pm – 2:00 pm | Lunch Break |

# Speaker Abstracts and Biographies

## Highlights of the BMV Guidance

Participants in the session will understand the following:

- The design of the Bioanalytical Method Validation Guidance
- What new sections have been added to the Guidance and why
- The changes that were made from prior versions of the Guidance

### Brian Booth, Ph.D., U.S. Food and Drug Administration

Brian Booth, Ph.D., joined the Office of Clinical Pharmacology, FDA, in 1998. In 2004, he became the Acting Team Leader in the Division of Oncology Drug Products, after serving as a reviewer/pharmacometrician in this division. In November 2006, Dr. Booth was selected as Deputy Director of the Division of Clinical Pharmacology 5. At the FDA, Dr. Booth has been involved with the clinical pharmacology development of several hundred new oncology drugs, ranging from phase 1 to phase 4. In addition to IND and NDA reviews, Dr. Booth has been involved with teaching and development of new clinical pharmacology reviewers and medical officers, development of Guidances for Industry for bioanalytical method validation, liposome drug products, hepatic impairment studies and food effect studies. He has authored 60 peer-reviewed articles and book chapters. Dr. Booth is a member of AAPS and ACCP.

# Bioanalytical Method Validation of LC/MS assays-what the clinical reviewer looks for

Session description unavailable.

Sriram Subrmaniam, Ph.D., U.S. Food and Drug Administration

Sriram Subramaniam, PhD is a Senior Clinical Pharmacology Reviewer at the Office Clinical Pharmacology, CDER, FDA. Dr. Subramaniam has been intimately involved in various aspects of bioanalysis at the CDER, FDA, initially at the Division of Scientific Investigations (currently, Office of Study Integrity and Surveillance), followed by the Office of Generic Drugs, and currently at the Office of Clinical Pharmacology. Dr. Subramaniam has vast regulatory experience in bioanalytical conduct and policy development including, review of bioanalysis in different types of drug applications, audits of bioanalytical facilities across the globe, and active participation in regulatory policy, guidance development, and presentations in conferences and workshops. Dr. Subramaniam's educational training includes both the physical and biological sciences in that he holds Bachelor's and Master's degrees in physics and biophysics, and a doctoral degree in physiology.

## Bioanalytical Method Validation of LBAs—what the clinical reviewer looks for

During this session, the following items will be presented.

- Clinical Pharmacology reviewer's perspective on submission and LBAs, a high-level overview of what reviewers look for, important points in BMV of LBA.
- BMV for LBA expectation
- Case examples on LBAs related review issues
- Clarity on the difference between bioanalysis for new versus biosimilar

### Thiengi Thway, Ph.D., U.S. Food and Drug Administration

Thiengi Thway is a senior staff fellow in Office of Clinical Pharmacology (OCP) at FDA. She is lead bioanalytical advisor for Therapeutic Biologic Program and a subject-matter-expert for biologics providing scientific advices to all OCP review Divisions. She is responsible for driving consistency and effectiveness of biologics reviews, identifying and leading strategic initiatives, and developing scientific and regulatory policies for biologics. Prior joining to FDA in 2017, she had 14-years of industry experience in biologic drug development. She joined Amgen Inc. in 2006 as a Scientist and assumed progressively greater responsibilities leading to Principal Scientist. She led a bioanalytical team supporting method development, method validations, and study supports for measurement of therapeutic proteins and biomarkers. She had a unique expertise for both pharmacokinetic and bioanalysis. She was a bioanalytical scientist at Tanox Inc, a subsidiary of Genentech Inc. and worked on the immunogenicity assessment of biologics from 2003 to 2006. She did her postdoctoral fellowship at the University of Texas Health Science Center, Houston, Texas. She has published numerous peer-reviewed articles and presented at various national meetings. She received her PhD in Molecular and Integrative Physiology from University of Kansas School of Medicine and BS from University of Pittsburg, Kansas.

# Bioanalytical Method Validation of ANDAs-what the reviewer looks for

Session description unavailable.

Nilfuer Tampal, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

## Bioanalytical Method Validation-OSIS inspections

Attendees at this session will understand common observations during bioanalytical laboratory and related inspections and how updates to the Bioanalytical Method Validation Guidance affect bioanalytical laboratory inspection*s.* This presentation will also familiarize attendees on the Office of Study Integrity and Surveillance (OSIS), the office that conducts inspections of laboratories that follow the Bioanalytical Method Validation Guidance

Sean Kassim, Ph.D., U.S. Food and Drug Administration

Dr. Kassim is the director of the Office of Study Integrity and Surveillance (OSIS) in the Office of Translational Sciences (OTS) in FDA's Center for Drugs (CDER). OSIS oversees bioequivalence and bioavailability studies and non-clinical laboratories in support of pharmaceutical development, as part of the Agency's Bioresearch Monitoring (BIMO) program. Previously, Sean was the director of the Office of Scientific Investigations (OSI), in CDER's Office of Compliance, overseeing compliance programs and enforcement for pharmaceutical BIMO (GCP, IRB) and post-market reporting (PADE, REMS, PMR) activities. In OSI, he also served as Deputy Office Director; Associate Director for Policy and Communication; acting Associate Director for Risk Science, Intelligence, and Prioritization; and team leader for the Informatics and Infrastructure Team. He started at FDA as a reviewer for the bioequivalence and GLP compliance program in OSI's predecessor, the Division of Scientific Investigations. Before coming to FDA, Sean worked at the University of Washington in Seattle, using proteomic and genomic approaches to identify novel proteinase targets, identifying biomarkers for heart disease, and evaluating pulmonary anti-bacterial defenses. Sean received his doctorate from Washington University in St. Louis and his undergraduate degree from the University of Maryland Baltimore County.

## Organizing Committee Biographies

### Brian Booth, Ph.D., U.S. Food and Drug Administration

Brian Booth, Ph.D., joined the Office of Clinical Pharmacology, FDA, in 1998. In 2004, he became the Acting Team Leader in the Division of Oncology Drug Products, after serving as a reviewer/pharmacometrician in this division. In November 2006, Dr. Booth was selected as Deputy Director of the Division of Clinical Pharmacology 5. At the FDA, Dr. Booth has been involved with the clinical pharmacology development of several hundred new oncology drugs, ranging from phase 1 to phase 4. In addition to IND and NDA reviews, Dr. Booth has been involved with teaching and development of new clinical pharmacology reviewers and medical officers, development of Guidances for Industry for bioanalytical method validation, liposome drug products, hepatic impairment studies and food effect studies. He has authored 60 peer-reviewed articles and book chapters. Dr. Booth is a member of AAPS and ACCP.