FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
SMALL BUSINESS AND INDUSTRY ASSISTANCE

How should I measure this? An FDA perspective on the Bioanalytical Method Validation (BMV)

June 17, 2019 - 10:00 a.m. to 2:00 p.m. Eastern

10:00 a.m.	SBIA Opening	Small Business and Industry Assistance (SBIA) | Center for Drug Evaluation and Research (CDER) | FDA
10:05	The Finalized Bioanalytical Method Validation Guidance: What's New for New Drug Applications (NDAs) and Biologics License Applications (BLAs)	**Brian Booth, Ph.D.** *Deputy Director* Division of Clinical Pharmacology V Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS) CDER | FDA
10:45	Bioanalytical Method Validation of Abbreviated New Drug Applications (ANDAs) - What the reviewer looks for (Part 1& Part 2)	**Leah Falade, Ph.D.** *Lead Pharmacologist* **Suman Dandamudi, Ph.D.** *Staff Fellow* Office of Bioequivalence (OB) Office of Generic Drugs (OGD) CDER | FDA
11:25	Break for Lunch	
11:55	Bioanalytical Inspections: Overview and Case Studies	**Seongeun (Julia) Cho, Ph.D.** *Division Director* **John Kadavil, Ph.D.** *Deputy Director* Division of Generic Drug Bioequivalence and Evaluation Office Study Integrity and Surveillance (OSIS) OTS | CDER | FDA
12:35	Accuracy and Precision in Bioanalysis: Review of Case Studies	**Charles Bonapace, Pharm.D.** *Director* **Arindam Dasgupta, Ph.D.** *Deputy Director* Division of New Drug Bioequivalence and Evaluation OSIS | OTS | CDER | FDA
1:15	Break	
1:25	Panel Discussion and Q&A	Brian Booth, Ph.D. Charles Bonapace, Pharm.D. Seongeun (Julia) Cho, Ph.D. Suman Dandamudi, Ph.D. Arindam Dasgupta, Ph.D. Leah Falade, Ph.D. John Kadavil, Ph.D. Sean Kassim, Ph.D.
1:55	SBIA Closing Remarks	Small Business and Industry Assistance (SBIA)

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