

Assay Guidance Workshop for High-Throughput Screening and Lead Discovery Agenda

Wiley Auditorium, Room 1A-003, Harvey W. Wiley Federal Building, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, Maryland 20740

Participants will receive a broad, practical perspective on assay development so that they can (1) improve research projects involving high-throughput screening/lead discovery and know where to find further information; (2) identify reagents, methods and instrumentation that are well suited to robust assays; and (3) develop robust assays and counter-assays for new targets. Additionally, participants will have the opportunity to seek practical advice about individual research challenges.

Tuesday, April 5, 2016 — 8:30 a.m. – 5:30 p.m. ET

- 8:30 – 8:50 a.m. **Robust or Go Bust: An Introduction to the Assay Guidance Manual**
Nathan P. Coussens, Ph.D., NCATS, NIH
- 9:00 – 9:50 a.m. **Treating Cells as Reagents to Design Reproducible Screening Assays**
Terry Riss, Ph.D., Promega Corporation
- 10:00 – 10:50 a.m. **Use of 3D InSight™ Human Liver Microtissues as a Tool for Prediction of Drug-Induced Liver Injury**
Ivy Mead, M.Sc., InSphero Inc.
- 11:00 – 11:50 a.m. **Identifying and Mitigating Assay Artifacts Arising from Chemical Library Screening**
James Inglese, Ph.D., NCATS, NIH
- 12:00 – 1:00 p.m. Lunch
- 1:00 – 1:50 p.m. **Basic Assay Statistics, Data Analysis and Rules of Thumb**
Thomas D.Y. Chung, Ph.D., Mayo Clinic
- 2:00 – 2:50 p.m. **Reproducibility and Differentiability of Compound Potency Results from Screening Assays in Drug Discovery**
V. Devanarayan, Ph.D., AbbVie Inc.
- 3:00 – 3:50 p.m. **Assay Operations: Keeping Your Assays Robust and Reproducible**
Jeffrey R. Weidner, Ph.D., AbbVie Inc.
- 4:00 – 5:30 p.m. **Special Topics Sessions**
A. Cell-Based Assays
B. Assay Artifacts and Statistics

Wednesday, April 6, 2016 — 9:00 a.m. – 4:00 p.m. ET

- 9:00 – 9:50 a.m. **Application of Quantitative High-Throughput Screening for *In Vitro* Toxicological Testing**
Menghang Xia, Ph.D., NCATS, NIH
- 10:00 – 10:50 a.m. ***In Vitro* Assessment of ADME Properties of Lead Compounds**
Xin Xu, Ph.D., NCATS, NIH
- 11:00 a.m. – 12:30 p.m. **Establishing Robust Biochemical and Cellular Assays**
Lisa Minor, Ph.D., In Vitro Strategies, LLC
- 12:30 – 1:30 p.m. Lunch
- 1:30 – 2:30 p.m. **Special Topics Sessions**
A. Biochemical Assays
B. Absorption, Distribution, Metabolism and Excretion (ADME) Assessment and Toxicity Assays
- 2:45 – 4:00 p.m. **Special Topics Sessions**
A. Special Topics on Data Evaluations (Design of Experiments for Assay Development, Multivariate Assay Correlations, Etc.)
B. Assay Operations and Automation