

FDA Product-Specific Guidances: Lighting the Development Pathway for Generic Drugs

May 5, 2021, 9:00 a.m. - 12:30 p.m. (Eastern, UTC-4)

Agenda

- 9:00: Welcome & Overview
- 9:05: Opening Remarks ([Lei Zhang, ORS/OGD](#))
- 9:15: Overview of the FDA Product-Specific Guidance Program ([Christine Le, ORS/OGD](#))
- 9:25: Non-Complex Drug Products and Product-Specific Guidances ([MJ Kim, ORS/OGD](#))
- 9:45: Product-Specific Guidances for Complex Generic Drugs ([Markham Luke, ORS/OGD](#))
- 10:05: Product-Specific Guidance Fundamentals from a Clinical Perspective ([Mitch Frost, ORS/OGD](#))
- 10:25: Break
- 10:35: Developing and Implementing Science-Based Standards in Bioequivalence Assessment ([Paramjeet Kaur, OB/OGD](#))
- 10:55: Bioequivalence Regulations and Product-Specific Guidances ([Dave Coppersmith, OGD/OGD](#))
- 11:15: Closing Remarks ([Rob Lionberger, ORS/OGD](#))
- 11:25: Q&A and Panel Discussion
([All speakers and Bing Li from OB/OGD will join the panel discussion](#))
- 12:30: Adjourn