FDA Public Meeting

BsUFA III Regulatory Science Program Interim Public Meeting

Agenda for FDA Public Meeting

September 18, 2025 / 9:00 am – 3:00 pm EST

Time	Event (and Proposed Speakers / Panelists)
9:00 – 9:15am	**Welcome and Introduction** (Darlese Solorzano)
9:15 – 9:30am	**The Role of Regulatory Science at the FDA and Impetus for the BsUFA III Regulatory Science Pilot Program** (Steve Kozlowski)
9:30 – 10:15am	**Pilot Program Overview:** Establishing the regulatory science pilot program and summary of stakeholder input (Emanuela Lacana and Darlese Solorzano)
10:15 – 10:30am Break	
10:30am – 12:00pm	**Research Progress Awardee Presentations*** (Moderated by Darlese Solorzano) Research Progress updates by Regulatory Impact 1 & 2: • Priority A: FDA/OTS-Landscape Analysis (Dr. Jeffry Florian) • Priority B: FDA/OPQ-Model Development and Verification of Stability Data (Dr. Uriel Ortega-Rodriguez and Dr. Mari Lehtimaki) • Priority C: FDA/OPQ-Bioassay (Dr. Carole Sourbier) • Priority D: AMCP/ BBCIC - Improving the Efficiency of Regulatory Decisions for Biosimilars (Dr. Cate Lockhart) • Priority E - FDA/OTS- Translating Clinical Pharmacology Biosimilars (Dr. Lakshmi Manasa Sakuntala Chekka) • Q&A/Panel with Presenters **Presentation selections based on stakeholder input from Jan 22, 2025 SBIA meeting*
12:00 – 1:15pm	**Lunch and In-Person Poster Session**
1:15 – 1:45pm	**Poster session Q&A** *(virtual and in-person)* with awardees who did not present (Moderated by Darlese Solorzano)
1:45 – 2:00pm	**Pilot Program Interim Evaluation and Next Steps** (Sarah Yim) • Interim ROI and lessons learned from 3 years of the Pilot Program • FDA's preliminary thoughts on the role of regulatory science in biosimilar development
2:00 – 3:00pm	**Industry Reactions and Panel Discussion:** (Moderated by Susan Winckler from the Reagan-Udall Foundation) • Current perspectives about the role of regulatory science in biosimilar development • Discussion questions and audience Q&A Panelists: • AAM (Cory Wohlbach) • Biosimilar Forum (Juliana Reed) • PhRMA (Sean Hilscher) • FDA (Emanuela Lacana and Sarah Yim)
3:00 – 3:10pm	**Conclusion and Close Out** (Emanuela Lacana and Darlese Solorzano)

Food and refreshments will be available for purchase during the break and lunch.

Have a question for the Q&A Session?

Submit your question via email to BsUFARegSciProgram@fda.hhs.gov or scan the QR code and include *Interim Public Meeting* in the subject line.