CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)
WEBINARS
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Version 4, September 6, 2023

BsUFA III Regulatory Science Pilot Program

Monday, October 16, 2023

For files and resources, please visit
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AGENDA

All times are Eastern (UTC-5)
View Start Time on World Clock

8:30 – 8:40

SBIA Welcome and Overview

Forest "Ray" Ford, Jr., PharmD, BCPS
Captain, United States Public Health Service
Pharmacist, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER) | FDA

8:40 – 8:55

Welcoming Remarks and Introduction

Darlese Solorzano, MS, MBA
Manager, BsUFA Regulatory Science Pilot Program
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ)
CDER | FDA

8:55 – 9:10

BsUFA III Overview: Putting the BsUFA Regulatory Science Program in Context

Sarah Yim, MD
Director, Office of Therapeutic Biologics and Biosimilars
Office of New Drugs (OND)
CDER | FDA

9:10 – 9:30

Overview and Current Status of the BsUFA III Regulatory Science Program

Steven Kozlowski, MD
Chair, BsUFA III Regulatory Science Subcommittee
Director, OBP | OPQ | CDER | FDA

9:30 – 9:40: BREAK

9:40 – 10:25

Awardee Presentations

Susan Kirshner, MSc, PhD
Director, Division of Biotechnology Review & Research III
OBP | OPQ | CDER | FDA

Cate Lockhart, PharmD, PhD
Executive Director
Biologics and Biosimilars Collective Intelligence Consortium

Diane McCarthy, PhD
Senior Scientific Director, Global Biologics
U.S. Pharmacopeia

Yow-Ming Wang, PhD
Associate Director for Biosimilars
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS)
CDER | FDA

10:25 – 10:40

Open Q&A and Panel Discussion

Moderated by:
Darlese Solorzano

Steven Kozlowski, Susan Kirshner, Cate Lockhart, Diane McCarthy, Yow-Ming Wang and

Kimberly Maxfield, PhD
Scientific Lead, BsUFA Regulatory Science Pilot Program
Office of Therapeutic Biologics and Biosimilars (OTBB)
OND | CDER | FDA

10:40 – 10:50: BREAK

10:50 – 11:20

Update on BsUFA III Regulatory Science Research Priorities in Roadmap 2.0

Kimberly Maxfield

11:20 – 11:50

Stakeholder Feedback and Discussion

Steven Kozlowski, Kimberly Maxfield, and **Darlese Solorzano**

11:50 – 12:00

Next Steps and Day One Closing Remarks

Steven Kozlowski, Kimberly Maxfield, and **Darlese Solorzano**

12:00: ADJOURN

BsUFA III Regulatory Science Pilot Program
Follow-Up Meeting

Monday, October 26, 2023

FDA will hold a follow-up meeting on Thursday, October 26, 2023 from 9 a.m. – 12 p.m. (ET) for interested participants from this October 16th webinar. The follow-up meeting will be **IN-PERSON ONLY at the FDA White Oak Campus** (10903 New Hampshire Ave, Silver Spring, MD 20903). If you are interested in attending the follow-up meeting, please be aware that:

1. There are a limited number of registration slots for this IN-PERSON meeting, and selections will be made based on the criteria listed below. **If selected, you will receive a final confirmed invitation to include registration information for the IN-PERSON session**. If you are interested in attending, **please mark your calendar.**
2. Final confirmed invitations to the IN-PERSON follow-up component of the meeting will be **contingent on attendance at the October 16th webinar** and will be first come, first served (i.e., based on timestamp of registration). If the number of interested registrants exceeds meeting capacity, invitees will be selected to maximize the number of stakeholder organizations represented in person.
3. Final confirmed invitations to the IN-PERSON component of the meeting will be sent **no later than October 18th**. Please note, represented organizations and a high-level summary of the IN-PERSON component of the meeting will be made publicly available.

Agenda for October 26:

9:00 – 9:20: Check-In and Arrival

9:20 – 9:30

Welcoming Remarks and Introduction

Darlese Solorzano, MS, MBA
Manager, BsUFA Regulatory Science Pilot Program
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ) | CDER | FDA

9:30 – 10:15

Roundtable #1 – Regulatory Impact Goal #1 (Revised Priorities A-D)

BsUFA III Pilot Program Leadership

10:15 – 10:30 BREAK

10:30 – 11:15

Roundtable #2 – Regulatory Impact Goal #2 (Revised Priorities E-H)

BsUFA III Pilot Program Leadership

11:15 – 11:30

Conclusions and Closing Remarks

BsUFA III Pilot Program Leadership

11:30 – 12:00: DEPARTURE