

FDA Public Workshop

Future Needs for the Development of Interchangeable Products

Agenda for FDA Public Workshop September 19, 2025 / 9:00 am – 1:00 pm EST

Time	Event (and Proposed Speakers / Panelists)
9:00 – 9:10am	Opening Remarks (Sarah Yim)
9:10 – 9:30am	Keynote Address (George Tidmarsh)
9:30 – 10:30am	Landscape of Stakeholder Perspectives: Future Needs for the Development of Interchangeable Products (15 min presentation each) <ul style="list-style-type: none">• AAM (Jessica Greenbaum)• Biosimilar Forum (Juliana Reed)• PhRMA (Kristy Lupejkis)
10:30 – 11:00am Break	
11:00 – 11:20am	Specific scientific topic: Analytical considerations around interchangeability of a biologic (CDER/OPQ – Maria-Teresa Gutierrez Lugo)
11:20 – 11:40am	Specific scientific topic: User interface and human factor considerations around interchangeability (CDER/OSE/DMEPA – Ariane O. Conrad and Matt Barlow)
11:40am – 12:00pm	Specific scientific topic: Other considerations around interchangeability of biological products (CDER OND – Stacey Ricci)
12:00 – 12:45pm	Panel Discussion (Moderated by Sarah Yim) <ul style="list-style-type: none">• Moderated dialogue/panel discussion between presenters• Panelists include speakers from earlier presentations (Representatives from AAM, Biosimilar Forum, PhRMA, OPQ, and DMEPA)• Audience Q&A
12:45 – 1:00pm	Summary and Close Out (Sarah Yim)

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

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 *Interchangeable Workshop* in the subject line.

