

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

and include *Interchangeable Workshop* in the subject line.



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