



Value Added Medicines Week

2022 Conference

Washington DC

October 24th – October 26th

Development and
Commercialization
Challenges of Biosimilars



Presented by:



What is VAM Week

A conference fully dedicated to furthering the understanding of Value-Added Medicine development, approval and commercialization.

The conference program has 2 separate tracks for professionals to learn. The mission of the conference is to increase the awareness and understanding of all types of Value-Added Medicines.



2022 VAM Week Conference

This year's conference focuses on biosimilar and 505(b)(2) products.

The conference is a hybrid conference with attendance available both in-person and virtually.

The conferences focus and expert speakers deliver a great way to learn about development and commercialization of all value-added medicine types.



Day 1: Monday, October 24th, 2022

	Business Track	Technical Track
9:00 – 10:00 am	Breakfast and Networking	
10:00 – 11:00 am	Keynote: Panel discussion to Initiate a consensus surrounding biosimilar and 505(b)(2) Challenges John Fowler, Wells Fargo	
11:00 – 12:00 pm	Combination Health Products Thomas Goss, Varanex Solutions	In Vitro Analytical Challenges to Biosimilarity
12:00 – 1:00 pm	Lunch	
1:00 – 2:00 pm	Digital Health and 505(b)(2)s Tom Cassel, Rock Health	In Vitro Immunogenicity fo Biosimilars Susan Krishner, FDA
2:00 – 3:00 pm	Biosimilar Regulatory Issues Lea Crystal, Amgen Keara Sauber, Novel351K	Challenges to Achieving Biosimilarity
3:00 – 3:30 pm	Break and Networking	
3:30 – 4:30 pm	Biosimilar Value, Access, Pricing, and Reimbursement Brian Siemak, Syneos	Panel Discussion
4:30 onward	Networking and Individual Meetings	

Day 1 featured speakers from: Wells Fargo, FDA, Amgen, Rock Health, Novel351K, Varanex, and Syneos

Learn more about combination health products, pricing and access challenges of biosimilars and the challenge of achieving biosimilarity



Day 2: Tuesday, October 25th, 2022

	Business Track	Technical Track
9:00 – 10:00 am	Breakfast and Networking	
10:00 – 11:00 am	Biosimilars Commercialization Dominic Marasco, BioAgilytix Chad Petit, Amgen	Clinical Studies to Demonstrate Interchangeability Stacy Ricci, FDA
11:00 – 12:00 pm	Avoiding Substandard Clinical Trials Cmdr. Wes Ishihara, FDA	Challenges to Demonstrate Interchangeability Hillel Cohen, Sandoz
12:00 – 1:00 pm	Lunch	
1:00 – 2:00 pm	Post-Approval Studies in the Value- Added Medicines Market Kevin Bugin, FDA	Semglee® Interchangeability Case Study David Rosen, Foley & Lardner
2:00 – 3:00 pm	Emerging Biosimilars Issues Chad Petit, Amgen	Cyltezo® Interchangeability Case Study
3:00 – 3:30 pm	Break and Networking	
3:30 – 4:30 pm	Emerging Biosimilars Issues Sonia Oskouei, Cardinal Biosimilars	Panel Discussion
4:30 onward	Networking and Individual Meetings	

Day 2 featured speakers
from: FDA, Sandoz, Amgen,
and Cardinal

Learn about the state of
the biosimilar industry
with reports from Amgen
and Cardinal, FDA views
and secrets of biosimilar
commercialization



Day 3: Wednesday, October 26th, 2022

	Business Track	Technical Track
9:00 – 10:00 am	Breakfast and Networking	
10:00 – 11:00 am	Value Added Medicines Outside the U.S. Maja Graf, Medicines for Europe Marta Baldrighi, Medicines for Europe	Labeling Biosimilar Products Ruby Wu, FDA
11:00 – 12:00 pm	Commercialization of Interchangeable Biosimilar Products Dominic Marasco, BioAgilytix Keara Sauber, Novel351K Sarfaraz Niazi, University of Illinois	
12:00 – 1:00 pm	Lunch	
1:00 – 2:00 pm	CMS/FDA Relationship Charlene Frizzera, CMS Susan Winckler, Reagan-Udall Foundation for the FDA	Comprehensive Biosimilars Panel Discussion
2:00 – 3:00 pm	Closing Session Panel discussion to initiate a consensus surrounding biosimilar and 505(b)(2) challenges	
3:00 – onward	Networking and Individual Meetings	

Day 3 featured speakers from: FDA, Medicines for Europe, Reagan-Udall Foundation, BioAgilytix, and others

Learn about Commercializing Biosimilars, the future of Value-Added Medicines outside the US, the CMS/FDA relationship and biosimilar labeling



Secure your seat!

Choose a Registration That Meets Your Needs

There are 2 types of registration for the conference

**In-person attendance
(limited FCFS)**



Online attendance



In-person spots are filling up fast
Register today

Register Today

