United States Pharmacopeia

May 20, 2025 8:00 AM - May 21, 2025 5:00 PM

12601 Twinbrook Pkwy, , Rockville, MD 20852-1717 , USA

DIA/USP Evolution of Biosimilars Development Workshop

Evaluating what we have learned and where we are headed

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Print Agenda

Day 1 May 20, 2025

8:00 AM — 4:45 PM

Conference Registration

8:00 AM — 9:00 AM

Networking Breakfast

9:00 AM — 9:15 AM

Welcome and Opening Remarks

Track: General Session

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

9:15 AM — 10:15 AM

Session 1: Keynote Address - State of the Industry

In this session, speakers will provide an overview of the biosimilars industry in the US, the FDA biosimilars program current and future state (evolution) as well as an overview of the industry from an economic perspective. The session will include insights on how the industry is responding to the new Administration, as well as planning for the future. In addition, the FDA will provide their insights on what the Agency sees and plans for the future of biosimilar development and regulatory oversight. Finally, Murray Aitken from IQVIA will provide an insightful analysis of the current biosimilars market place, the opportunity for biosimilars in the US and the "biosimilars void" that needs to be addressed and solved for by the attendees of this important conference so that industry can continue to develop low cost biosimilars for the patients who need them.

Learning Objective :

- Understand the current and future state of the US biosimilar industry
- Articulate the evolving perspectives of the FDA OTBB on the regulatory landscape for biosimilar development, review, and approval in the US
- Explore the US biosimilars market, identify the "biosimilars void," and discuss necessary changes to address this gap and foster biosimilar development in the US

Session Chair(s)

Juliana Marguerite Reed, MS

Executive Director
The Biosimilars Forum, United States

Juliana been engaged in global biosimilar policy for over 15 years through her current position as well as her previous work for Hospira, Coherus BioSciences and as the President of the Biosimilars Forum. Ms. Reed has direct pre and post approval market experience in multiple countries across at least 9 biosimilars on the market today. In addition to her corporate positions, Ms. Reed has previously served on the board of the Generic Drug Association in the US, the board of Medicines for Europe, and was a co-founder of the US Biosimilars Forum where she is currently serving as the Forum's Executive Director.

Speaker(s)

Current and Future Perspectives of the FDA Biosimilars Program

Sarah Yim, MD

Director, Office of Therapeutic Biologics and Biosimilars, OND, CDER
FDA, United States

Sarah Yim, M.D. has been the Director of the Office of Therapeutic Biologics and Biosimilars, in CDER's Office of New Drugs (OND), FDA since 2019. Prior to that, she spent 2 years as Director of the Division of Clinical Review in the Office of Generic Drugs, and 11 years in various roles in rheumatology drug review in OND. She received her undergraduate degree from Stanford University, her Doctor of Medicine degree from the Uniformed Services University of Health Sciences, and completed a postdoctoral fellowship in rheumatology at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), at the National Institutes of Health.

Current and Future US Biosimilars Market, and the "Biosimilars Void and What to do About it"

Murray Aitken, MBA

Executive Director
IQVIA Institute for Human Data Science, United States

Murray Aitken is a senior vice president of IQVIA and Executive Director of the IQVIA Institute for Human Data Science. The Institute undertakes independent research for publication, drawing upon the resources of IQVIA, and focuses on improving understanding of critical healthcare issues around the world, including the role of medicines in patient care, the disruptive impact of technology, productivity in research and development, and the value of information in improving decision-making. Murray directs the research agenda and co-authors reports, while also engaging externally with a broad range of healthcare decision-makers in the public and private sectors.

10:15 AM — 10:30 AM

Networking Break

10:30 AM — 11:45 AM

Session 2: Global Regulatory Updates for Biosimilars

This session will build on the previous session (Session 1 US State of the Industry) and put evolution of biosimilar development into the global context of one scientific approach that can enable to the same streamlined biosimilar development package to achieve licensure in multiple jurisdictions ideally concurrently.

While EU and US are the leading markets for biosimilars considerations will be given to recent changes in other regions (ideally representing each of the main continents), with reviews of regulatory developments from US, Europe, Canada, Japan, Korea, and Brazil. A compare and contrast approach will be taken with discussions centering around the opportunities to harmonize, and the revised WHO Guidelines (Apr22) will be discussed as an umbrella for the immediate opportunity for improved regulatory efficiency.

In particular, assuming that the ICH Biosimilar Guideline proposed by US FDA November 2024 is endorsed by the ICH Management Committee in March, the aspirations of that guideline will be discussed. This will comport with the IPRP White paper being developed on CES.

Learning Objective :

- Describe the expectations across jurisdictions for the development of biosimilars and recognize their fundamental basis in analytical comparability
- Differentiate between biosimilars and originator biologics in terms of the primary regulatory basis of their approval
- Recognize that all biologics are subject to the same quality requirements in any ICH-compliant jurisdiction, and be able to describe those principles

Track: General Session

Session Chair(s)

Gillian Woollett, PhD, MA

Vice President, Head Regulatory Strategy and Policy
Samsung Bioepis, United States

Dr. Gillian Woollett joined Samsung Bioepis in November 2021 as VP, Head Regulatory Strategy and Policy, US (SBUS), to stand up a U.S. presence for science-based regulatory strategy and policy in the leading global market for biologics. Previously, she was SVP and Principal Regulatory Scientist at Avalere Health and, prior to that, Chief Scientist and Administrator at Engel & Novitt, LLP. Dr. Woollett was VP of Science and Regulatory Affairs at BIO and AVP at PhRMA, where she worked on biosimilars policy. Dr. Woollett earned her B.A., M.A. in Biochemistry from the University of Cambridge, and her D.Phil. in Immunology from the University of Oxford. She was a post-doc at the University of Edinburgh and the Biomedical Research Institute.

Speaker(s)

Expectations for an ICH Guideline on biosimilars – Why Now and How Far?

Sarah Yim, MD

Director, Office of Therapeutic Biologics and Biosimilars, OND, CDER
FDA, United States

Sarah Yim, M.D. has been the Director of the Office of Therapeutic Biologics and Biosimilars, in CDER's Office of New Drugs (OND), FDA since 2019. Prior to that, she spent 2 years as Director of the Division of Clinical Review in the Office of Generic Drugs, and 11 years in various roles in rheumatology drug review in OND. She received her undergraduate degree from Stanford University, her Doctor of Medicine degree from the Uniformed Services University of Health Sciences, and completed a postdoctoral fellowship in rheumatology at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), at the National Institutes of Health.

EMA Concept Paper and Considerations for the EMA Reflections Paper

Steffen Thirstrup, MD, PhD

Chief Medical Officer
European Medicines Agency, Netherlands

Dr. Steffen Thirstrup, MD, PhD, has been Chief Medical Officer at the European Medicines Agency (EMA) since June 2022. A specialist in clinical pharmacology, he has held leadership roles at the Danish Medicines Agency, served as a CHMP member at EMA, and co-chaired the European Commission's biosimilar market access group. An adjunct professor at the University of Copenhagen, Dr. Thirstrup has authored over 40 publications and co-edited a key Danish pharmacology textbook. He divides his time between Amsterdam and Værløse, Denmark.

Speaker

Representative Invited

World Health Organization, Switzerland

11:45 AM — 12:45 PM

Networking Luncheon

12:45 PM — 2:00 PM

Session 3: Enhancing Patient Access by Streamlining the Development of Safe, Effective, and High Quality

Biosimilars

Breaking the clinical comparative efficacy study barrier will redefine the trajectory for the development of safe, effective, and high quality biosimilars, providing a critical tool for addressing the “biosimilar void” and enhancing patient access. Global regulatory authorities are increasingly recognizing that a robust biosimilarity program can be supported by comprehensive analytical and pharmacokinetic studies, with comparative efficacy studies—the least sensitive tool for detecting differences—as scientifically unnecessary. Beyond comparative efficacy studies, there exist additional opportunities to enhance development and review efficiencies, without any compromise to safety, effectiveness, or quality, such as shifting towards a global comparator, or, at minimum, an “analytical only” bridge to justify the use of foreign comparators.

Learning Objective :

- Identify the scientific rationale for eliminating the need for comparative efficacy trials as well as other strategies to streamline biosimilar development
- Evaluate regulatory perspectives on streamlining development
- Analyze how streamlining development can reduce development costs and address the biosimilar void, thereby enhancing patient access to safe, effective, and high quality biosimilars

Track: General Session

Session Chair(s)

Jessica Greenbaum

Director, Regulatory Affairs Policy U.S.
Sandoz Inc., United States

Speaker(s)

Speaker

Representative Invited

AGES, Austria

René Anour started his doctoral studies at the Institute of Pathophysiology at the University of Veterinary Medicine, Vienna where his research was focused on bone and mineral homeostasis. After graduation he was invited as a visiting scientist to Harvard School of Dental Medicine, Boston, where he continued his research. He is working as a senior clinical expert for the Austrian Federal Office for Safety in Health Care, where he is involved in centralised Marketing Authorisations and Scientific Advice. He participates in the EMA’s Biosimilar Working Party, and is the manager of National Scientific Advice at the Austrian Agency.

Speaker

Stacey Ricci

Director, Scientific Review Staff, OTBB, CDER

US FDA, United States

Dr. Stacey Ricci is the Director of the Scientific Review Staff in the Office of Therapeutic Biologics and Biosimilars at CDER. She has contributed to FDA guidance and standards for biotechnology-derived therapeutic proteins, particularly biosimilars. Dr. Ricci leads a multidisciplinary team overseeing the review of biosimilar and interchangeable products, advancing biosimilar policy, scientific research, and stakeholder engagement. Before joining the FDA in 2005, she completed post-doctoral research at the University of Pennsylvania and earned her Doctor of Science from Tulane University, along with a Master of Engineering and Bachelor of Science from Cornell University

Speaker

João Tavares Neto, MSc

Regulatory Specialist
Brazilian Health Regulatory Agency (ANVISA), Brazil

Mr. João Tavares Neto, MSc, has been a staff member at the Brazilian Health Regulatory Agency (Anvisa) since 2005. He headed the Drug Bioequivalence Department, where he participated in the development of regulations related to biowaivers and bioanalytical methods. Since 2018, he has been working in the field of biological products and has contributed to the development of recent regulations on post-approval changes for biologicals, biosimilar registration, and bioanalysis. He represents the biological products division in the ICH Q2/Q14 Implementation Working Group and the IPRP Biosimilars Working Group.

2:00 PM — 3:15 PM

Session 4: Role of Analytics in Meeting Regulatory Expectations

Biosimilar developers around the world are evaluating the ability of new analytical technologies to establish biosimilarity. More comprehensive analytical testing can increase regulatory confidence, and ultimately improve efficiency and help with risk management related to clinical assessment. Participants will discuss approaches to facilitating greater analytical similarity, including the role of harmonized methods, guidances, standards, and other tools that can enhance global convergence and improve efficiency of testing and regulatory review.

Learning Objective :

- Describe strategies for implementing new ICH guidelines Q2(R2) and Q14
- Define analytical tools and platform approaches for biosimilar characterization
- Identify emerging technologies to improve efficiency
- Discuss opportunities for greater analytical convergence

Session Chair(s)

Diane McCarthy

Senior Director, Science and Standards ,Global Biologics Department
USP, United States

Dr. McCarthy is Senior Director, Science and Standards in the Global Biologics Department at the US Pharmacopeia. She leads development and maintenance of standards and tools to support quality of medicines and oversees the USP biologics laboratories in the US and India. Her team supports a diverse range of biological therapies, including monoclonal antibodies and other protein therapeutics, vaccines, peptides, and cell and gene therapy. Prior to joining USP, Diane worked for several small CROs that focused on the use of mass spectrometry for characterization of biologics, host cell proteins, and biomarkers. Dr. McCarthy earned her Ph.D. in Biochemistry from the University of Texas at Austin.

Speaker(s)

Strategies for Implementing ICH Guidelines- Regulator Perspective

Representative Invited

US FDA, United States

Dr. Joel Welch is the Deputy Office Director for the Office of Product Quality Assessment III in the Office of Pharmaceutical Quality at CDER, FDA. His office assesses product quality for small molecule APIs and biological products (excluding microbiology). He serves as the Rapporteur for the ICH revision to Q5A(R1) and Chair for the Emerging Technology Program. Previously, Dr. Welch was Associate Director for Science & Biosimilar Strategy, focusing on policy and emerging issues in the biosimilar program. He has held roles as Review Chief, Team Leader, Primary Assessor, and Regulatory Project Manager. Prior to FDA, he worked in industry for six years on late-stage analytical development of small molecules

The Importance of International Standards in the Product Life Cycle of Biosimilars

Sandra Prior

Principal Scientist, NIBSC
MHRA, United Kingdom

Assay Standardization and Compendial Approaches in Support of Biosimilars' Development

Kevin Carrick, PhD

Senior Director, Science and Standards, Biologics
United States Pharmacopei, United States

Dr. Kevin Carrick is a Senior Director of Science & Standards in USP's Global Biologics Department. Dr. Carrick and his team work with the five USP Expert Committees and multiple Expert Panels in the area of biologics to develop standards that support biopharmaceutical quality assessment. These standards include documentary (monographs and general chapters) and physical reference standards for varied products from oligonucleotides to gene therapies.

3:15 PM — 3:30 PM

Networking Break

3:30 PM — 5:00 PM

Session 5: BsUFA III Regulatory Research Pilot Program

The Commitment Letter for the last reauthorization of the Biosimilar User Fee Act specified a new regulatory science pilot program with funding derived from biosimilar user fees. The research programs were to be directed towards advancing the development of interchangeable products and improving the efficiency of biosimilar product development. Requests for project proposals were issued, and FDA selected six research projects to be conducted by external scientists and 14 by FDA scientists. Some data is now available. This session will review the status of the program as well as the data obtained from several of the research projects.

Learning Objective : At the conclusion of this session, participants should be able to:

- Describe the status of the Biosimilar Regulatory Research Pilot Program
- Summarize the results obtained from some of the funded projects
- Understand how these results might be applied to future biosimilars

Track: General Session

Session Chair(s)

Hillel P Cohen, PhD

Biosimilars Expert
Retired, United States

Dr. Hillel P. Cohen PhD is Executive Director of Scientific Affairs at Sandoz, helping explain the principles of biosimilars and biosimilar policies to the healthcare community, patient advocacy groups, and health authorities. He has published and given presentations in the areas of biosimilar education, switching, interchangeability, naming and safety. Dr. Cohen led Sandoz efforts for the first biosimilar presentation (Zarxio®) to an FDA advisory committee and participated in both BsUFA 2 and BsUFA3 negotiations on behalf of industry. Hillel is active on the Education Committees including the Biosimilars Council and the Biosimilars Forum. Dr. Cohen received a BA from New York University and a PhD in Biology from Dartmouth.

Speaker(s)

Kimberly Maxfield, PhD

Pharmacologist and BsUFA Reg Sci Lead
FDA, United States

Speaker

Diane McCarthy

Senior Director, Global Biologics
US Pharmacopeia, United States

Speaker

Anne De Groot, MD

CEO
EpiVax, United States

Dr. De Groot graduated with an M.D. from Pritzker School of Medicine / University of Chicago in 1983, with a specialty in Internal Medicine. In 2008, she became a faculty member at the University of Rhode Island. She established EpiVax, an immunoinformatics company, in May 1998

Speaker

Anna Schwendeman

William I. Higuchi Collegiate Professor, Pharmaceutical Sciences
University of Michigan, United States

Day 2 May 21, 2025

8:00 AM — 4:00 PM

Conference Registration

8:00 AM — 8:30 AM

Networking Breakfast

8:30 AM — 8:50 AM

Welcome to Day Two: Set the Stage for Workshops

This full-day workshop series will explore the evolving global landscape of biosimilar development, addressing regulatory complexities, scientific advancements, and opportunities for greater efficiency. Through interactive discussions and collaborative exercises, participants will analyze regulatory similarities and differences across key markets, identify roadblocks to streamlined development, and envision the future state of biosimilar innovation. Attendees will engage with industry leaders, regulators, and stakeholders to map out actionable strategies that drive regulatory convergence, optimize development pathways, and enhance global patient access to biosimilars.

Track: General Session

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

8:50 AM — 10:20 AM

Workshop #1: What's the Same and What's Different: Navigating Global Biosimilar Regulations

Biosimilar development is governed by a complex web of regulatory requirements that vary across global markets. This interactive workshop will engage participants in evaluating key similarities and differences in biosimilar regulations across regions, including the U.S., EU, Canada, Japan, Korea, and Brazil. Through a collaborative mapping exercise, attendees will identify areas of alignment, analyze regulatory fragmentation, and explore opportunities for greater efficiency and global harmonization. The session will conclude with a discussion on actionable strategies to advance regulatory convergence and streamline biosimilar development worldwide.

Learning Objective :

- Compare and contrast biosimilar regulatory frameworks across major global markets, identifying key areas of alignment and divergence
- Evaluate regulatory challenges related to biosimilarity definitions, data requirements, reference product selection, and post-market expectations

- Identify opportunities for regulatory efficiency and harmonization to facilitate a more streamlined global biosimilar development process

Track: General Session

Session Chair(s)

Gillian Woollett, PhD, MA

Vice President, Head Regulatory Strategy and Policy
Samsung Bioepis, United States

Dr. Gillian Woollett joined Samsung Bioepis in November 2021 as VP, Head Regulatory Strategy and Policy, US (SBUS), to stand up a U.S. presence for science-based regulatory strategy and policy in the leading global market for biologics. Previously, she was SVP and Principal Regulatory Scientist at Avalere Health and, prior to that, Chief Scientist and Administrator at Engel & Novitt, LLP. Dr. Woollett was VP of Science and Regulatory Affairs at BIO and AVP at PhRMA, where she worked on biosimilars policy. Dr. Woollett earned her B.A., M.A. in Biochemistry from the University of Cambridge, and her D.Phil. in Immunology from the University of Oxford. She was a post-doc at the University of Edinburgh and the Biomedical Research Institute.

10:20 AM — 10:35 AM

Networking Break

10:35 AM — 12:05 PM

Workshop #2: Identifying the Roadblocks and Pathway to Streamlined Development

As biosimilars continue to expand global access to critical therapies, optimizing the development and regulatory approval process remains a key priority. This interactive workshop will explore the current biosimilar landscape, highlighting scientific, regulatory, and stakeholder challenges that hinder efficiency. Participants will engage in a structured discussion to identify roadblocks, examine opportunities to streamline clinical and regulatory requirements, and address concerns about patient and provider acceptance. The session will conclude with actionable strategies to drive regulatory convergence and industry collaboration for a more efficient biosimilar development pathway.

Learning Objective :

- Analyze key scientific, regulatory, and stakeholder challenges that impact the efficiency of biosimilar development and approval
- Evaluate opportunities to streamline scientific requirements, such as reducing comparative efficacy trials and utilizing global comparators

- Develop strategies to enhance regulatory flexibility, promote industry-regulator collaboration, and improve patient and provider confidence in biosimilars

Track: General Session

Session Chair(s)

Jessica Greenbaum

Director, Regulatory Affairs Policy U.S.
Sandoz Inc., United States

12:05 PM — 1:05 PM

Networking Luncheon

1:00 PM — 2:35 PM

Workshop #3: Future State of Efficient Biosimilar Development

As biosimilar development evolves, scientific and regulatory advancements are paving the way for a more efficient and globally harmonized approach. This forward-looking workshop will explore emerging technologies, analytical innovations, and regulatory strategies that can reduce development burdens while ensuring biosimilar safety and efficacy. Participants will discuss key insights from regulatory research initiatives, examine opportunities for analytical convergence, and identify the policies, guidances, and collaborations needed to shape the future of biosimilar development. The session will conclude with actionable strategies for industry and regulators to drive innovation and efficiency.

Learning Objective :

- Evaluate emerging scientific and regulatory advancements that can streamline biosimilar development and reduce clinical trial requirements
- Identify opportunities for enhanced analytical convergence and regulatory flexibility to support a more efficient biosimilar approval process
- Develop actionable strategies for industry and regulatory collaboration to accelerate biosimilar innovation and global access

Track: General Session

Session Chair(s)

Diane McCarthy

Senior Director, Global Biologics
US Pharmacopeia, United States

2:35 PM — 3:15 PM

Workshop Reportouts and Closing Remarks

3:15 PM — 3:15 PM

Workshop Adjourns