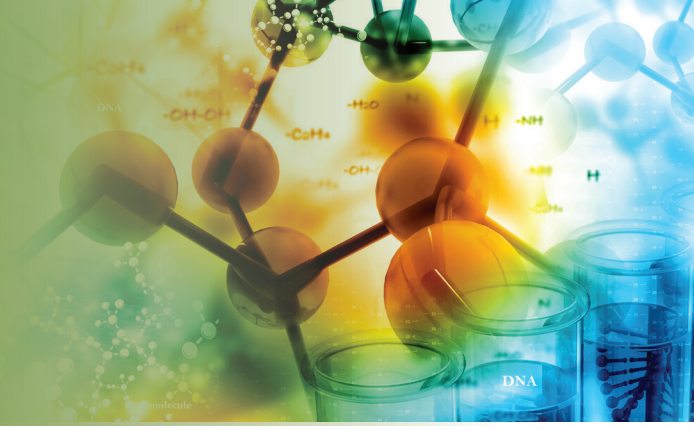
DIA
Biosimilars Conference

October 24-25 | Hyatt Regency Bethesda | Bethesda, MD



PROGRAM CHAIR

Cecil J. Nick, MS, FTOPRA
Vice President (Technical)
PAREXEL Consulting, United Kingdom

PROGRAM COMMITTEE

Leah Christl, PhD
Associate Director for Therapeutic Biologics, TBBS, Office of New Drugs
CDER, FDA

Hillel Cohen, PhD
Executive Director, Scientific Affairs
Sandoz, Inc.

Thomas Felix, MD
Medical Director, R&D Policy, Global Regulatory Affairs and Safety
Amgen, Inc.

Julie Marechal-Jamil, MSc
Director Biosimilars Policy and Science
Medicines for Europe, Belgium

Laura McKinley, PhD
Director, US Regulatory Policy and Intelligence
Pfizer Essential Health
Pfizer, Inc.

John Pakulski, RPh
Head, Regulatory Science, Biologics
Mylan, Inc.

Juliana Marguerite Reed, MS
Vice President, Government Affairs
Coherus BioSciences

Emily Shacter, PhD
Independent Consultant
ThinkFDA, LLC

Cornelia Ulm
Head of Regulatory Affairs, Biosimilars
Fresenius Kabi, Switzerland

Jian Wang, MD, PhD
Chief, Clinical Evaluation Division - Haematology/Oncology, HPFB
Health Canada

Overview

As the landscape of biosimilar development and requirements evolves, new areas of focus include uptake and life cycle management of these products. DIA's *Biosimilars Conference* brings you the most current science and regulatory developments for biosimilars, as well as the newest thinking and approaches on pharmacovigilance, prescriber and patient education, and access in the US, EU, Canada, and other regions.

Highlights

- Review the state of science analytical tools and biological assays in the evaluation of molecular similarities and differences and the assessment of significance of differences
- **Ask the Regulators Session:** Dedicated question and answer session on regional-specific and global alignment issues with regulators from the EU, FDA, Health Canada, and PMDA
- Direct discussion with patients, prescribers, and payers on how these stakeholders perceive the role of biosimilars in health care
- A deep focus on the postmarket phase of biosimilars, from fundamental life cycle management issues and differences from original biologics, to changes needed to meet the opportunity for interchangeability

Who Should Attend

Professionals involved in:

- Biosimilar/Biologic Pharmaceuticals
- Biomedical Product Development and Manufacturing
- Regulatory Affairs
- Clinical and Nonclinical Research
- Biostatistics and Data Management
- Business Development
- Marketing and Commercialization
- Medical Communications/MSLs
- Patient Advocacy/Patient Support Programs

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#Biosimilars17 | DIAglobal.org

As of October 12, 2017.

Schedule At-A-Glance

DAY ONE | TUESDAY, OCTOBER 24		ROOM
7:00AM-5:30PM	Registration	Regency Ballroom Foyer
7:00-8:00AM	Continental Breakfast and Networking	Regency Ballroom Foyer
8:00-8:20AM	**Welcoming Remarks**	Regency Ballroom I&II
8:20-8:45AM	**Opening and Introduction to the Conference**	Regency Ballroom I&II
8:45-10:30AM	**Session 1:** Emerging Approaches to Demonstrating Structural and Functional Similarity	Regency Ballroom I&II
10:30-11:00AM	Refreshment and Networking Break	Regency Ballroom Foyer
11:00AM-12:30PM	**Session 2:** Role of Clinical Trials in Biosimilar Development	Regency Ballroom I&II
12:30-1:30PM	Luncheon and Networking	Terrace
1:30-2:45PM	**Session 3:** Impact of US FDA Final Naming Guidance for Biologics	Regency Ballroom I&II
2:45-3:30PM	**Session 4:** How Will BsUFA II Modify the Development and Approval of Biosimilars in the US?	Regency Ballroom I&II
3:30-3:45PM	Refreshment and Networking Break	Regency Ballroom Foyer
3:45-5:30PM	**Session 5:** Penetrating the Market	Regency Ballroom I&II
5:30-6:30PM	**Networking Reception**	Regency Ballroom Foyer
DAY TWO | WEDNESDAY, OCTOBER 25		
7:00AM-3:15PM	Registration	Regency Ballroom Foyer
7:00-8:00AM	Continental Breakfast and Networking	Regency Ballroom Foyer
8:00-8:10AM	**Opening Remarks**	Regency Ballroom I&II
8:10-10:10AM	**Session 6:** Taking the International Pulse: What's New in the Policy and Regulatory Landscape?	Regency Ballroom I&II
10:10-10:30AM	Refreshment and Networking Break	Regency Ballroom Foyer
10:30-11:15AM	**Session 7:** Ask the Regulators	Regency Ballroom I&II
11:15AM-12:15PM	**Session 8:** Postmarketing Phase: Approval is Just the Beginning	Regency Ballroom I&II
12:15-1:30PM	Luncheon and Networking	Terrace
1:30-3:00PM	**Session 9:** Interchangeability	Regency Ballroom I&II
3:00-3:15PM	Closing Remarks	Regency Ballroom I&II

Learning objectives

At the conclusion of this conference, participants should be able to:

- Describe recent advances in powerful analytic techniques for demonstrating biochemical, physicochemical, and functional similarity of molecules
- Explain how regulators and sponsors justify or reject molecular and functional differences
- Identify the procedural changes necessary to adhere to the US FDA final naming guidance for biologics and their system-wide impact on stakeholders
- Assess the impact of the implementation of BsUFA II provisions on biosimilar development and approval processes
- Discuss the range of perspectives of patients, payers, and prescribers on the use of biosimilar therapies
- Analyze how international policy and regulatory developments may affect local biosimilar programs
- Compare and contrast the life cycle management of a biosimilar with that of an original biologic
- Define the US expectations for demonstration of interchangeability

Continuing Education

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 12.5 contact hours or 1.25 continuing education units (CEUs). Participants must attend both days of the conference in order to be able to receive an ACPE statement of credit. **No partial credit will be awarded.**

ACPE Credit Requests MUST BE SUBMITTED by FRIDAY, DECEMBER 8, 2017.

Type of Activity: Knowledge; 0286-0000-17-068-L04-P

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DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer the up to 1.3 CEUs. Participants must attend the entire conference, in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the conference, fill out the attendance verification form in your folder and hand it in at the end of the conference, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, November 8, 2017**.

The online evaluation closes on **Wednesday, November 15, 2017**.

This event is approved by the Regulatory Affairs Professionals Society for 12 RAC credits.

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**Presentations will be available for six months post conference.*

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

DAY ONE | TUESDAY, OCTOBER 24

7:00AM-5:30PM	**Registration** (Regency Ballroom Foyer)
7:00-8:00AM	**Continental Breakfast and Networking** (Regency Ballroom Foyer)
8:00-8:20AM	**Welcoming Remarks** (Regency Ballroom I&II) **Sudip Parikh, PhD** Senior Vice President and Managing Director, Americas DIA
8:20-8:45AM	**Opening and Introduction to the Conference** (Regency Ballroom I&II) **Cecil Nick, MS, FTOPRA** Vice President (Technical) PAREXEL Consulting, United Kingdom
8:45-10:30AM	**Session 1** (Regency Ballroom I&II) Emerging Approaches to Demonstrating Structural and Functional Similarity **Session Chair** **Emily Shacter, PhD** Independent Consultant ThinkFDA, LLC This session will address tools used for the demonstration of similarity based on biochemical, physicochemical, and functional comparison of a proposed biosimilar to a reference product. Presentations and a panel discussion will provide data and insights on the use of state of the art analytical techniques and biological assays that can identify and quantify molecular similarity and differences. The use of quantitative approaches for evaluation of the similarity data as well as application of scientific considerations to the acceptability of observed differences will be discussed. **Patrick Lynch, PhD** Biologist, Product Quality Reviewer CDER, FDA **Martin Schiestl, PhD** Chief Science Officer Sandoz GmbH, Austria **Elizabeth Pollitt, PhD** Director BioPharma CMC Regulatory Consultancy Services, Ltd., United Kingdom **Kyung-Ah Kim, PhD** Vice President, Quality Evaluation Team Samsung Bioepis, Republic of Korea
10:30-11:00AM	**Refreshment and Networking Break** (Regency Ballroom Foyer)

DAY ONE | TUESDAY, OCTOBER 24

11:00AM-12:30PM

Session 2 (Regency Ballroom I&II)
Role of Clinical Trials in Biosimilar Development

Session Chair
Cecil J. Nick, MS, FTOPRA
Vice President (Technical)
PAREXEL Consulting, United Kingdom

Clinical trials currently represent a fundamental component of the biosimilar development program but are the trials that are currently advocated by the regulators designed to address the right questions, and how feasible will such trials be in the future? Often the potential for therapeutic equivalence may be obvious from in vitro, PK, and PD studies without the need for extensive therapeutic equivalence trials. Still, residual uncertainties might persist that only clinical studies in patients can address. Speakers will explore what these issues are and whether clinical trials are always needed; where trials are needed, what questions they should address, and if better approaches exist than are currently applied.

Cecil J. Nick, MS, FTOPRA
Vice President (Technical)
PAREXEL Consulting, United Kingdom

Richard Markus, MD, PhD
Vice President, Global Development
Amgen, Inc.

Julie Ann Rosenberg, MD
Development Asset Lead, Oncology Biosimilars
Pfizer Essential Health

Sue Lim
Medical Officer, Therapeutic Biologics and Biosimilars Staff
FDA

12:30-1:30PM

Luncheon and Networking (Terrace)

1:30-2:45PM

Session 3 (Regency Ballroom I&II)
Impact of US FDA Final Naming Guidance for Biologics

Session Chair
Hillel Cohen, PhD
Executive Director, Scientific Affairs
Sandoz, Inc.

In January 2017, the FDA issued a Final Guidance on the naming of biologics, including originator biologic medicines and biosimilars. The FDA is developing plans to roll out this new naming convention both prospectively and retrospectively. Likewise, numerous stakeholders throughout the US health care system have already or will adapt their current processes to accommodate the Final Guidance. This session will explore considerations for implementing the new system and provide an overview of some of these plans.

Kellie Taylor, PharmD, MPH
Associate Director, Office of Medication Error Prevention and Risk Management, Office of Surveillance and Epidemiology
CDER, FDA

Thomas Felix, MD
Medical Director, R&D Policy, Global Regulatory Affairs and Safety
Amgen, Inc.

Tammy Powell, MLIS, MS
Health Program Specialist
National Library of Medicine

Thomas Bizzaro, RPh
Vice President, Health Policy and Industry Relations
First Databank, Inc.

2:45-3:30PM

Session 4 (Regency Ballroom I&II)
How Will BsUFA II Modify the Development and Approval of Biosimilars in the US?

Session Chair
Thomas Felix, MD
Medical Director, R&D Policy, Global Regulatory Affairs and Safety
Amgen, Inc.

FDA and industry have negotiated a series of enhancements to the Biosimilars User Fee Act (BsUFA II). These include a revised review process meant to increase transparency and to facilitate an increase in the likelihood of first-cycle approvals; FDA commitments to complete and publish several draft and final guidance documents; FDA commitments to strengthen staffing levels of the biosimilars program; and enhancements to the user fee structure and management that will allow greater transparency, predictability, and long-term stability of biosimilar development programs in the US. This session will review these enhancements and the impact they are intended to have on the development and approval of biosimilars in the US.

Leah Christl, PhD
Associate Director for Therapeutic Biologics, TBBS, Office of New Drugs
CDER, FDA

Bruce Leicher, JD
Senior Vice President and General Counsel
Momenta Pharmaceuticals, Inc.

3:30-3:45PM

Refreshment and Networking Break (Regency Ballroom Foyer)

DAY ONE | TUESDAY, OCTOBER 24

3:45-5:30PM

Session 5 (Regency Ballroom I&II)
Penetrating the Market

Session Chair
Juliana Reed, MS
Vice President, Government Affairs
Coherus BioSciences

As the number of approved biosimilars in the US marketplace increases, understanding the perspectives and needs of the patient, payer, and prescriber are key requirements to ensure the successful uptake of biosimilars. This session will explore those perspectives and ways to address the needs of these important stakeholders.

Suzette Kox, MPharm
Senior Director International, Biosimilar Medicines Group
Medicines for Europe, Belgium

Angus Worthing, MD
Chair, Government Affairs Committee
American College of Rheumatology

Leah Howard, JD
Vice President, Government Relations and Advocacy
National Psoriasis Foundation

Chris Davis
Diector, Government Affairs
Express Scripts

Sarah Ikenberry
Health Communication Specialist/Press Officer
FDA

Cheryl Schwartz
General Manager, US Biosimilars
Pfizer, Inc

Tania Teixeira
FDA Liason
European Medicines Agency, EU

5:30-6:30PM

Networking Reception (Regency Ballroom I&II)

DAY TWO | WEDNESDAY, OCTOBER 25

7:00AM-3:15PM

Registration (Regency Ballroom I&II)

7:00-8:00AM

Continental Breakfast and Networking (Regency Ballroom Foyer)

8:00-8:10AM

Opening Remarks (Regency Ballroom I&II)

Cecil Nick, MS, FTOPRA
Vice President (Technical)
PAREXEL Consulting, United Kingdom

8:10-10:10AM

Session 6 (Regency Ballroom I&II)
Taking the International Pulse: What's New in the Policy and Regulatory Landscape?

Session Chair
Suzette Kox, MPharm
Senior Director International, Biosimilar Medicines Group
Medicines for Europe, Belgium

In this session, international regulators from the European Union, Japan, Canada, and the World Health Organization will each provide an overview of recent and future policy and regulatory developments in their country/region in the field of biosimilar medicines.

An update on lessons learned over the years of existence of the biosimilar pathway will set the scene for what's coming next and how experience will be factored in regulatory science to shape future evolutions in the biosimilar medicines field in terms of local/regional guidance and its implementation. The impact of international information exchange and collaboration platforms (bilateral and multi-lateral) will also be examined.

Ivana Knezevic, MD, PhD
Scientist, Technologies, Standards and Norms Team, Group Lead
World Health Organization, Switzerland

Cathy Parker
Director General, Biologics and Genetic Therapies Directorate, HPFB
Health Canada

Kyoto Sakurai, PhD
Reviewer, Cellular and Tissue-Based Products
Pharmaceuticals and Medical Devices Agency (PDMA), Japan

Leon Van Aerts
Senior Assessor
Medicines Evaluation Board, The Netherlands

Leah Christl, PhD
Associate Director for Therapeutic Biologics, TBBS, OND
CDER, FDA

10:10-10:30AM

Refreshment and Networking Break (Regency Ballroom Foyer)

DAY TWO | WEDNESDAY, OCTOBER 25

10:30-11:15AM

Session 7 (Regency Ballroom I&II)
Ask the Regulators

Session Chair
Juliana Reed, MS
Vice President, Government Affairs
Coherus BioSciences

Use this unique opportunity to share your pressing questions with the FDA and global regulatory and policy experts. Panelists will address questions posed live during the conference or submitted in advance to the DIA registration desk onsite. Questions may focus on information shared during the sessions, but may also branch out into other areas of biosimilars.

Leah Christl, PhD
Associate Director for Therapeutic Biologics, TBBS, OND
CDER, FDA

Cathy Parker
Director General, Biologics and Genetic Therapies Directorate, HPFB
Health Canada

Leon Van Aerts
Senior Assessor
Medicines Evaluation Board, The Netherlands

Jian Wang, MD, PhD
Chief, Clinical Evaluation Division, Haematology/Oncology, HPFB
Health Canada

Kyoto Sakurai, PhD
Reviewer
Pharmaceuticals and Medical Devices Agency (PDMA), Japan

11:15AM-12:15PM

Session 8 (Regency Ballroom I&II)
Postmarketing Phase: Approval is Just the Beginning

Session Chair
Charles Barr, MD, MPH
Chief Science Officer
AMCP Biologics and Biosimilars Collective Intelligence Consortium

Approval of a biosimilar is just the beginning. This session will address postmarketing opportunities and challenges, postmarket safety monitoring and risk management, and areas where life cycle management of biosimilars can differ from original biologics. Among topics to be explored: What changes will be needed to meet the opportunity for interchangeability? What happens when changes are made to the reference biologic? How do considerations for new indications, additional dosage forms and presentations, PREA requirements, labeling maintenance, and manufacturing changes differ when your product is a biosimilar rather than an original biologic?

Carlos Sattler, MD
Vice President, US Clinical Development and Medical Affairs
Sandoz, Inc.

Mark J. Cziraky, PharmD, CLS, FAHA, FNLA
Vice President, Industry Sponsored Research
Healthcore, Inc., A Subsidiary of Anthem, Inc.

12:15-1:30PM

Luncheon and Networking (Terrace)
Sign up for Round Table Discussions at the Registration Desk

1:30-3:00PM

Session 9 (Regency Ballroom I&II)
Interchangeability

Session Chair
Laura McKinley, PhD
Director, US Regulatory Policy and Intelligence, Pfizer Essential Health
Pfizer, Inc

The term “interchangeable” when applied to biosimilars has different meanings in different parts of the world. This session will begin with a review of terminology, including differences in US and EU definitions of interchangeability and regulatory and legal frameworks as they relate to substitution of biologics. You will then explore the US FDA draft guidance for industry on considerations in demonstrating interchangeability with a reference product, highlighting data expectations, and relaying industry perspectives on demonstrating interchangeability; discussing combination product considerations; and sharing perspectives on value and implementation in the US.

Daniel Alvarez, MD
Senior Director
Pfizer, Inc

Cindy Cao, PhD
Head, US Regulatory Affairs, Biopharmaceutical
Sandoz, Inc.

Jonah Houts
Vice President, Government Affairs
Express Scripts, Inc.

Daniel Nam
Executive Director of Federal Programs
America’s Health Insurance Plans

Leah Christl, PhD
Associate Director for Therapeutic Biologics, TBBS, OND
CDER, FDA

3:00-3:15PM

Closing Remarks (Regency Ballroom I&II)

3:15PM

Conference Adjourned