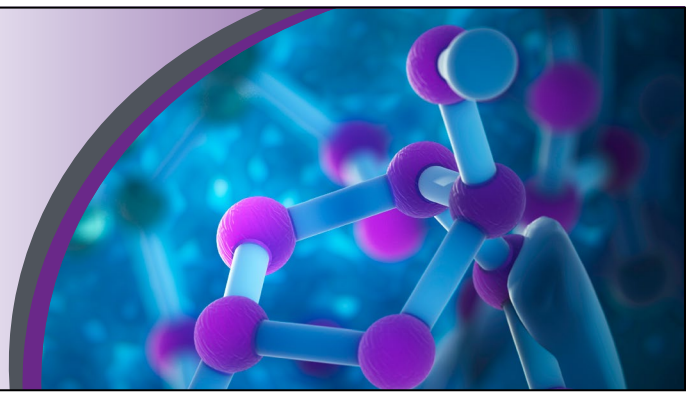
DIA Biosimilars 2014

September 18-19
Washington, DC



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

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Chief Science Officer
Sandoz Biopharmaceuticals
Chair of the European Biopharmaceuticals Group (EBG)
European Generic Medicines Association (EGA)

Register at **diahome.org/Biosimilars14**

DIA GLOBAL CENTER
21 Dupont Circle, NW, Suite 300
Washington, DC 20036

WORLDWIDE OFFICES
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OVERVIEW:

With the expiration of numerous patents for originator biologicals and the development of follow-on products, the market for biosimilars is growing at a rapid pace. These biosimilars and follow-on biologics have garnered great interest for their cost-effective benefits in patient care as well as development opportunities for sponsors who see a new revenue stream.

As biosimilars become more available to patients, there are important factors for patients and health care providers that must be addressed. This meeting will focus on the innovations, technologies, and regulatory information surrounding biosimilars.

This meeting will focus on:

- **US Regulatory Developments**
- **Scientific Advances: The Concept of Biosimilarity**
- **Global Regulatory Landscape**
- **Naming, Labeling and Postmarketing Activities**
- **Clinical Trial Designs**
- **US State Laws on Biosimilar Substitution**

LEARNING OBJECTIVES:

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

- Identify the unique challenges and complexities associated with demonstrating biosimilarity to a reference product
- Examine the implications for patients and healthcare professionals as biosimilars and (potentially) interchangeable biologics are introduced into the market

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CONTINUING EDUCATION CREDIT ALLOCATION

- Session 1 - **Scientific Advances: The Concept of Biosimilarity:** 1.5 contact hours or .15 CEUs, 0286-0000-14-078-L04-P
- Session 2 - **Policy Considerations:** 2 contact hours or .2 CEUs, 0286-0000-14-079-L04-P
- Session 3 - **Naming, Labeling and Postmarketing Activities:** 2 contact hours or .2 CEUs, 0286-0000-14-080-L04-P
- Session 7 - **Regulatory Update:** 1 contact hour or .1 CEU, 0286-0000-14-081-L04-P

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- Regulatory Affairs Certificate Program: 8 Elective Units

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THURSDAY, SEPTEMBER 18

7:45-8:45AM REGISTRATION AND CONTINENTAL BREAKFAST

8:45-9:00AM WELCOME AND OPENING REMARKS

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

Joerg Windisch, PhD
Chief Science Officer
Sandoz Biopharmaceuticals

9:00-10:00AM KEYNOTE SESSION

Speaker Invited

10:00-10:30AM REFRESHMENT BREAK

10:30AM-12:00PM SESSION 1

Scientific Advances: The Concept of Biosimilarity

Session Chair

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

Value of Physiochemical and Biological Data in Demonstrating Biosimilarity

FDA Speaker Invited

Quantitative Approach to Quality and Biological Data

EMA Speaker Invited

Value of Nonclinical and Clinical Data in Supporting Biosimilarity & Extrapolation

Joerg Windisch, PhD
Chief Science Officer
Sandoz Biopharmaceuticals

12:00-1:00PM LUNCHEON

1:00-3:00PM SESSION 2

Policy Considerations

Session Chair

David R. Gaugh, RPh
Senior Vice President
Sciences and Regulatory Affairs
Generic Pharmaceutical Association (GPhA)

FDA Perspective

FDA Speaker Invited

Will State Law Substitution Statutes and Unique Naming Restrict Biologic Innovation?

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

Pharmocovigilance

Thomas Felix, MD
Director, Research and Development Policy
Amgen Inc.

Panel Discussion

Gerald K. McEvoy, PharmD
Assistant Vice President, Drug Information
Editor-in-Chief, AHFS Drug Information and
Consumer Medication Information
American Society of Health-System Pharmacists

3:00-3:30PM REFRESHMENT BREAK

3:30-5:30PM SESSION 3

Naming, Labeling and Postmarketing Activities

Session Chair

Sundar Ramanan, PhD
Director
Global Biosimilars R&D Policy
Amgen Inc.

Naming: A Global Perspective

Speaker Invited

Geoff Eich
Executive Director
Regulatory Affairs - R&D Policy
Amgen

Labeling Product Information

Speaker Invited

PV and Risk Management

John D. Ayres, JD, MD
Senior Director, Product Safety Assessments
Global Patient Safety
Eli Lilly & Company

Pharmacy Practice

Gerald K. McEvoy, PharmD
Assistant Vice President of Drug Information
Editor-in-Chief, AHFS Drug Information and Consumer Medication Information
American Society of Health-System Pharmacists

Panel Discussion

5:30-6:30PM NETWORKING RECEPTION

FRIDAY, SEPTEMBER 19

7:30-8:30AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00AM SESSION 4

Global Regulatory Landscape

Session Chair

Jian Wang, MD, PhD
Chief
Clinical Evaluation Division - Haematology/Oncology,
Centre for Evaluation of Radiopharmaceuticals & Biotherapeutics
Biologics and Genetic Therapies Directorate
HPFB, Health Canada

Europe

EMA Speaker Invited

Canada

Catherine Parker
Senior Executive Director
Biologics and Genetic Therapies Directorate
Health Products and Food Branch
Health Canada

Korea (Virtual Presentation)

Jeewon Joung, PhD
Deputy Director
Korean Ministry of Food and Drug Safety (MFDS)

Panel Discussion

10:00-10:30AM REFRESHMENT BREAK

10:30AM-12:30PM SESSION 5

Clinical Perspectives

SESSION CHAIR

Stan Bukofzer, MD
Corporate Vice President
Chief Medical Officer
Hospira, Inc

Constructs of Biosimilar Approval

Rachel Sherman, MD, MPH, FACP
Principal
Drug and Biological Drug Products
Greenleaf Health

FDA Draft Guidance Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product

Darrell R. Abernethy, MD, PhD, FACP
Associate Director for Drug Safety
Office of Clinical Pharmacology
FDA

Interchangeability

Mark McCamish, MD, PhD
Global Head Development
Sandoz Biopharmaceuticals

Extrapolation

Sumant Ramachandra, MD, PhD
Senior Vice President, R&D and Medical Affairs
Chief Scientific Officer
Hospira, Inc.

Panel Discussion

12:30-1:30PM LUNCHEON

1:30-3:30PM SESSION 6

Commercialization

Session Chair Invited

Cost of Investing in Biosimilar Development

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

Sustainability Studies

Speaker Invited

Panel Discussion

3:30-4:00PM REFRESHMENT BREAK

4:00-5:00PM **SESSION 7**

Regulatory Update

SESSION CHAIR

Joerg Windisch, PhD
Chief Science Officer
Sandoz Biopharmaceuticals

Panel Discussion

Darrell R. Abernethy, MD, PhD, FACP
Associate Director for Drug Safety
Office of Clinical Pharmacology
FDA

Catherine Parker
Senior Executive Director
Biologics and Genetic Therapies Directorate
Health Products and Food Branch
Health Canada

Jian Wang, MD, PhD
Chief
Clinical Evaluation Division - Haematology/Oncology,
Centre for Evaluation of Radiopharmaceuticals & Biotherapeutics
Biologics and Genetic Therapies Directorate
HPFB, Health Canada

Additional Speakers Invited

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