DIA Biosimilars Conference 2016

Short Course: October 26 | Conference: October 27–28 | Renaissance Washington DC Dupont Circle Hotel | Washington, DC

PROGRAM CHAIR

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

PROGRAM COMMITTEE

Leah Christl, PhD
Associate Director for Therapeutic Biologics, OND Therapeutic Biologics and Biosimilars Team (TBBs), Office of New Drugs
CDER, FDA

Hillel P. Cohen, PhD
Executive Director, Scientific Affairs
Sandoz Biopharmaceuticals (a Novartis company)

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Merck Biopharma, Switzerland

Emily Shacter, PhD
Independent Consultant
ThinkFDA, LLC

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

Who Should Attend

- Pharmaceutical Executives
- Biomedical Product Developers
- Regulatory Affairs Professionals
- Clinical and Nonclinical Researchers
- Biostatisticians and Data Managers
- Business Development Executives
- Marketing and Commercialization staff involved with biosimilars

Overview

The development of biosimilars is increasing at a rapid pace in all global regions, including the US with FDA's approval of multiple biosimilars. With their potential for improving access to effective biological therapies through reduced costs, biosimilars have garnered great interest among industry, regulators, and payers. The 2016 conference will address issues around biosimilars science, global regulatory pathways, evidence for clinical applications, and education for prescribers and patients that are key to successful uptake of these products.

Highlights

Keynote Speaker
John K. Jenkins, MD
Director, Office of New Drugs, CDER
FDA

- Join your colleagues Thursday night, October 27, for a Networking Reception at 5:30PM
- Participate in the *Ask the Regulators* session with leaders from global regulatory agencies, Friday, October 28, 10:45-11:45AM
  - Panelists will address questions posed via written questions turned in to the registration desk, or by asking live at the session. Questions submitted in advance, must be received by 10:15AM on Friday, October 28
- **NEW** - Round Table Discussions during the luncheon on Friday, October 28, 11:45AM-1:00PM
  - Advance table registration is required. Contact Nadege Toth at Nadege.Toth@DIAglobal.org or stop by the registration desk

Message from Program Committee

Dear Colleagues,

We are pleased to welcome you to the DIA Biosimilars Conference 2016!

This conference is unique in setting the stage for an open, collaborative discussion of important topics related to biosimilar drug development among global representatives from industry, academia, nonprofit organizations, and regulatory agencies.

We will kick off with a preconference short course on Wednesday afternoon and the main conference will begin in the morning on Thursday, and will feature a keynote address, "The Current State of Biosimilars and Prospects for the Future", followed by sessions dedicated to the totality of the evidence, analytics, clinical considerations, education, real-world evidence, access, the science of biosimilars, and closing with a call to action.

We hope you will take advantage of the many opportunities to actively engage in discussions and with each other. Be sure to join us Thursday evening for the Networking Reception, and Friday during the luncheon for our new Round Table Discussions.

Best Regards,

The Biosimilars 2016 Program Committee

Just Released Podacast
Biosimilars Have at Last Come of Age in the United States
with DIA and Cecil Nick

Visit diapublications.podbean.com

TO ACCESS MY TRANSCRIPT:

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
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- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for the forum.

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Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder

Schedule At-A-Glance

SHORT COURSE | WEDNESDAY, OCTOBER 26

12:30–5:00PM	Short Course Registration
1:30–5:00PM	**Short Course:** Navigating the Complexities of Biosimilars Clinical Trial Development

DAY ONE | THURSDAY, OCTOBER 27

7:15AM-5:30PM	Registration
7:15-8:15AM	Continental Breakfast, Exhibits, and Networking
8:15–8:25AM	**Welcome and Opening Remarks**
8:25–8:45AM	**Keynote Address:** The Current State of Biosimilars and Prospects for the Future
8:45–9:45AM	**Session 1:** Determining Biosimilarity: By Use of Totality of the Evidence
9:45-10:15AM	Refreshments, Exhibits, and Networking Break
10:15–11:45AM	**Session 2:** Critical Quality Attributes (CQA)
11:45AM–1:00PM	Luncheon, Exhibits, and Networking
1:00–3:00PM	**Session 3:** Value/Relevance of Clinical Data: Challenges of Designing Clinical Studies and Generating Clinical Data
3:00-3:30PM	Refreshments, Exhibits, and Networking Break
3:30–4:30PM	**Session 4:** The Role of Real-World Evidence (RWE) in the Post-Approval Setting
4:30–5:30PM	**Session 5:** Education
5:30–6:30PM	Networking Reception

DAY TWO | FRIDAY, OCTOBER 28

7:30AM–5:00PM	Registration
7:15–8:15AM	Refreshments, Exhibits, and Networking Break
8:15–8:30AM	**Welcome to Day Two**
8:30–10:15AM	**Session 6:** Global Harmonization and Regulator Update
10:15–10:45AM	Refreshment Break and Networking
10:45–11:45AM	**Session 7:** Ask the Regulators
11:45AM–1:00PM	**Luncheon and Round Table Discussions**
1:00–2:30PM	**Session 8:** Patient Access
2:30–2:45PM	Refreshments, Exhibits, and Networking Break
2:45–4:45PM	**Session 9:** Transitions and Interchangeability
4:45–5:00PM	**Closing Session:** Summary of Take-a-Ways and Calls to Action

Learning Objectives

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

- Describe how the totality of evidence, including CMC, in vitro, non-clinical, and clinical data, can be amalgamated to demonstrate biosimilarity and meet regulatory expectations for approval of biosimilar applications
- Discuss the concept of the clinical relevance of critical quality attributes and the assessment of their impact on potency, PK, immunogenicity, and safety
- Explain the extent to which critical quality attributes need to align with the reference product and the application of statistical approaches that will meet regulatory requirements for acceptance of biosimilarity
- Discuss the challenges in generating the requisite clinical data to confirm biosimilarity and considerations for designing a successful biosimilar clinical trials program to meet global requirements
- Examine the impact of adoption of biosimilars and (potentially) interchangeable biologics by prescribers and health care professionals on their introduction to patients
- Outline the need and potential approaches for education on the concept and value of biosimilars

Continuing Education Credit

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 13.0 contact hours or 1.3 continuing education units (CEU's). Type of Activity: Knowledge
Day 1: UAN: 0286-0000-16-109-L04-P; 0.675 CEUs
Day 2: UAN: 0286-0000-16-110-L04-P; .0.625 CEUs

ACPE Credit Requests MUST BE SUBMITTED by Friday, December 2

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.

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 up to .3 CEUs for the short course and up to 1.3 CEUs for the main program. Participants must attend the entire program (and short course(s), if applicable) 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 (short course if applicable), sign in at the DIA registration desk each day, 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 **Friday, November 11.**

View DIA's Grievance Policy at DIAglobal.org/Grievance

WEDNESDAY, OCTOBER 26

12:30-5:00PM	**Short Course Registration**
1:30-5:00PM	**Short Course: Navigating the Complexities of Biosimilars Clinical Trial Development**

Instructor

Bruce Babbitt, PhD
Vice President - Technical (Drug Development & Regulatory Affairs)
PAREXEL Consulting

In the determination of biosimilarity, clinical data may play a role in assessing the clinical relevance of differences between critical quality attributes of the reference and comparator products. Once the biosimilar developer has answered key questions about why, whether, and how much clinical data should be collected, the work of trial design can begin. Biosimilar clinical trials differ in significant ways from studies on new biological entities, giving rise to multiple challenges in trial conduct and data generation. Appropriate trial design and anticipation of operational difficulties can help to mitigate these challenges.

This short course will apply learnings from regulatory guidances and from the programs of recently approved biosimilar products to provide insights on optimizing biosimilar clinical trial development, conduct, and data generation. Rather than focusing on any single class of biosimilar, the content will be inclusive of many classes, e.g. growth factors, monoclonal antibodies, fusion proteins.

You will work through the sequential steps of developing a given biosimilar product starting with analytical assessments and proceeding into comparative efficacy trials. Through a broad case study, you will make key decisions as you proceed towards demonstrating a high degree of biosimilarity to the approved reference product.

Learning Objectives

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

- Describe the role of clinical data in demonstrating biosimilarity of a proposed biosimilar product
- Identify the unique features, challenges, and complexities of biosimilar trials and generating clinical data to address the clinical relevance of differences between reference and comparator products
- Discuss factors in determining the purposes and amount of clinical data to be collected
- Describe detailed considerations in designing biosimilar clinical trials to meet regulatory requirements and other study purposes

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THURSDAY, OCTOBER 27

7:15AM-5:30PM — **Registration**

7:15AM-8:15AM — **Continental Breakfast, Exhibits, and Networking**

8:15-8:25AM — **Welcome and Opening Remarks**

Sudip S. Parikh, PhD
Senior Vice President and Managing Director, DIA Americas
DIA

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

8:25-8:45AM — **Keynote Address: The Current State of Biosimilars and Prospects for the Future FDA**

John K. Jenkins, MD
Director, Office of New Drugs, CDER
FDA

8:45-9:45AM — **Session 1: Determining Biosimilarity: By Use of Totality of the Evidence**

Session Chair
Bruce Babbitt, PhD
Vice President - Technical (Drug Development and Regulatory Affairs)
PAREXEL Consulting

Regulators' Perspective

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

Industry Perspective: Application of Regulation to Development

Lisa Bell, DrSc, PhD
Senior Vice President Global Regulatory
Coherus BioSciences

Panel Discussion
Joining the session speakers

Hubert C. Chen, MD
Chief Medical Officer
PFEnex Inc.

Martina Weise, DrMed, MD
Head, Licensing Division 2, German CHMP Alternate
BfArM, Germany

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

In the US, Europe, and other regions, biosimilarity is demonstrated through a totality of evidence approach. This session will examine the picture of biosimilarity presented by the components of evidence, including the foundations laid by CMC/analytics, non-clinical data, analysis of critical quality attributes (CQAs), and clinical data to address the clinical relevance of differences, from the perspectives of the regulator and of industry. What is the regulator's view of the organizing framework and how the data work together to demonstrate biosimilarity, especially for complex biologics? From the industry view, when is stepwise development preferable to a parallel development process, and how is decision making, about residual uncertainty or risk for example, influenced by each of these paradigms? What does the totality of evidence mean for development versus marketing applications? Global regulators will join the session speakers in an interactive panel discussion to address audience questions.

9:45-10:15AM — **Refreshments, Exhibits, and Networking Break**

THURSDAY, OCTOBER 27

10:15-11:45AM

Session 2: Critical Quality Attributes (CQA)

Structural and functional characteristics of a protein that can impact clinical activity are understood to be critical quality attributes (CQAs). Given the complexity and inherent heterogeneity of protein products, biosimilars will inevitably show some molecular differences when compared to the reference product. The challenge, then, is to demonstrate that the differences that are seen will have no meaningful clinical impact. This session will explore how the knowledge and analysis of CQAs contributes to the overall similarity evaluation; the role that clinical studies can and cannot play in determining similarity; how molecular and clinical knowledge of one product can contribute to the understanding of other products; and how the FDA uses the totality of the analytical, non-clinical, and clinical evidence to determine whether there may be clinically-meaningful differences between a proposed biosimilar and the US-licensed reference product.

Session Chair
Emily Shacter, PhD
Independent Consultant
ThinkFDA, LLC

Analytics Data

Steven Kozlowski, MD
Director, Office of Biotechnology Products, OPQ
CDER, FDA

Evaluation of Quality Attributes in Biosimilar Development

Martin Schiestl, PhD
Chief Science Officer
Sandoz GmbH, Austria

Clinical Relevance of Critical Quality Attributes in Biosimilar Development

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

Panel Discussion

11:45AM-1:00PM

Luncheon, Exhibits, and Networking

1:00-3:00PM

Session 3: Value/Relevance of Clinical Data: Challenges of Designing Clinical Studies and Generating Clinical Data

This session explores the challenges of biosimilar clinical trial study design and implementation, as well as the challenges of generating clinical data and its contribution in supporting a claim of biosimilarity. Sponsors must conduct clinical studies that are adequately sensitive to detect clinically meaningful differences between the biosimilar product and the comparator product. There may be significant challenges in replicating the original trial population of reference product vs. placebo-controlled superiority trial. Recruitment for the trial may be difficult as it may not be of interest to either academicians or to patients who have access to newer therapeutic agents. Further, the market for biosimilars clinical trials is crowded, with many sponsors conducting studies with similar clinical trial designs, competing for a limited patient pool.

Session Chair
Julie Ann Rosenberg, MD
Senior Director, Asset Lead, Biosimilars
Pfizer Worldwide Research and Development

Biosimilars: Current Considerations with Clinical Trials

Robert M. Rifkin, DrMed, FACP
Medical Director - Biosimilars
McKesson Specialty Health
US Oncology Research

Clinical Pharmacology Studies in Support of Biosimilar Development and Approval

Jurgen Venitz, MD, PhD
Professor, Pharmaceutics
VCU School of Pharmacy

Operational Complexities Specific to Biosimilar Clinical Trials

Vivienne Jenkins
Clinical Operations Program Lead
Pfizer Ltd., United Kingdom

An FDA Reviewer's Thoughts on Generating Clinical Data in a Biosimilar Development Program

Steven J. Lemery, MD
Lead Medical Officer, Office of Hematology and Oncology Drug Products, Office of New Drugs
CDER, FDA

Relevance of Clinical Data-A European Perspective

Martina Weise, DrMed, MD
Head, Licensing Division 2, German CHMP Alternate
BfArM, Germany

Panel Discussion

THURSDAY, OCTOBER 27

3:00-3:30PM — **Refreshments, Exhibits, and Networking Break**

3:30-4:30PM

Session 4: The Role of Real-World Evidence (RWE) in the Post-Approval Setting

This session will explore the role of RWE in the post approval setting for biosimilars. RWE can be used for a range of purposes that span Product Safety to Commercial interests. The presentations and the panel discussion will focus on the current state of RWE to inform pharmacovigilance, extrapolated indications, comparative effectiveness, product utilization, and value assessments. The utility of the FDAs Sentinel Initiative as a source for biologic and biosimilar studies will be assessed.

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

Key Questions Stakeholders Ask About Biosimilars Post-Approval

Nancy Dreyer, PhD, MPH
Senior Vice President and Global Chief of Scientific Affairs, Real-World and Late-Phase Research
Quintiles

Key Challenges to Addressing Post-Approval Biosimilar Questions

Brian Bradbury, MA
Executive Director and Head, Data and Analytic Center, CfOR
Amgen, Inc.

Methodologies for Addressing CER/CSR: Strengths and Limitations

Alan Brookhart
Professor, Department of Epidemiology
Gillings School of Global Public Health,
UNC- Chapel Hill

Panel Discussion

4:30-5:30PM

Session 5: Education

Because the US approval pathway for biosimilars and interchangeable biologics is relatively new, it is important to ensure that appropriate information about these products is available for those making critical decisions about prescribing or their own treatment options. In this session, an assessment of the current understanding of US healthcare professionals and the public of the concepts of biosimilars and interchangeable biologics will provide insights into the areas for which education is needed. Ongoing and future programs designed by a patient advocacy group and a professional society for their memberships will illustrate varied approaches to accomplishing goals for biosimilar education.

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

Awareness, Knowledge and Perceptions of Biosimilars Among Specialty Physicians

Dorothy McCabe, PhD, FCP
Executive Director
Boehringer-Ingelheim

Biosimilars Education - Patient Needs and Perspectives

Samantha Roberts, PhD
Director, Scientific Affairs
Friends of Cancer Research

AMCP Initiatives on Biosimilars Education

Mary Jo Carden, BSN, JD, LLM, RPh
Vice President, Government and Pharmacy Affairs
Academy of Managed Care Pharmacy (AMCP)

Panel Discussion

Joining the session speakers

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

5:30-6:30PM — **Networking Reception**

FRIDAY, OCTOBER 28

7:30AM-7:00PM — **Registration**

7:30-8:15AM — **Continental Breakfast, Exhibits, and Networking**

8:15-8:30AM — **Welcome to Day Two**

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

8:30-10:15AM — **Session 6: Global Harmonization and Regulator Update**

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

Biosimilars developed for launch in multiple regions require a planned and focused strategy, involving the selection of the suitable reference product(s), defining the extent of comparative process and product characterization, and design of nonclinical and clinical studies to meet regulatory requirements. A clear and concise understanding of the regulatory framework of major regions and regulatory convergence activity among regions would be desirable for a good business strategy. This session will bring together regulatory authorities to discuss current regulatory evolution and convergence for biosimilars in the various global locations.

FDA Update

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

Health Canada Update

Cathy Parker
Director General, Biologics and Genetic Therapies Directorate, Heath Products and Food Branch
Health Canada

CHMP Update

Martina Weise, DrMed, MD
Head, Licensing Division 2, BfArM; German CHMP Alternate
Bfarm, Germany

10:15-10:45AM — **Refreshments, Exhibits, and Networking Break**

10:45-11:45AM — **Session 7: Ask the Regulators**

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

Use this unique opportunity to share your pressing questions for the FDA and global regulatory agencies in person.

You may submit a written question at anytime during the conference to the DIA registration desk. You can also present your question live at the session. Questions may focus on the various sessions, but may also branch out into other areas of biosimilars.

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

Cathy Parker
Director General, Biologics and Genetic Therapies Directorate Heath Products and Food Branch
Health Canada

Martina Weise, DrMed, MD
Head, Licensing Division 2, BfArM; German CHMP Alternate
Bfarm, Germany

FRIDAY, OCTOBER 28

11:45AM-1:00PM

Luncheon and Round Table Discussions

NEW this year! Join a discussion led by a leader within the Biosimilars Community. Approximately 15 minutes into the luncheon, leaders within the Biosimilars community will facilitate discussions, while also encouraging you to connect with your colleagues and share your experiences and questions. This is an optional activity. If you haven't already preselected a table, you can select a seat from an open table by visiting the registration desk.

Table 1: Biosimilar Substitution and Switching
Hillel Cohen, PhD
Executive Director, Scientific Affairs
Sandoz Inc.

Table 2: Statistical Tools for CQA Comparisons
Martin Schiestl, PhD
Chief Science Officer
Sandoz GmbH, Austria

Table 3: Evaluating Analytical Similarity
Emily Shacter, PhD
Independent Consultant
ThinkFDA, LLC

Table 4: Navigating Regulatory Requirements: Clinical Trial Design, Population, and Endpoints
Jian Wang, MD, PhD
Chief, Clinical Evaluation Division - Haematology/Oncology, HPFB
Health Canada

Table 5: Regulatory Considerations for Global Development
Cornelia Ulm
Head of Regulatory Affairs, Biosimilars
Merck Biopharma, Switzerland

Table 6: Real World Evidence
Thomas Felix, MD
Medical Director, R&D Policy, Global Regulatory Affairs and Safety
Amgen Inc.

Table 7: Patient Access
Michael Muenzberg, MD
Vice President, Director Medical Affairs Biosimilars
Ares Trading S.A, Switzerland

Table 8: PK/PD Issues in Biosimilar Development
Jurgen Venitz, MD, PhD
Professor, Department of Pharmaceutics
Virginia Commonwealth University

Table 9: Need for Education of Health Care Providers
Mary Jo Carden, BSN, JD, LLM, RPh
Vice President, Government and Pharmacy Affairs
Academy of Managed Care Pharmacy

1:00-2:30PM

Session 8: Patient Access

Biologic medicines play an increasing role in the patient care across a growing number of disease areas. Access to these modern therapies remains restricted due to the high cost of these medicines. This session will look at the current barriers to accessing existing biologic therapies and how the emergence of biosimilar medicines across Europe and in the United States brings the promise to overcome those, offering opportunities for health systems to expand access for more patients, but also foster investment in new areas of care while providing relief on health care budgets.

Session Chair
Mike Muenzberg, MD
Vice President, Director Medical Affairs Biosimilars
Ares Trading S.A., Switzerland

Increasing Information for Patients About Accessing Treatments Biosimilars and Clinical Trials
Paulo Moreira
Vice President, Global Clinical Operations, Head of External Innovation
EMD Serono

An Overview of Current Biosimilars Reimbursement Practice and Medicare
John Carlsen, MHA
Vice Presidnet
Covance Market Access Services Inc.

AARP's Perspective on Access to Biologic Medicines
Leigh Purvis, MPA
Director, Health Services Research
American Association of Retired Persons (AARP)

Panel Discussion
Joining the session speakers
Robert M. Rifkin, DrMed, FACP
Medical Director - Biosimilars
McKesson Specialty Health
US Oncology Research

FRIDAY, OCTOBER 28

2:30-2:45PM — **Refreshments, Exhibits, and Networking Break**

2:45-4:45PM — **Session 9: Transitions and Interchangeability**

This session will span the current state of global discourse on biosimilar product single transitions conducted under medical supervision to the US concept of interchangeability intended to guide pharmacy-level substitution of self-administered biologics. We will start with a review of terminology to level-set and focus on concepts that are globally discussed, but often with confusing terms. International and US perspectives will be contribute to the discussion. If the NOR-SWITCH study results are released, these will be highlighted. If the US FDA draft guidance on interchangeability is released prior to this meeting it will be reviewed.

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

Introduction: Terminology Interchangeability vs Switching vs Transition vs Substitution

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

Immunogenicity of Biologics and Biosimilars

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

Interchangeability: Who Decides? Core Principles, Regional Perspectives, and Applications

Gino Grampp, PhD
Biosimilars R&D Policy Director
Amgen

Evidence-Based Switching and Interchanging of mAb Biosimilars

Stanley SeungSuh Hong, PhD
Senior Advisor
Celltrion Healthcare, Republic of Korea

Panel Discussion
Joining the session speakers

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

4:45-5:00PM — **Closing Session: Summary of Take-a-Ways and Calls to Action**

Julie Ann Rosenberg, MD
Senior Director, Asset Lead, Biosimilars
Pfizer Worldwide Research and Development

Save the Date Coming Soon!
DIA Biosimilars Conference
Fall 2017

Take part in the 2017 planning process by completing this year's conference evaluation. A link to the on-line evaluation form will be sent at the conclusion of the conference. We look forward to reading your 2017 content considerations!

DIA's eLearning Solutions

Improve your teams knowledge using DIA's eLearning programs. Reduce training costs, eliminate time out of the office, and meet your organization's training needs.

DIA's eLearning programs provide unique, realistic opportunities for professionals to learn best practices in their fields with Internet-based courseware that is conveniently accessible 24 hours a day, 7 days a week.

Drug Safety

Drug safety is a primary concern throughout the medical product development life cycle. Developed with DIA expertise to meet the unique needs of its stakeholders and members, the Drug Safety eLearning Program's six modules provide the knowledge you need, from regulations and requirements through premarket review and postmarket monitoring.

- Introduction to Drug Safety
- Drug Safety Regulatory Requirements
- Premarketing Clinical Trial Safety
- Postmarketing Safety Management
- Basics of Signal Detection and Pharmcoepidemiology
- Safety Audits and Inspection

Drug Development and Life Cycle Management

Drug development is an incredibly complex and risky endeavor, one that even experienced organizations will fail at more often than they succeed. This six module program will help you understand how companies structure their efforts and utilize their resources to improve the odds of successful development, and minimize the risks associated with shepherding a new drug candidate through the development process.

- Overview of Drug Development
- Phase 2 Studies
- Discovery and Preclinical Testing Phases
- Phase 3 Studies and Regulatory Review
- Phase 1 Studies
- Phase 4 and Life Cycle Management

Medical Communications

DIA's Medical Communications Program includes eight modules that cover topics that any medical and scientific communications professional needs to know.

- Literature Searching
- Literature Evaluation
- Database Management and Medical Inquiries
- Medical Response Excellence
- Statistics for Medical Affairs
- US Regulatory and Compliance Considerations
- Crisis Management
- Product Labeling

Informed Consent

This module is designed to provide an informative overview of the key concepts of informed consent that will benefit qualified physicians, pharmacists, physician assistants, nurse practitioners, research scientists, and clinical research professionals. It is also designed to provide a detailed explanation of all the components of a complete and appropriate consent form, as well as guidance for the creation and appropriate wording of these components.

Clinical Trial Fundamentals

This program designed to provide a practical context to help clinical research professionals learn about conducting clinical trials. Using an interactive case study with realistic scenarios designed to illustrate the learning points, this three module program follows the activities of a fictitious clinical investigator and her staff as they conduct a clinical trial.

- Clinical Trials: Study Preparation
- Clinical Trials: Study Initiation
- Clinical Trials: Conducting the Study

Group Discounts and Licensing Available
DIA offers licensing and discounted rates to organizations interested in purchasing modules for 10+ users. Contact Heej.Ko@DIAglobal.org

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