Activity Outline
DDI Webinar Series: Overview of the Regulatory Framework and the Development and Approval of Biosimilar Products in The U.S.
December 5, 2017 1:00-2:00pm EST
Webinar

Description
This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety. This webinar will provide an overview of the regulatory framework for biosimilar products, including a background, information on terminology and the general requirements of the approval pathway for biosimilars. The webinar will also talk about the approach and scientific concepts used in the development of biosimilar products.

References

1. Biosimilars: https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm
2. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf
3. Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291134.pdf
4. Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM397017.pdf
5. Considerations in Demonstrating Interchangeability With a Reference Product Guidance for Industry: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf
6. Statistical Approaches to Evaluate Analytical Similarity: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM576786.pdf

Series Learning Objectives
- Explain how to utilize FDA's drug information, medication safety resources, and regulatory guidance documents, to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling changes which would impact prescribing and medication management to optimize patient care.

Session Learning Objectives After completion of this activity, the participant will be able to:
- Define the difference between biosimilar and interchangeable products and how they are prescribed/dispensed.
- Explain the goals of a standalone and biosimilar development pathways and the stepwise evidence approach used to generate data in support of a demonstration of biosimilarity
- Recognize the importance of the analytical foundation and how FDA assesses analytical similarity
- Describe the role of clinical studies in the biosimilar development process

Target Audience
This activity is intended for physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals.

Schedule

Time	Title	Lecturer(s)
1:00 PM to 2:00 PM	DDI Webinar Series: Overview of the Regulatory Framework and the Development and Approval of Biosimilar Products in The U.S.	Leah Christl, PhD FDA/ CDER/OMPT/OND Sue Lim, MD FDA/CDER/OMPT/OND

Continuing Education
Accreditation

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number 0601-0000 17-153-L04-P, and ACPE Universal Activity Number 0601-0000-17-154-L04-T, for 1 contact hour.

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1 contact hour.

Requirements for receiving CE credit
Physicians, pharmacists, nurses and those claiming non-physician CME: attendance is verified by a sign-in sheet and completion of the final activity evaluation. For multi-day activities, participants must sign in every day. Final activity evaluations must be completed within two weeks after the activity.

Pharmacy participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Statements of Credit
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty
- Leah Christl, PhD, Associate Director for Therapeutic Biologics, FDA/ CDER/OMPT/OND – nothing to disclose
- Sue Lim, MD, Director of the Scientific Review Staff within the Therapeutic Biologics and Biosimilars Staff at FDA/ CDER/OMPT/OND – nothing to disclose

Planning Committee
- Kara Burke, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI- nothing to disclose
- Kimberly DeFronzo, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI- nothing to disclose

- Virginia Giroux, MSN, ARNP, CE Program Administrator, FDA/CDER/OEP/DLOD- nothing to disclose
- Danielle Molnar, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI- nothing to disclose
- Lesley Navin, RN, MSN, Consumer Safety Officer, FDA/CDER/OCOMM/DDI- nothing to disclose
- Edward Weinstein, MD, Medical Officer, FDA/CDER/OND/OAP/DAIP- discloses the following "spouse receives salary from EndoCentre of Baltimore as an employee"

CE Consultation and Accreditation Team

- Justin Gorinson, CHES®, ORISE Fellow, FDA/CDER/OEP/DLOD-nothing to disclose.
- Karen Zawalick, CE Consultation and Accreditation Team Leader, FDA/CDER/DLOD- nothing to disclose

Registration Fees and Refunds
Registration is complimentary therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the lectures (verified by a sign-in sheet).