Biologics and Biosimilars: Preparing for the Future

Statewide Videoconference Program

November 17, 2015: 7:00-8:00pm or
November 18, 2015: 7:00-8:00am

A biosimilar product, as described by the U.S. FDA, "is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products."

The Patient Protection and Affordable Care Act (Affordable Care Act) of 2010 created an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. Recent approval of the first U. S. FDA-deemed biosimilar of filgrastim (Neupogen) and recent submissions for other biosimilars signals the development of, and interest in, biosimilars as a means to increase patient access to these types of therapy and reduce cost of treatment. But other important considerations include the development and manufacturing process (including batch to batch variation), interchangeability, and indication extrapolation.

Join Dr. Charlie Bennett, an expert in preventing drug adverse events and improving drug safety, to learn more about this emerging field.

(Source: www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/)

Objectives

At the conclusion of this program, participants will be better able to:

- Define "biosimilar" based current FDA guidance and describe similarities and differences between biosimilar and originator biologic agents
- Review key aspects of the comparability exercise for approval of biosimilars per current FDA guidance
- Evaluate experience with biosimilars in the EU
- Describe current and emerging biosimilars in the US

Instructor: Charlie Bennett, MD, PhD, MPP
Josie M. Fletcher Professor and SC SmarState Center in Medication Safety and Efficacy
Endowed Chair of Center for Medication Safety and Efficacy, MUSC
CPOS, South Carolina College of Pharmacy

Locations

Over 35 hospital locations statewide.Find locations at **www.scahec.net/schoolsregistration**

Credit

Provided at no-cost for physicians and pharmacists.

Register

This program is FREE! **Register at www.scahec.net/schoolsregistration**

This program is being broadcast over the SCHOOLS videoconferencing network across South Carolina. Participants will be able to fully interact with the speakers from participating locations.

This program will be held in room number 803-555-1199

Accreditation Statement
The France Foundation is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Credit Designation
Physicians
The France Foundation designates this live activity for a maximum of *1.0 AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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The France Foundation is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education and will award 0.1 CEU to pharmacists who complete the activity and evaluation form. There is no fee to participate in this activity. This is a knowledge-based educational activity. Your CE credits will be submitted electronically to the CPE Monitor. CE providers must upload participant information within 60 days from the date the participant completed the live activity. Please submit all evaluations and credit requests no later than 30 days after this live activity to ensure your credit fulfillment, as CE credit cannot be awarded past 60 days from the activity date. ACPE No. 0391-0000-15-188-L04.

Method of Participation/How to Receive Credit

1. There are no fees for participating in and receiving credit for this activity.
2. Review the activity objectives and CME/CE information.
3. Complete the CME/CE activity.
4. Go to the Web site (www.scahec.net/schoolsregistration) provided at the activity to complete the CME/CE evaluation/attestation form. The form provides each participant with the opportunity to comment on how participating in the activity will affect their professional practice; the quality of the instructional process; the perception of enhanced professional effectiveness; the perception of commercial bias; and his/her views on future educational needs.
5. Credit documentation/reporting:
   - If you are requesting *AMA PRA Category 1 Credits™* or a certificate of participation—your CME/CE certificate will be available for download
   - If you are requesting ACPE pharmacy credit—your CE credits will be submitted electronically to the CPE Monitor.

Register at www.scahec.net/schoolsregistration

SCHOOLS Locations - Check for Participation

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AnMed Health
Beaufort Memorial Hospital
Cannon Memorial Hospital
Carolina Pines Regional Medical Center
Chesterfield General Hospital
Clarendon Memorial Hospital
Edgefield County Hospital
Fairfield Memorial Hospital
Greenville Health System
KershawHealth
Laurens County Memorial Hospital
Lowcountry AHEC (Walterboro)
McLeod Loris Seacoast
McLeod Medical Center Darlington
Mid-Carolina AHEC (Lancaster)
Newberry County Memorial Hospital
North Greenville Hospital
Novant Health Gaffney Medical Center
Pee Dee AHEC (McLeod Florence)
Roper St. Francis Healthcare
South Carolina AHEC (MUSC)
Southern Palmetto Hopsital - Barnwell
The Regional Medical Center
Tidelands Health - Georgetown & Waccamaw
Upstate AHEC (Greenville)
Wallace Thomson Hospital

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