

Biosimilars: An Overview for Healthcare Professionals

This expert-led, peer-to-peer program will provide healthcare professionals (HCPs) with an understanding of why biosimilars are being developed and the scientific and clinical considerations used by the US Food and Drug Administration (FDA) to grant them approval.

Attendees will gain an increased knowledge of the types of scientific and clinical data that are required for biosimilar approval by the FDA. This foundation may assist HCPs who choose to incorporate biosimilars into their practice or institution.

Duration: 1 hour

Key Topics:

- Biologics and biosimilars: US healthcare landscape and the EU experience
- FDA considerations for biosimilar development and approval
- The basics of extrapolation and the US FDA interchangeability designation
- How biosimilars may help bring value to patients

Beyond Being Biosimilar: A Closer Look at Extrapolation of Biosimilarity

This expert-led, peer-to-peer program will provide HCPs with an in-depth understanding of FDA evaluations of extrapolation after biosimilarity to the reference biologic is established

Duration: 1 hour

Key Topics:

- Licensure for extrapolated indications is based on scientific justification and is not automatic
- Scientific justification for extrapolation is based on the totality of evidence

Biosimilar Implementation: Potential Best Practices and Other Considerations

This expert-led, peer-to-peer program is designed to provide strategic considerations relevant to biosimilar evaluation by the P&T and potential best practices for tactical execution for biosimilar implementation.

Attendees will gain increased understanding of key topics of consideration for biosimilars when deciding to include them on the institution or practice formulary. It is recommended that attendees participate in the Biosimilars Overview Program OR have an understanding of biosimilar and extrapolation regulatory and development concepts as a foundation to build on.

Duration: 1 hour

Key Topics:

- Overview of evaluation and strategic considerations by the P&T committee, including clinical review of the comparative clinical data to support biosimilarity, financial assessments evaluating the value of implementing biosimilars, and example considerations of enablement of pharmacy informatics and the Electronic Health Record (EHR)
- Emerging considerations and potential best practices for tactical execution, including communication across stakeholders, and post-implementation monitoring and education of healthcare providers, patients, and staff

CME credit is not available for these programs.



For more information about Biosimilars, visit PfizerBiosimilars.com



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