OVERVIEW

Biosimilars provides an overview of the science, biomanufacturing technology, and regulatory requirements for receiving approval to market biosimilar products. The course begins by taking an in-depth look at the science, specifically how a therapeutic protein’s structure dictates its function. With this foundational knowledge, users understand how biomanufacturing conditions can alter a biosimilar, causing it to function differently than its reference product. The course ends with some tested approaches to demonstrating biosimilarity that have been acceptable to the FDA and EMA.

Five Takeaways:
1. Understanding how a protein’s structure dictates its function.
2. Ability to discuss how post-translational modifications can change a protein’s intended function.
3. A comprehensive understanding of how biosimilars may differ from its reference product once it has been manufactured.
4. FDA and EMA requirements for biosimilar approval and the underlying scientific/quality/regulatory principles involved.
5. General considerations of animal/clinical/in vitro studies, as well as the FDA’s Totality-of-the-Evidence approach.

AGENDA

- **Protein Function** reinforces a deep understanding of proteins by describing their various cellular functions through examples. Biosimilars are proteins.
- **Protein Synthesis** explains protein structure and the steps involved in making a protein. By understanding that a protein’s structure influences its functions, one can begin to understand how a reference product and biosimilar may not be identical.
- **Post-Translational Modifications** points out that both genes and cells influence the type of post-translational modification and the degree to which the protein is modified. This modification determines if a therapeutic will work or not work.

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• **Biologics** list the functions of therapeutic proteins and compares and contrasts biologics with small molecule drugs.

• **Introduction to Biosimilars** reviews the EMA and FDA definitions of biosimilars.

• **The Product Is the Process** lists the steps of biomanufacturing explaining the goal of each step. This section identifies where variations can occur between two identical production campaigns, demonstrating how a biosimilar may not be identical to the reference product. Itemize key formulation parameters and examples of where protein stability testing are highlighted.

• **Biosimilars Safety and Regulation** takes an in-depth look at immunogenicity, a main safety concern of biosimilars. A discussion of how companies test for immunogenicity and predict immune response to a therapeutic protein is given. The course ends by explaining how companies gain approval for a biosimilar.