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Analytical assessment of biosimilarity-Considerations in study design

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The demonstration of biosimilarity is critical to the approval of biosimilar products. While confirmatory studies may be required to confirm safety in animals and in the clinical setting, these studies are limited in their ability to assess differences between the biosimilar and the reference product. Analytical characterization has therefore become the key to the assessmet of biosimilarity.

One of the most difficult aspects of the demonstration of biosimilarity is the design of the biosimilarity study. This includes the determination of how many lots of reference material must be analyzed as well as which analytical methods are required for the comparison. A strong analytical package should include release assays as well as extended characterization methods. The specific methods are dependent on the individual product. Procurement strategies for reference product must also be considered. Asessment of the reference product should be a survey of the product quality over time, as opposed to a snapshot of product quality for a single lot. Cost of the reference products can become a critical factor in procurement strategy and study design. This goal of this presentation is to provide some guidance on the design of biosimilarity studies for the analytical characterization of the biosimilar product, looking both at release characteristics as well as degradation pathway assessments.

Biography

Christina Vessely, earned her PhD at the University of Colorado Health Sciences Center, and has about 20 years experience in analytical and formulation development within the biotechnology industry. Her experience ranges from early stage research through late stage development and commercialization for small and large pharmaceutical companies. Her areas of expertise include analytical method development and validation, development of reference standards, stability strategy and evaluation, and establishment of comparability and/or biosimilarity. Her product experience includes vaccines, insulin analogs, cytokines, monoclonal antibodies, and other therapeutic proteins. She has been involved in the development and execution of CMC/Regulatory strategy for both novel and biosimilar products.

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