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CMC considerations for biosimilar drug development

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Developing a biosimilar from a CMC perspective is a scientific and risk based approach and not a list with checkboxes to be ticked off. Following the quality strategy, the biosimilarity cannot be tested in the clinical trials but must be demonstrated on the drug substance and product level. For this, there are typical road maps always starting with a quality target product profile of the originator molecules. This talk will focus on typical analytical modules on the road map also touching the comparison of degradation profiles and impurities of biosimilar and originator molecules in a side-by-side analytical situation. All that must be adapted to the company's strategy for market, time for development, budget and partners. Typical examples will be presented combined with pitfalls that companies are facing during the development.

Biography

Ulrike Konrad has more than 10 years of experience in Biotech/Pharma with focus on protein analytics and biosimilar development to reach and demonstrate biosimilarity. She graduated in Chemistry from the University in Heidelberg, Germany and has done her Master of Business Administration. She has worked as a Project Manager in different Biotech companies and joined Protagen Protein Services in 2012. In her role, she has supported numerous biosimilar developments including the consulting for the analytical and regulatory strategy for Europe, USA, India, Korea, Brazil and Mexico.

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