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How to meet FDA requirements for demonstration of interchangeability?

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There is a great interest from global companies who are developing biosimilars to pursue interchangeability designation for commercialization of their products in the US. An interchangeability designation will not only allow the substitutability at the pharmacy level without the intervention of a health care provider but the first sponsor who is able to garner interchangeability designation will also receive twelve months of marketing exclusivity. This presentation will highlight our current understanding of FDA expectations with regards to demonstrating interchangeability.

Recent Publications

1. Chance K and Reeve R (2016) - Overcoming regulatory and statistical hurdles of biosimilars drug development: designing smarter trials. insight brief: Applied Clinical Trials. Pages. 3-9.
2. Huml R, Chance K et al. (2016) - Challenges with the development of biosimilars in Asia for western markets: an overview and suggested solutions. Therapeutic Innovation & Regulatory Science. 51(2): Page numbers.
3. Goel N and Chance K (2016) Biosimilars in rheumatology: understanding the rigor of their development. Rheumatology. 56(2):187-197.
4. Goel N, Chance K et al. (2015) Operational challenges associated with biosimilar drug development. Journal for Clinical Studies. 7(2):20-27.
5. Goel N and Chance K (2014) The biosimilar landscape: a systematic review of its current status. Arthritis & Rheumatology Journal. 66:S662

Biography

Kamali Chance has a PhD in Nutrition/Nutritional Biochemistry, Master's in Public Health and Regulatory Affairs Certification from Regulatory Affairs Professional Society. She is the CEO & Executive Consultant of KC Biopharma Consulting, LLC, USA. She has an extensive regulatory strategy/ regulatory affairs experience working at a Clinical Research Organization and for pharmaceutical and biotechnology companies. She advises pharmaceutical and biotechnology companies in the development of region specific and/or global regulatory strategy for the development of biosimilars/biologics/drugs. She has authored/co-authored numerous articles on the development of biosimilars and small molecule drugs. Her work experience includes strategic regulatory planning including clinical development plans, preparing and submitting meeting requests to regulators, guiding the client through meeting preparations and attendance at FDA/EMA meetings, regulatory submissions including IND and IND maintenance, ANDA/NDA/BLA/MAA preparations and submissions. She is proficient in performing due diligence assessments for investments and acquisitions for biopharmaceutical/pharmaceutical products.

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