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Integrated strategy for biosimilar development: A multidisciplinary approach for risk reduction

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Abstract

Many companies have recently entered the biosimilar space. After the initial excitement, reality set in resulting in a number of attritions. Some could have been avoided if companies had invested in understanding the dynamics and challenges of developing and commercializing a biosimilar. This includes the impact of commercial issues on the development strategy, considerations which even impact the choice of biosimilar target. Often companies focus on developing a data package to address regulatory requirements and don't ask the pivotal question, what is needed to ensure commercial success with the multitude of target audiences: payors, physicians, patients, and the threat of large biotech counterstrategies. Competition for patient recruitment is also overlooked.

The CMC challenge is also great. The quality target product profile (QTPP) based on data collected on the reference product is required at the onset of process development. Thus, the analytical burden is higher and occurs earlier compared to developing a new biologic. In addition, many of the attractive candidates are glycosylated and demonstration of biosimilarity includes thorough carbohydrate analysis. Glycosylation is defined by the cells and sensitive to changes in process conditions. Pursuing cost reduction, biosimilar manufacturers are tempted by novel expression systems which may introduce atypical glycosylation and higher variability as compared to the reference product. Thus, the understanding of the glycobiology of expression systems is critical in pursuing this endeavor.

Given the number and intricate correlation of the challenges involved, it is critical to take an integrated approach to the development of biosimilars.

Biography

Dr. Manzi is a Managing Director of Atheln, a firm that creates product development strategies integrating commercial and technical disciplines to maximize product value. This unique approach to consulting is rooted in a deep understanding of the complete path from early research to launching and life-cycle management of pharmaceuticals. Atheln's experts in the US and EU, with experience at major pharma/biopharma companies, span all disciplines required for developing a marketable biopharmaceutical. This holistic approach is of unique value to companies considering new areas such as biosimilars.

Dr. Manzi has been Sr. Director Research, Baxter; Director, Analytical Development, Nextran and Cytel; Director, Glycobiology Core, UCSD. She has published 28 papers and 20 book chapters, received her BS/MS and PhD (Chemistry) from the University of Buenos Aires, Argentina and conducted Postdoctoral Research in glycobiology at UCSD.