

A case study: Scientific challenges for the bioanalytical method development of biosimilars

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According to a recent FDA guidance, a biosimilar is a biological product which is shown to be highly similar to a reference product, notwithstanding minor differences in clinically inactive components. It is essential to demonstrate that there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. Accurate and reliable bioanalytical and immunogenicity data are critical to demonstrating the safety and efficacy of a biosimilar and to show comparability between the innovator compound and the biosimilar.

Demonstration of comparability between a biosimilar and the innovator compound could be challenging due to the different methods used to establish the strength of the drugs. This may lead to significantly different concentrations between the biosimilar and innovator drug. If the concentration differences cannot be resolved, it may require two assays to measure pharmacokinetic samples for innovator and biosimilar drugs. The use of two separate assays may indicate that the two products are significantly different and require the analysis of both compounds using both assays.

Proving that the biosimilar and the innovator have similar immunogenicity can also be quite challenging due to the fact that these types of assays are generally qualitative. The rate of immunogenicity can be particularly difficult when the incidence of positive response is low. In addition, small process changes during the manufacturing of therapeutic proteins may lead to significant changes in the rate of immunogenicity. Due to these reasons, it is necessary to develop two robust immunogenicity assays, one for the biosimilar and one for the innovator, with comparable sensitivity, precision, specificity and drug tolerance.

Celerion recently developed an exenatide assay to support multiple biosimilar programs. This presentation will explore the challenges described and present solutions using the exenatide assay as a case study.

Biography

Rafiq Islam is the Director of Bioanalytical Services at Celerion Inc. In his current role he is responsible for the scientific and operational leadership for both small and large molecule bioanalysis. He is also responsible for developing and executing a strategic plan to deliver scientific, operational and service excellence to Celerion clients.

Previously, Rafiq was the Scientific Director for Biopharma Services at EMD Millipore. He held similar positions at Covance and Huntingdon Life Sciences. He has a BS Biology and MS in Data Mining. He has 14 years of industry experience developing bioanalytical assays for biotechnology and pharmaceutical clients.

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