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Bioanalytical challenges of biosimilar development; making you wish you had a mirror to put in front of the innovator drug

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Biosimilars are entering the landscape as patents for major branded large molecule products start to expire over the next few years. This rapid drive is fueled by the potential to reduce treatment costs and increase the accessibility of treatments for everyone around the world. However, generation and approval of biosimilars are not trivial as a biosimilar medicine is essentially a new biological product that is similar (not identical) to a medicine that has already been authorized to be marketed. In this presentation, I will review the bio-analytical challenges and solutions that apply specifically to the analysis of biosimilars in biological samples with a focus on the PK, immunogenicity, biomarker and cell-based assays.

Biography

Afshin Safavi, PhD, Founder and CSO at BioAgilytix, is a Veteran Biochemist with extensive experience in establishing and leading bio-analytical teams in support of the development of biological products in preclinical and clinical-trial laboratories. Prior to founding BioAgilytix Labs, he was the Director of Ligand Binding and Immunoassay. At Grifols, he led the Pre-clinical and Clinical Assay Development team, building on his experience as a senior scientist at Nobex Corporation, GlaxoSmithKline and IGEN International. He is considered an expert in the area of immunoassay with a wide working knowledge of various platforms.

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