

5th European Biosimilars Congress

June 27-29, 2016 Valencia, Spain

Immunogenicity of biosimilars

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A biosimilar is a biological medicinal product which is similar to authorized biological medicine (reference medicinal product). A biosimilar and its reference product are expected having the same safety, efficiency profile, and are generally used for treating the same conditions. There are many factors which contribute to immunogenicity includes: First, product related factors which include structural properties such as sequence for protein, presence of exogenous or endogenous epitopes, degree of glycosylation, exposure of antigenic sites and solubility, formulation and storage, downstream processing, impurity level or presence of contaminants, second, host related factors, such as the genetic predisposition of a patient may influence the production of neutralizing antibody, the genetic sequence that encodes for endogenous equivalent of the therapeutic protein, concomitant illnesses, such as kidney and liver diseases, which may influence immunogenicity, and dose and route of administration. There are many methods for measuring the immunogenicity which includes: Radio immuno precipitation assay (RIPA), Direct ELISA (enzyme linked immunosorbant assay), Bridging ELISA, Electrochemical luminescence assay, and Surface Plasmon resonance.

Biography

Samer M Al-Hulu is an Assistant Professor of Microbiology and has completed his PhD at from Babylon University/College of Science. He has published more than 14 papers in microbiology field. He had training at Ministry of Health at Laboratory of Babylon Maternity and Children Hospital. Currently, he is working at Al-Qasim Green University/College of Food Science.

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