

8TH ASIAN BIOLOGICS AND BIOSIMILARS CONGRESS

August 10-12, 2017 Beijing, China

Heterogeneity of monoclonal antibody and challenges in developing biosimilar of it

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Monoclonal antibodies are high molecular weight proteins (~150 kDa). As it is common for biotech-derived molecules of this size, they have highly complex secondary and tertiary structures, subject to post-translational modifications. Heterogeneity of monoclonal antibodies due to the vast number of modifications presents great challenge to the thorough characterization of the molecules. Different orthogonal techniques are required to understand the structure and stability of the molecules thoroughly. The major challenge in developing biosimilar monoclonal antibody is to evaluate what impact certain quality attributes do have on clinical efficacy and safety and what level of difference is acceptable from a biosimilarity perspective. Different modifications and challenges in developing biosimilar monoclonal antibody will be discussed.

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