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## 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 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.

### Biography

Dr. Sunit was trained as Developmental/Cardiovascular Biologists in Leuven, Belgium where he received his PhD. He worked in industry (Mermaid Pharmaceuticals, Hamburg Germany) for several years where he was involved in target identification using model system. He has spent time at Max Planck Institute where he was involved in the CNS development related project. After coming back to India in 2007, he joined Avesthagen where he headed the biosimilar group. He was responsible for development of biologics including recombinant protein and monoclonal antibodies using mammalian expression system. He is associated with Zumutor Biologics since its inception and currently heads the Product Development team.

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