Symposium SANDOZ

TARGET-DIRECTED DEVELOPMENT OF BIOSIMILAR MONOCLONAL ANTIBODIES

Dr Jan Visser,
Head Global Analytical Characterization & Bioanalytics, Sandoz Biopharmaceuticals

Abstract: Biosimilars are high-quality, more affordable versions of biological medicines that have lost patent protection. Regulatory biosimilar guidelines are in place in regulated markets, and approved biosimilars are recognized as safe and effective medicines. Comparability to the reference product from the originator is shown at different levels. Similarity at the level of the molecule's physicochemical and biological characteristics lays the foundation for biosimilarity, which is further confirmed by subsequent preclinical and clinical studies. Monoclonal antibodies are large and complex molecules, which may have multiple mechanisms contributing to their mode of action. However, using state-of-the-art analytical methods, it is possible to characterize monoclonal antibodies very thoroughly. When possessing the required cell line and process development capabilities, biosimilar monoclonal antibodies can be engineered to match the quality attribute ranges of the reference product. The availability of approved biosimilar monoclonal antibodies in the near future has the potential to transform healthcare by lowering costs and increasing patient access.