

Development of antibody arrays for measuring biosimilar conformational comparability at molecular level

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For Biosimilar development, the three dimensional structure of the molecule is closely related to its efficacy and safety including immunogenicity. Recent guidelines from FDA on Biosimilars gave specific instructions on the analysis of protein tertiary structure. This presentation described a new approach to measure biosimilar molecule conformational changes systematically and at molecular level. A large number of different antibodies were developed toward a single biosimilar molecule to cover the whole protein sequence, and interrogate its conformational changes and compare the information with that of the innovator molecule. Case studies will be presented to demonstrate that this sensitive and robust technology can be applied to biosimilar cell line selection, process and formulation development, and many other aspects of biosimilar drug development.

Biography

Xing Wang, Ph.D. is President of Array Bridge Inc. since 2011. Before establishing Array Bridge Inc., Xing worked at Pfizer for 15 years and was a Group Leader and Associate Research Fellow. His experience includes small molecule and protein therapeutics drug discovery and development, successful application of proteomics, genomics and bioinformatics to target identification and validation in the small molecule drug discovery. For the past 8 years, his focus is on the development of protein therapeutics, building platforms for the identification and characterization of process-related impurities such as host cell proteins (HCPs) and residual DNA (rDNA). Xing has more than 30 publications including many in biologics development.

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