xMAP® Protein Conformational Array for Novel and Biosimilar mAB Development

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Biologics Higher Order Structure (HOS) is important to its safety and efficacy but difficult to define. A novel technology is developed using antibody arrays to analyze monoclonal antibody Higher Order Structure which is closely related to immunogenicity. This technology provides a sensitive, systematic and high-throughput approach for mAb Higher Order Structure comparability analysis, generating valuable information for cell line selection, process development and formulation development. It has been used by many of the leading biotech companies and biosimilar developers in mAb development including regulatory filings. Case studies from using the Luminex xMAP platform will be presented to demonstrate the application of the antibody array in biosimilar as well as novel mAb development and its complementary value to the bioassays and other analytical technologies.