

CHALLENGES AND SUCCESSES IN DEVELOPING AND MANUFACTURING MULTIPLE FORMATS OF BISPECIFIC ANTIBODIES

Weichang Zhou, Ph.D., WuXi Biologics, China
weichang_zhou@wuxibiologics.com

Bispecific antibodies have been increasingly introduced as new therapeutic modalities. They are generally complex and various molecule formats are used. As a consequence, development and manufacturing of these molecules for clinical and commercial applications have been very challenging. This presentation will highlight some of our experiences and learning derived from developing more than 80 different bispecific antibody molecules starting from developability assessment to large-scale manufacturing in many different formats. Several case studies will highlight various strategies for cell line engineering, cell culture and purification process design as well as analytical characterization in order to enhance product expression and product quality as well as to ensure large-scale manufacturing successes.