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Downstream process development for purification of a novel anti-MRSA antibody: A case study for antibody aggregation removal

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Staphylococcus aureus is gram-positive bacteria that commonly causes human health problem such as skin and respiratory infections, and food poisoning. *S. aureus* has multiple virulence factors including hemolysins, toxins and superantigens, and the strains have high genetic variability. Some strains of *S. aureus* are also resistant to antibiotics (MRSA and VRSA), resulting in an infection that is difficult to control. XBiotech has screened the blood of hundreds of human individuals to find antibodies that directly and specifically target *S. aureus*. One of these true-human antibodies, 514G3, has shown positive results in pre-clinical studies against *S. aureus* and is currently being evaluated in a Phase I/II study. During the purification of 514G3 antibody, an unusually high level of protein aggregation (up to 20%) was observed. Therefore, the protein aggregation problem was first analyzed by a series of analytical methods. Then, downstream processes were developed to remove the aggregated antibodies. This presentation will describe our strategies of resin screen and optimization for the removal of antibody aggregates.

Biography

Yanfeng Zhang completed his PhD from Michigan State University and Post-doctoral studies from Pacific Northwest National Laboratory and University of Texas Health Science Center at San Antonio. He is Senior Scientist of Process Development of XBiotech, USA, the world's leading developer of next-generation True Human therapeutic antibodies. He has published more than 20 papers in reputed journals and has been serving as an editorial board member of international journals.

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