

# ANTIBODIES, BIO THERAPEUTICS & B2B & GENETIC AND PROTEIN ENGINEERING

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## Purification and characterization of antibody therapeutics: Challenges and solutions during lead candidate selection

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Monoclonal antibody therapies continue to be the focus of biopharmaceutical industry. Hundreds of antibodies are in pre-clinical and clinical development. Purification and characterization of the lead molecules is vital during the lead optimization and candidate selection stage. Protein A affinity chromatography and additional polishing steps are used to purify panels of antibody hits against specific target. Throughout the process, biochemical and biophysical assessment for developability and manufacturability are applied to select lead candidate. This talk will review the methods, the challenges, and how the purification and characterization data contributes to lead selection. A case study will be discussed on a small scale purification method scouting for difficult proteins which facilitated the development of the large scale process and shortened development timeline.

### Biography

Haiyan has over 19 years of industry experience in the pharmaceutical and diagnostics areas. Haiyan joined Centocor R&D in 2004, which was later named Janssen BioTherapeutics. In the past 13 years at Janssen Haiyan leads a protein biochemistry group, focusing on developing and optimizing biotherapeutic lead molecules. She leads the group to work on purification and characterization of monoclonal antibodies, alternative scaffolds including bispecific antibodies, target antigens, receptors and other proteins for various research projects; developing new technologies to improve HTP purification and biochemical QC analyses; aligning with the methods from Discovery to Development process to ensure the smooth transfer of the therapeutic candidates from Lead optimization to Development stages. Haiyan received her Ph.D. in Microbiology at the University of Iowa. She then took a postdoctoral position at Eli Lilly and Company (Indianapolis). From 2000 to 2004, Haiyan worked at Roche Diagnostics Division (New Jersey) to lead a group responsible for developing purification process and manufacturing of recombinant DNA polymerases which were used for disease diagnosis.

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