ChE SEMINAR

Immunogenicity of Therapeutic Proteins

Challenges and Advances in the Drug Development Process

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Dept. of Chemical Engineering
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ABSTRACT

All therapeutic proteins have the potential to induce anti-drug antibodies (ADA). Clinically relevant ADA are those that can impact the efficacy and/or safety of the therapeutic. Depending on the characteristics of the antibody response, ADA can block the therapeutic from binding to the target; clear the therapeutic from circulation, induce a cross-reactive immune response to endogenous proteins, and/or result in hypersensitivity reactions. An immunogenicity assessment strategy of biological therapeutics typically evaluates the absence or presence of antibodies that bind the therapeutic and if present, determines the ATA ability to neutralize the effect of the therapeutic to its target. Hence the goal of molecular engineering design of therapeutic proteins require a detailed understanding of the critical quality attributes, ability to predict potential immunogenicity and thereby minimize safety adverse events. Case studies of molecules will be presented which has resulted in advances in the process involved in quality by design.

About the Speaker

Naren Chirmule, Ph.D. is Principal at 7immune Consulting. He has held senior leadership positions at Amgen (Thousand Oaks, CA) and Merck (Philadelphia, PA) in the departments of Clinical Immunology. His expertise is in the area of immune responses to biologics and vaccines, which include immunogenicity prediction and assessment, predictive toxicology and quality-by-design initiatives. He was closely involved in interactions with regulatory agencies in support global approvals for biologics (Prolia, Nplate, and Vectibix) and vaccines (Gardasil, Rotateq, Zostavax and Proquad). Over the past

five years, he has systematically studied aggregation of proteins and their influence on the immune response. He has published more than 100 manuscripts across various disciplines. He has a PhD from University of Mumbai, post-doctoral training at Cornell University Medical College, and was Assistant Professor in the Human Gene Therapy Unit of University of Pennsylvania. He is an advisor to the Filovirus consortium at NIH, and a reviewer on the HIV vaccine study section.