

세미나 초록

성명	하경수
소속	오송첨단의료산업진흥재단 신약개발지원센터
발표 주제	바이오의약품의 면역원성 분석
발표 내용	<p>Unlike small molecules, biological therapeutics are frequently recognized as foreign proteins and can potentially induce unwanted immune responses in patients. Since these harmful immune responses lead to a wide range of side effects, such as anaphylaxis, serum sickness and autoimmunity, elimination of the potential immunogenicity risk of biotherapeutics is essential for successful drug development. General <i>in vitro</i> immunogenicity assessment tools for the prediction of immunogenic properties of biologic drugs include both <i>in silico</i> prediction and MHC-peptide binding assays as well as human PBMC-based analyses. In preclinical immunogenicity assessment, the national administration guidelines mention that <i>in vivo</i> animal models are not necessarily predictive for immunogenicity in human due to species differences, therefore <i>in vitro</i> immunogenicity assays based on innate and adaptive immune cells are recommended and could be helpful in revealing cell-mediated responses. As a part of the critical safety and efficacy analyses in drug development, the evaluation of immunogenicity should be considered at the early stages of drug development. We believe that both <i>in silico</i> and <i>in vitro</i> immunogenicity assessment we established will help in advancing research on the development of new biotherapeutics.</p>