세미나 초록

성명	하경수
소속	오송첨단의료산업진흥재단 신약개발지원센터
발표 주제	바이오의약품의 면역원성 평가
발표 내용	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 *in vitro* immunogenicity assessment tools for the prediction of immunogenic properties of biologic drugs include both *in silico* prediction and MHC-peptide binding assays as well as human PBMC-based analyses. In preclinical immunogenicity assessment, the national administration guidelines mention that *in vivo* animal models are not necessarily predictive for immunogenicity in human due to species differences, therefore *in vitro* 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 *in silico* and *in vitro* immunogenicity assessment we established will help in advancing research on the development of new biotherapeutics.