

Critical Factors in the Assessment of Immunogenicity of Therapeutic Proteins
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Despite advancements in recombinant protein expression technology, virtually all therapeutic proteins (TP) produce antibody responses in at least a fraction of the human or animal subjects receiving them. Most often antibody development does not lead to serious adverse events in patients, however severe and sometimes life threatening conditions linked to antibody development occasionally occur. Additionally, development of anti-TP antibodies can accelerate drug clearance and result in altered pharmacokinetics. Early detection of anti-TP antibodies is therefore very important for the proper interpretation of preclinical and clinical study outcomes. Immunogenicity testing has evolved considerably to enable more sensitive detection of anti-TP antibodies and to improve the ability to detect those antibodies in the presence of high levels of TP. This presentation will provide an overview of the risk factors for immunogenicity, a summary of anti-TP antibody detection methodology and the validation requirements for anti-TP antibody assays.