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## **Immunogenicity of Therapeutic Biological Products**

Editors: F. Brown, A.R. Mire-Sluis

Immune responses to biological products have occurred with many approved therapeutics. The proportion of patients mounting an immune response is product dependent and the clinical significance of the immune response also varies with the nature of the product. Some products can induce production of significant levels of antibodies without any detectable effect on the activity of the product. However, neutralizing antibodies can attenuate the efficacy of the treatment and significant adverse clinical events can be seen if neutralizing antibodies cross react with patients' endogenous proteins.

Prediction of immunogenicity includes the use of bio informatics to predict T-cell epitopes, T-cell stimulation assays and in vivo transgenic animal models. Approaches to prevent immunogenicity involve methods to design out immunogenic sequences, protein pegylation and inducing tolerance.

Current methods for assessing and detecting immunogenicity include in vivo animal models, antibody assays and biological assays. The advantages and disadvantages of the various methods illustrate that a battery of tests is required to appropriately monitor patients' immune responses during clinical trials.

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