

Title : Immunogenicity of Therapeutic Proteins

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Abstract :

The immunogenicity of human protein therapeutics is a complex process and cannot currently be predicted based upon animal models. There are many factors that can affect a protein's immunogenicity including oxidation, aggregation, purification, storage, route and frequency of administration, and the immune status of the patient population. It is important to choose and validate the appropriate platform for detecting antibodies to each protein to support the development of the therapeutic. If an immune response is identified in a patient, the characterization of that immune response, including measuring the concentration, isotype(s), affinity, and neutralizing capability can be very informative.

The clinical relevance of antibodies against therapeutic proteins can be determined by monitoring the effect of the antibodies in patients.