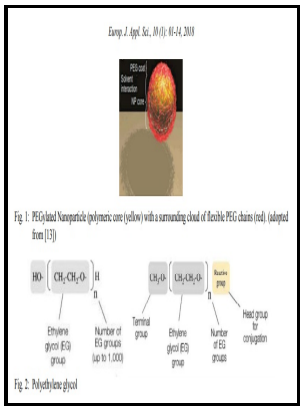
Immunogenicity of biopharmaceuticals

Springer - Immunogenicity of Biopharmaceuticals: An Example from Erythropoietin



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Immunogenicity Assessment and Regulatory Approval of Biologics

All antibodies bind the therapeutic drug and can cause antibody—drug immune complexes that are cleared quickly from the serum and decrease efficacy. In the case of Eprex, no changes in aggregate content were found between recent bulk and historical lots.

Immunogenicity of biopharmaceuticals

Biosimilar medicines—their use in the treatment of inflammatory bowel diseases. These products often exhibit forms of immunotoxicity that often only come to light during clinical studies. Key concepts and critical issues on epoetin and filgrastim biosimilars.

Toxic Effects of Immunogenicity to Biopharmaceuticals

Selecting the optimal assay for ADA screening is a key consideration in biopharmaceutical development and must take into account the properties of the therapeutic to be tested. Biotechnology-derived therapeutic proteins are playing an ever-increasing role in the pharmaceutical market.

Immunogenicity Assessment and Regulatory Approval of Biologics

Moreover, clinical trials are unlikely to detect immune responses that result in severe or life-threatening, yet uncommon, safety issues.

Immunogenicity of biopharmaceuticals

Immunogenicity of Biopharmaceuticals is the first book to comprehensively address the potential of an immune response to biopharmaceuticals. Neither subcutaneous administration nor the use of polysorbate 80 represent a sufficient explanation for the increase in PRCA. However, specialized animal models including genetically engineered mice and major histocompatibility complex-defined primates clinically mimic critical aspects of the human immune response, such as tolerance and T-repertoire and, therefore, may justify their high costs of development Chirino et al.

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