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Analyzing Immune Responses to Biopharmaceuticals

Basawaraj Kadangi[1] and Dr. Ashish M kandalkar[2]
Research Scholar, Department of Pharmacy[1]
Research Guide, Department of Pharmacy[2]
Sunrise University, Alwar, Rajasthan, India

Abstract: *Biopharmaceuticals may increase an immunogenic response in patients receiving treatment, which might have an effect on the medication's safety and effectiveness. Therefore, it is crucial to assess immunogenicity at every stage of a biopharmaceutical's clinical development, including post-marketing surveillance. Regulatory agencies mandate a thorough assessment of biopharmaceutical immunogenicity, but there are no consistent guidelines regarding the kind, amount, and caliber of evidence, nor are there guidelines for designing immunogenicity assays or comparing the immunogenicity of biopharmaceuticals. Additionally, significant technical advancements in immune response assessment methodologies have led to greater immunogenicity rates using contemporary assays, which restricts the comparison of biopharmaceuticals' immunogenicity outside of head-to-head clinical trials. Because of this, research initiatives, regulatory bodies, and medical professionals must stay up to date with the always changing assessments of immunogenicity. Here, we go over the variables that affect how immunogenic biopharmaceuticals are, possible clinical consequences, the latest regulatory guidelines for assessing immunogenicity, and how to measure immunogenicity in both non-clinical and clinical research. Additionally, we outline unique factors to take into account when assessing the immunogenicity of potential biosimilars*

Keywords: Antibody Formation, Immune Response, Risk Assessment, Clinical Trials.