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Search for unknown immunogenicity: An overview

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The scope of this speech is to show a general consideration regarding the evaluation of immunogenicity in bio-therapeutic products. Biological drugs and their biosimilars are highly complex molecules derived from living cells or organisms. The success of biological drugs has been focused on unwanted immunogenicity of these products. Evaluation of unwanted immunogenicity is an important consideration in development of bio-therapeutics products. Immunogenicity to protein based biological drugs is a complex process that involves numerous factors such as general patient´s immunity, amino-acid sequence of proteins, as well as biological drugs formulation (i.e. protein aggregates, impurities or excipients improper choice) and the drug administration. With new platforms, new technologies and development of novel therapeutics and treatment modalities, the assessment of immunogenicity will continue to require products approved on safety as well as on efficacy perspectives. Correlation between immunogenicity and clinical sequelae entirely depends on the appropriate detection, measurement and characterization of antibodies against biological therapeutics. These include conventional approaches such as ELISA and radioimmunoprecipitation assays. Alternative technologies use instruments based in nanobiosensors as surface plasmon resonance (SPR) and quartz crystal microbalances (QCM) to detect and characterize antibodies against therapeutic proteins and other molecular interactions. The purpose of this presentation is to show a general overview on the ability to detect therapeutic induced antibodies in plasma and sera of treated patients with biological drugs, using nanobiosensors. The evaluation, safety and efficacy of biosimilars require more rigorous testing than conventional generic drugs. The profiles of biosimilars must demonstrate similar physicochemical and biological characteristics, efficacy and safety in accordance with the approval requirements of regulatory authorities.

Biography

Rosa Helena Bustos Cruz works on nanobiosensors development for evaluation and characterization of molecular interaction in biological drugs. She introduced the nanobiosensors (surface plasmon resonance and quartz crystal microbalance) as new research technology in Colombia. She is also the Group Leader of Therapeutic Evidence Group at Universidad de La Sabana. She and her group works on safety and efficacy in drugs, clinical pharmacology and pharmacovigilance. She has also participated in the elaboration of evaluation guidelines for biosimilars according to regulatory affair (INVIMA).

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