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Immunological properties of nanotechnology-based complex drug formulations and challenges in their preclinical characterization

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Delivery of drugs, antigens and imaging agents benefits from using nanotechnology carriers. Successful translation of nanoformulations into clinic involves a thorough assessment of their safety profiles, which among other end-points, includes evaluation of immunotoxicity. This presentation will discuss current knowledge and experiences from the US Nanotechnology Characterization Laboratory to highlight most prominent pieces of nanoparticle-immune system puzzle and discuss achievements, disappointments and lessons learned from past ten years of preclinical immunological characterization of nanomaterials. I will present translational case studies to highlight common challenges in the preclinical characterization of nanotechnology carriers and nanoparticle based complex drug formulations. The presentation will focus on areas such as structure-activity relationships, effects on blood coagulation system, activation of complement, effects on the immune cell function, endotoxin detection and quantification, nanoparticle interference with traditional immunological tests, and applicability of traditional *in vivo* immune function tests to engineered nanomaterials.

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