

## **Preclinical assessment of the immunological safety of nanomedicine candidates**

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The production and use of engineered nanomaterials is constantly expanding, but there remain uncertainties surrounding the potential risks posed to human health and environment. Nanomaterials vary considerably with respect to their composition, charge, surface area, solubility, crystal structure, surface chemistry and shape and these characteristics are known to influence their biocompatibility. Many nanomaterials have been shown to interact with the immune system by either stimulating or suppressing various responses through their interaction with proteins found within blood. Many nanomaterials interact with serum proteins such as opsonins (e.g. antibodies, complement) and are rapidly taken up into cells of the mononuclear phagocyte system (e.g. macrophages). It is clear that a coherent understanding of the interaction of nanomaterials with human immunological and haematological systems is vital to the translation of promising materials to the clinic in order to remove, or possibly incorporate, nanoparticle properties that may result in an immunological response. We are investigating the relationships between nanoparticle characteristics in an attempt to define structure-activity relationships. In order to truly define these relationships there is a requirement for standardisation of analysis between laboratories. The recent initiation of the European Nanotechnology Characterisation Laboratory (EU-NCL) aims to address this requirement for methodological harmonisation to more clearly define the biocompatibility of nanomaterials. This presentation will provide an overview of the current understanding of biocompatibility of nanomaterials in terms of interactions with the immune system.