



Nanotechnology and medical devices: Risk, regulation and 'meta' registration

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(Received 30 July 2012; accepted 18 February 2013)

Abstract

A new approach to risk assessment for nanotechnology in healthcare includes the mapping of particles to risk profiles and the potential channels for the collection of relevant information. This relates assay type to processes probed and the recognition of the relevance of this to particle pathways. It is only by ensuring the sound regulation of this throughout the 'life cycle' of translational research and development, which we can ensure the true provenance of materials that we intend to use in the clinical environment.

Key words: Nanotechnology, Orthopaedics, Intercalation complex, Nano-kaolinite, Power ultrasonic

1. Introduction

The standardisation of risk assessment and the subsequent management of this information, challenges the development of new biomedical devices, especially those incorporating nanotechnology (Maynard and Kuempel, 2005). At the nanoscale, electromagnetic forces become much more important, conferring unique properties to a material of this scale. Nanomaterials not only have different thermal, optical and magnetic properties compared to their bulk counterparts, but also have dramatically different biological interactions. Size will influence the ability of a particle to penetrate biological barriers (skin, tissue and cell membranes)

and due to the massive increase in ratio of surface area to mass; nanomaterials will have markedly different reactivity rates.

It is for precisely these unique properties at the nanoscale (*e.g.* optical, thermal properties, reaction rates and dissemination within the body) that nanomaterials could revolutionize modern medicine and are of increasing interest to scientists, clinicians and manufacturers. Nanomaterials are already being used in medical diagnosis and treatment, and commercially for cosmetics, sunscreens and stain-resistant clothing etc. Indeed the vast array of nanomaterials being developed (Table 1) presents one of the hurdles to effective risk management *i.e.*