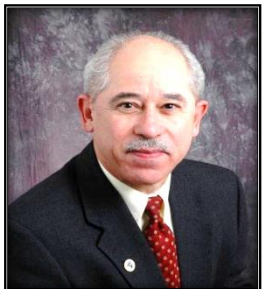

REGULATORY SCIENCE RELEVANT TO NANOMATERIALS: BIOLOGICAL AND PHYSICO-CHEMICAL EVALUATION OF IMMOBILIZED NANOSTRUCTURES

A Distinguished Lecture

By

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Abstract: Nanotechnology and nanoscience research represent a key aspect for the development of new chemical and biomedical products. Nanomaterials (nanoparticles, nanospheres, nanotubes, nanostructural surfaces, etc) are used in applications such as ceramics, textiles, cosmetics, and optics, and in the chemical industry at large. In addition, they are applied in biomedicine as nano-biomaterials, nanospheres for drug release, nanotubes for gene therapy, and as medical products incorporating nanostructured surfaces. The Food and Drug Administration (FDA) is increasingly receiving and reviewing regulatory submissions for medical products incorporating nanostructured surfaces, ranging from cardiovascular to neurovascular devices and catheters to orthopedic implants, and indications suggest that this number will dramatically continue to increase in the next 3-5 years. Due to the considerable development of surface nanostructures and products that incorporate them, it is imperative that the scientific and regulatory communities develop an understanding of this technology, especially how such nanoscale features influence biological responses. The aim of this presentation is to provide an overview of key issues that are associated with the development of non-clinical biological and biocompatibility models to evaluate medical devices which incorporate coatings and surfaces manipulated on the nanoscale range.

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