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Regulatory challenges of nano therapeutics

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In recent years, nanotechnology has been increasingly applied to the area of drug development and treating various diseases because nanotechnology is a revolutionary field in the world of medicines through micro-manufacturing of individual atoms and molecules by manipulation of their characteristics. Regulating nanotechnology based drug delivery systems has been a challenging task due to the absence of harmony between the various government and non-government organizations involved in the development of these technologies. Nevertheless, proactively addressing this issue constitutes the need to establish appropriate regulatory guidelines for facilitating a rapid market approval of safe, efficient and sustainable nanoparticulate drug carriers. Nanomaterials have become part of formulation development in the pharmaceutical industry and offer exciting opportunities in the area of targeted drug delivery. Regulatory challenges arising from the use of nanomaterials in the medical sector present particular challenges due to the wide spectrum of their applicability, the diverse characteristics of resulting applications and a large range of technological, scientific, normative, conceptual and institutional uncertainties. Recent studies of nanomaterials used in various medical applications, such as medical imaging, disease diagnoses, drug delivery, cancer treatment, and gene therapy, have shown the potential positive impact of nanotechnology; however, the potential adverse effects on human health of these nanomaterials are still largely unknown and remain to be evaluated. This review summarizes challenges likely to be encountered during the development and approval of nanoparticle-based therapeutics, and focus on potential strategies for drug developers and regulatory agencies to accelerate the growth of this important field.

Biography

Arpit A Patel has completed his BPharmacy from University of Pune, and now pursuing MS Forensic Pharmacy (Regulatory Affairs and management) at the age of 26 from Gujarat Forensic Sciences University. He has published one research paper in IJPRD and working on another two papers.

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