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Nanosimilars: Overview of critical regulatory attributes

Arpit A Patel

Gujarat Forensic Sciences University, India

First generation nanomedicine patents are going to expire for numbers of products. Time consumed by companies to launch first generic version of Taxol® magnifies issues of nanotechnology based product development and regulations. Regulating nanotechnology based drug delivery systems has been a challenging task due to lack of any consensus between various regulatory agencies. In these circumstances, stands of EMA and FDA for 'Nanosimilar' products become imperative for regulatory regime of nanomedicine in the world. It was noted earlier that liposomal drug products have specific and certain distribution pattern linked to manufacturing and formulation, and that similar plasma concentrations achieved may not necessarily correlate with therapeutic performance. Such exemplar cases make regulation for nanomedicine more obscure. Furthermore, regulatory challenges with the assessment of the comparability of existing nano-formulations, the adequacy of tools for risk characterisation and the classification of converging technologies are required to be responded. The objectives of present analysis are to emphasize current regulations for nanosimilar products in the leading regulatory agencies of the world. Moreover, the presentation also highlights the potential next generation nanotech products to be considered in regulatory framework as nanosimilars in future. A section is also depicting potential regulatory parameters in safety and efficacy of nanosimilar drug products.

Biography

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

arpit_p88@yahoo.co.in