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REGULATORY APPROVAL OF NEW DRUG DELIVERY SYSTEMS: BRIDGING THE GAPS

Ripal Gharia
Cliantha Research Ltd., India

Bringing a new drug through discovery, clinical testing, development and regulatory approval is currently estimated to take a decade and cost well over $120 million. Scientists are working on different aspects to reduce this cost. New Drug Delivery System (NDDS) refers to the formulations, systems and technologies for transporting a pharmaceutical compound in the body as it is needed to safely achieve its desired therapeutic effects. NDDS technologies usually combine already approved drugs with different delivery system for either same or different indication and/or route of administration. Regulatory approval process requires less preclinical and clinical studies compared to NCE, but more than generics. NDDS can pose challenges regarding their classification for authorization by regulatory agencies, particularly with respect to nanomedicine and nanotechnology. There are currently no specific requirements from the regulatory agencies (FDA and EMA) for the preclinical and clinical testing of nanoparticle based drug delivery systems and only reflection papers providing guidelines on the pharmaceutical development of a specific type of nanoparticle based drug delivery systems have been published and to date the evaluation process follows a similar path as for small-molecule drugs. The development of a new drug starts with preclinical testing followed by the submission of an Investigational New Drug (IND) application in order to initiate the clinical trials. Intended therapeutic benefits needs to be taken into account for designing preclinical and clinical studies. Application of quality by design concepts early in the development will help the developer to build quality in and will ultimately improve clinical translation.

BIOGRAPHY

Ripal Gharia currently working as Assistant General Manager at Cliantha Research Ltd., she has about 12+ years of working experience in clinical research. She is working as safety expert, medical monitor and medical writer mainly in therapeutic areas of oncology, cardiology, dermatology, ophthalmology, urology, pain medicine, obstetrics and gynecology and respiratory for various regulatory submissions such as FDA, EMA and DCGI. She was also conducted training programs for project teams located in India and USA. She has a close rapport with KOLs and subject experts in various therapeutic areas. She is a part of more than 70+ studies in different phases of drug development. She is interested in the areas of medical and regulatory affairs, pharmacovigilance, NDDS, medical devices and vaccines.

rgharia@cliantha.in

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