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The key roles & responsibilities of pharmacists in biosimilars development

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Biosimilars development is a landmine of complexities with respect to regulatory, manufacturing, marketing and pharmacovigilance aspects, making it one of the most expensive development propositions in the pharmaceutical industry. A typical development program of biosimilars includes analytical and bioanalytical assays, manufacturing, pharmacology and/or toxicology studies in animals and clinical trials. A pharmacist plays a imperative role in ensuring quality assurance and regulatory compliance in the conduct of clinical trial and pharmacovigilance activities.

A pharmacist plays an important role in making formulary decisions about Biosimilars, educating health care administrators, providers, legislators, policymakers, sponsors, and patients about these products. A vital role is warranted in the pharmacovigilance to detect, assess, and prevent adverse effects and other drug-related problems from biopharmaceuticals.

The clinical pharmacist should take a leadership role in a multidisciplinary effort to evaluate biosimilars for use in the institution through the formulary process, an objective analysis of comparative data demonstrating the efficacy and safety (especially immunogenicity) of a biosimilar for specific patient populations treated at the institution is needed. The manufacturing pharmacist should be aware of the types of data required to establish biosimilarity and interchangeability. Today, pharmacist's role is far more crucial in the wake of multifaceted challenges in the biosimilars industry.

Biography

N Srinivas has completed his PhD from JNT University Hyderabad in the area of bioanalysis & clinical pharmacokinetics. He is the Professor and Principal of Malla Reddy Institute of Pharmaceutical Sciences, Secunderabad and has a blend of 18 years teaching and 4 years industrial experience. His prior experience includes training of clinical research to life science students and industry professionals. He has 10 papers in reputed journals and has guided 20 post graduate projects. He is serving as Member in institutional ethics committees (IEC) of couple of reputed hospitals.

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