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Optimising the bang for buck in the realm of therapeutic ontology using patent and XP documents

Sankar Sundaram and Shubhankar Joshi
Department of Pharmaceutical Chemistry, JSS University, India

It is becoming harder and harder to discover a new Drug. A part could be attributed to "the low-hanging fruits have already been plucked" maxim and another part to the huge expenses involved in the design, synthesis, preclinical and clinical evaluation of a new therapeutic intervention. It is therefore, desirable to reduce the cost of Drug Discovery by adopting low-cost outsourcing of custom-synthesis, cost-effective and sure-shot screening methods, bedrock Safety-profiling etc. Before committing one's resources to the above Business development strategy, it is advisable to thoroughly estimate the elbow room available under one's command. Enter the Patent and XP Documents, whose gleaning, determines the first step in ascertaining the metes and bounds of business risk propensity. A few case studies are being discussed, to get an insight of smarter staking in the realm of New Drug Development business.

Biography

Sankar Sundaram, the son of a Registered Nurse, has completed his PhD in Pharmaceutical Sciences, from The Tamil Nadu Dr MGR Medical University and Bachelor of General Laws' from the Annamalai University. He is a Registered Patent agent (IN/PA-666) in the Indian Intellectual Property Office and has drafted more than fifteen patents pertaining to the field of Pharmaceutical Products. Currently, he is guiding PhD scholars in New Drug Discovery and is teaching Medicinal Chemistry for graduate students at the JSS University, Mysore.

iprsankar@gmail.com

Population pharmacokinetics and its relevance to pharma Industry

Shobha Rani R Hiremath
Al-Ameen College of Pharmacy, India

Rapidly evolving changes in health care economics and consumer expectations make it unlikely that traditional drug development approaches will succeed in the future. There is a need to focus on the implementation of pharmacokinetic-pharmacodynamic (PK-PD) studies and modeling as essential tools for drug development. Population pharmacokinetics (PPK) has evolved from therapeutic drug monitoring and plays a key role in clinical pharmacology and drug development. PPK methods are used throughout the drug development process to summarize the data and most importantly for phase II and III studies in the efficient development of safe and effective drugs. PPK combined with simulation methods helps in estimating the expected range of concentrations for the given dose. The PPK study plan for each drug development project must have a strategy for data management, data collection, data quality assurance, staff training for data collection, data analysis and model validation. The application of population approaches to drug development is recommended in several US Food and Drug Administration (FDA) guidance documents. Population pharmacokinetic analyses may be undertaken in 3 steps: exploratory data analysis, model development and model validation. Documentation for regulatory purposes should include a complete inventory of key runs, accompanied by objectives, assumptions, hypotheses and diagnostic analyses of goodness of fit as evidence of reliability of results. The use of the population approach by the pharmaceutical industry needs to be encouraged to provide valuable information not obtainable by other techniques. The acceptance of population PK-PD analyses by regulatory agencies also needs to be encouraged.

Biography

Shobha Rani R Hiremath has 25 years of teaching experience, guided 47 M. Pharm and 9 Ph.D students. She has attended more than 80 conferences/workshops in India and abroad. She has 75 national and international publications. Dr. Shobha Rani has 2 patents to her credit. She has achieved several grants and awards in her career and she is a consultant to various pharmaceutical industries. Dr. Hiremath is the secretary of Independent Ethics Committee in Bangalore Allergy Centre, Bangalore. She is the Editor-in-chief of the quarterly journal entitled "Indian Journal of Pharmacy Practice" published by Association of Pharmaceutical Teachers of India, India.

shobha24@yahoo.com