conferenceseries.com

Vijay Jagdale, J Clin Toxicol 2017, 7:3(Suppl)
DOI: 10.4172/2161-0495-C1-024

9th Euro-Global Summit on

Toxicology and Applied Pharmacology

June 22-24, 2017 Paris, France

Vijay Jagdale

Sai Life Sciences Ltd., India

Strategy for the early drug discovery assays and toxicology screening

Developing a new drug from original idea to the launch of a finished product is a complex process where strategic planning plays crucial role to reduce usual time (12–15 years) as well as cost (1 billion $) for all the processes. The pharmaceutical industry has been evolving worldwide in the recent years, which made numerous CROs and biotech companies conducting such programs through services in various countries. The proper selection and applications of correct models, as well as appropriate data interpretation, are critically important in decision making and successful advancement of drug candidates. The successful discovery program includes strategic execution and read outs from initial assays like physicochemical characterization (kinetic solubility, thermodynamic solubility, pH dependent solubility and lipophilicity), absorption (PAMPA, MDCK permeability, Caca-2 permeability, MDCK-MDR1 permeability), metabolism (liver microsomes, hepatocytes, S9 fraction, reaction phenotyping, CYP inhibition and time dependent inhibition) and other preliminary assays (PPB, brain/tissue binding, blood to plasma ration, plasma stability, SGF/SIF stability, buffer stability, etc.) to prioritize leads for the further *in-vivo* assays. Pharmacokinetics assays needs appropriate execution to rank order compounds based on promising clearance (CL), bioavailability (F%), exposure (AUC), half-life ($t_{1/2}$), and distribution volume (L). Selective *in-vivo* PK studies are valuable to confirm whether the applied *in vitro* assays (*in vitro* metabolism and absorption) can serve as good predictive models for *in vivo* PK in terms of plasma clearance and bioavailability. The early application of preclinical safety assessment-both new molecular technologies as well as more established approaches such as standard repeat-dose rodent toxicology studies can identify predictable safety issues earlier in the testing paradigm. These earlier identification of dose-limiting toxicities will provide chemists and toxicologists the opportunity to characterize the dose-limiting toxicities, determine structure–toxicity relationships and minimize or circumvent adverse safety liabilities. Early stages includes nonclinical safety studies on candidate drugs to assess general toxicology (through *in vivo* experiments), safety pharmacology (effects on major organ systems) and basic genetic toxicity tests during early discovery phase in non-GLP conditions. Because of this, there is a strong need for personnel involved with toxicology and pharmacology studies need to understand the varied tools and approaches to perform early drug discovery safety analysis.

Biography

Vijay Jagdale is Veterinarian by profession and has expertise in Preclinical Toxicology as a Toxicologist as well as Pathologist working with various CRO's and discovery/generic pharmaceutical companies. He has contribution in building strategic discovery platform for preclinical assays to facilitate smooth pathway for the lead candidates. He has expertise in the area of preclinical research in drug discovery and development in CROs with adequate exposure to preclinical toxicology, toxico-pathology, DMPK and laboratory animal facility set up, management and operation. Complete understanding of preclinical GLP toxicology with multiple types of therapeutics areas adhering to the various national and international regulatory guidelines. He also has experience in establishment, operation and management of national and international (AAALAC/OLAW) accredited rodent facilities with preclinical toxicology laboratory.

vijay.j@sailife.com

Notes: