

SAR Safety Assessment

Stan Roberts is the President of SAR Safety Assessment, an independent consulting company providing a full range of services for preclinical toxicology and ADME/PK studies for both biotherapeutics (NBE) and small molecular weight new chemical entities (NCE). A partial list of these services include; preparing/reviewing preclinical toxicology and ADME/PK development plans, devising and conducting research to assess relevance of preclinical findings to humans, preparing competitive bids for preclinical CRO's, building comprehensive and preclinical budgets, preparing/reviewing preclinical study protocols and reports, monitoring/managing preclinical studies, assembling/writing/issuing preclinical study reports, conducting gap analyses, performing in-licensing and out-licensing due diligence reviews and preparing/reviewing regulatory study reports and packages for all types of submissions. Stan has extensive experience in directly conducting all types of preclinical studies and in leading research groups in both toxicology and ADME/PK over the past 30 years. He has direct experience with a diversity of NBE and NCE's across all types of human disease targets. Stan has been responsible for composing, managing, editing and reviewing numerous successful regulatory submissions (e.g., IND, NDA, BLA, PLA) as well as all types of communications and interactions (e.g., face-to-face and telecoms) with regulatory scientists and agencies. He has been very active in post-graduate education and has served on numerous PhRMA and BIO scientific leadership committees that have worked with the FDA to develop guidances and develop better techniques to improve the quality of new drug candidates. Currently, Stan serves on both the BioSafe Leadership Committee plus the Pharmacokinetics and Disposition Expert Working Group.

Contact Information

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