

Safety Pharmacology in Pharmaceutical Development and Approval, 2003, 208 pages, Shayne C. Gad, 0849313805, 9780849313806, Taylor & Francis, 2003

The Propulsid and Seldane drug disasters could have easily been avoided with more rigorous safety pharmacology studies of these compounds prior to any human clinical trials. Unfortunately, safety pharmacology has been overlooked by all but a few developers. With recent drug withdrawals from the market and the implementation of the International Conference on Harmonization (ICH) guidelines, safety pharmacology will become a more important phase in drug development. Safety Pharmacology in Pharmaceutical Development and Approval spells out the whys and hows of safety pharmacology testing. The book covers the background, history, and concerns that have evolved from lackluster safety pharmacology activities in the past. It details regulatory requirements, provides comprehensive information on study designs, and covers both the required battery of studies and the supplemental, follow-up battery. Until recently, pharmacovigilance has been product-rather than utilization-oriented and often invisible in clinical medicine. It is clear that definitive safety pharmacology standards are needed to combat the increase in adverse reactions seen in the last 20 years. Giving you a head start in this emerging field, Safety Pharmacology in Pharmaceutical Development and Approval addresses how best to implement ICH safety standards and how to integrate pharmacology safety evaluations into existing safety evaluations.

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