Publication

Overview of Safety Pharmacology.

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Abstract

Safety pharmacology entails the assessment of the potential risks of novel pharmaceuticals for human use. As detailed in the ICH S7A guidelines, safety pharmacology for drug discovery involves a core battery of studies on three vital systems: central nervous (CNS), cardiovascular (CV), and respiratory. Primary CNS studies are aimed at defining compound effects on general behavior, locomotion, neuromuscular coordination, seizure threshold, and vigilance. The primary CV test battery includes an evaluation of proarrhythmic risk using in vitro tests (hERG channel and Purkinje fiber assays) and in vivo measurements in conscious animals via telemetry. Comprehensive cardiac risk assessment also includes full hemodynamic evaluation in a large, anesthetized animal. Basic respiratory function can be examined in conscious animals using whole-body plethysmography. This allows for an assessment of whether the sensitivity to respiratory-depressant effects can be enhanced by exposure to increased CO2 . Other safety pharmacology topics detailed in this unit are the timing of such studies, ethical and animal welfare issues, and statistical evaluation.