Strategy and Phasing for Nonclinical Drug Safety Evaluation in Discovery and Development of Pharmaceuticals

1 INTRODUCTION

The preclinical assessment of the safety of potential new pharmaceuticals represents a special case of the general practice of nonclinical safety assessment (Gad, 1996, 2000; Meyer, 1989) possessing its own peculiarities and special considerations and differing in several ways from the practice of toxicology in other fields—for some significant reasons. Because of the economics involved and the essential close interactions with other activities (e.g., clinical trials, chemical process optimization, formulation development, regulatory reviews), the development and execution of a crisp, timely, and flexible, yet scientifically sound, program are prerequisites for success. The ultimate aim of preclinical assessment also makes it different. A good pharmaceutical safety assessment program seeks to efficiently and effectively move safe, potential therapeutic agents into, and support them through, the clinical evaluation, then to registration, and, finally, to market. This requires the quick identification of those agents that are not safe. At the same time, the very biological activity which makes a drug efficacious also acts to complicate the design and interpretation of safety studies.

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