# *Nonrodent Animal Studies*

## 1 INTRODUCTION

Most safety assessment studies are conducted in rodents (rats, mice, and hamsters) or their close "cousins" rabbits and guinea pigs. Outside of the pharmaceutical, medical device, and veterinary product industries, it has become rare for the practicing toxicologist to have close familiarity with the nonrodent animal species addressed in this chapter. Indeed, it is unlikely that a toxicologist has received any significant academic experience or training with these species. Additionally, use of these species in the European Union (EU) even for therapeutics has become very difficult at best. However, the proper use of nonrodent species is essential in the evaluation of potential new therapeutic entities, on both scientific and regulatory grounds. Indeed, there are numerous studies showing significantly better concordance between humans and nonrodents than humans and rodents for detection of adverse responses to pharmaceuticals (Olson et al., 2000). This is tacitly recognized in regulatory practice for in those new product development plans where a single species is deemed appropriate and sufficient (medical devices, protein therapeutic, and 505(b)(2) approval candidates), the single species is overwhelming a nonrodent.

In addition to rodent studies, regulatory guidelines for pharmaceuticals require that repeated-dose safety studies of up to nine months (in the United States, six months elsewhere) in duration be conducted in a nonrodent species. The most commonly used nonrodent species is the dog followed by an NHP

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