Application of In Vitro Techniques in Drug Safety Assessment

1 INTRODUCTION

The key assumptions underlying modern toxicology are (1) that other organisms can serve as accurate predictive models of toxicity in humans, (2) that selection of an appropriate model to use is the key to accurate prediction of potential hazard in humans, and (3) that understanding the strengths and weaknesses of any particular model is essential to translating potential hazards identified in these models to assess relevant hazards in humans and in the subsequent management of actual risks. The nature of models and their selection in toxicological research became the subject of critical scientific review starting in the 1980s. Usually in toxicology, when we refer to "models," we really have meant test organisms or systems, although, in fact, the manner in which parameters are measured (and which parameters are measured to characterize an endpoint of interest) is also a critical part of the model (or, indeed, may actually constitute the model).

Although there have been accepted principles for test organism selection, these have not generally been the actual final basis for such selection. It is a fundamental hypothesis of both historical and modern toxicology that adverse effects caused by chemical entities in higher animals are generally the same as those induced by those entities in humans. There are many who point to individual exceptions to this and conclude that the general principle is false.

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