REGULATORY ISSUES IN PRECLINICAL SAFETY STUDIES (U.S. FDA)

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1 INTRODUCTION

In drug development, it is important to know and understand the legislation and other "high level" documents (e.g., case law) establishing the regulatory authority of the FDA as well as the specific enabling documents that have been published (e.g., 21 CFR, ICH Guidances, FDA Guidances) and the supporting guidelines [1–10]. However, it is of practical importance to understand the scientific approach that ultimately drives decision making in the drug review divisions that constitute the real world of pharmaceutical development. The pivotal individual in applying pharmacology/toxicology principles and practice to drug development is the FDA reviewer. This individual has the task of interpreting data submitted by the sponsor and making the decisions critical to clinical drug development. Sometimes in trying

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