Regulation of Human Pharmaceutical Safety

1 INTRODUCTION

The safety of pharmaceutical agents, medical devices, and food additives are the toxicology issues of the most obvious and longest-standing concern to the public. A common factor among the three is that any risk associated with a lack of safety of these agents is likely to affect a very broad part of the population, with those at risk having little or no option as to undertaking this risk. Modern drugs are essential for life in our modern society, yet there is a consistent high level of concern about their safety.

This chapter examines the regulations which establish how the safety of human pharmaceutical products are evaluated and established in the United States and the other major international markets. As a starting place, the history of this regulation will be reviewed and the current organizational structure of the U.S. Food and Drug Administration (FDA) will be briefly reviewed along with the other quasi-governmental bodies that also influence the regulatory processes. The current structure and context of the regulations in the United States and overseas will also be presented. From this point the general case of regulatory product development and approval will be presented. Toxicity assessment study designs will be presented. The broad special case of biotechnology-derived therapeutic products and environmental concerns associated with the production of pharmaceuticals will be briefly addressed. The significant changes in regulation brought about by harmonization are also reflected.

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