



Genotoxic Impurities: Strategies for Identification and Control

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This book examines genotoxic impurities and their impact on the pharmaceutical industry. Specific sections examine this from both a toxicological and analytical perspective. Within these sections, the book defines appropriate strategies to both assess and ultimately control genotoxic impurities, thus aiding the reader to develop effective control measures. An opening section covers the development of guidelines and the threshold of toxicological concern (TTC) and is followed by a section on safety aspects, including safety tests in vivo and vitro, and data interpretation. The second section addresses the risk posed by genotoxic impurities from outside sources and from mutagens within DNA. In the final section, the book deals with the quality perspective of genotoxic impurities focused on two critical aspects, the first being the analysis and the second how to practically evaluate the impurities.

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