Pharmaceutical Industry Practices on Genotoxic Impurities (Chromatographic Science Series)

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A great deal of confusion and uncertainty over genotoxic impurity (GTI) identification, assessment, and control exists in the pharmaceutical industry today. **Pharmaceutical Industry Practices on Genotoxic Impurities** strives to facilitate scientific and systematic consensus on GTI management by presenting rationales, strategies, methods, interpretations, practices, and case studies from the pharmaceutical industry. Featuring the contributions of industry leaders from nine major pharmaceutical companies, this authoritative text:

- Explores the safety, quality, and regulatory aspects of GTIs
- Provides an overview of the latest FDA and EMEA guidelines
- Explains the how and why of various GTI control tactics and practices
- Describes genotoxicity evaluation, acceptable exposure calculation, and analytical methods for testing
- Includes real-life examples of GTI control in drug substance and drug product development processes

Containing case studies from large and small pharmaceutical firms in multiple geographical regions, **Pharmaceutical Industry Practices on Genotoxic Impurities** supplies an overview of—and a current framework for—GTI control in the pharmaceutical industry, demonstrating how proper management of GTIs can occur with the appropriate guidance, a firm grasp of the practical implications, and effective information sharing between disciplines.

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