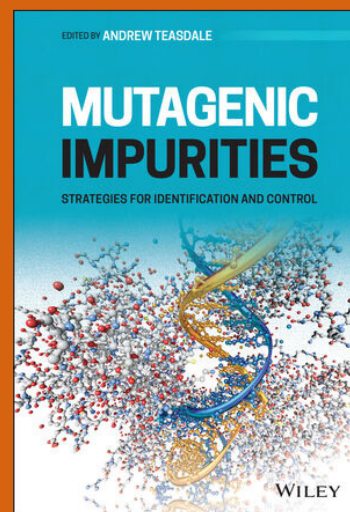


# Mutagenic Impurities: Strategies for Identification and Control

Andrew Teasdale (Editor)

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## Learn to implement effective control measures for mutagenic impurities in pharmaceutical development

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In *Mutagenic Impurities: Strategies for Identification and Control*, distinguished chemist Andrew Teasdale delivers a thorough examination of mutagenic impurities and their impact on the pharmaceutical industry. The book incorporates the adoption of the ICH M7 guideline and focuses on mutagenic impurities from both a toxicological and analytical perspective.

The editor has created a primary reference for any professional or student studying or working with mutagenic impurities and offers readers a definitive narrative of applicable guidelines and practical, tested solutions. It demonstrates the development of effective control measures, including chapters on the purge tool for risk assessment.

The book incorporates a discussion of N-Nitrosamines which was arguably the largest mutagenic impurity issue ever faced by the pharmaceutical industry, resulting in the recall of Zantac and similar drugs resulting from N-Nitrosamine contamination.

Readers will also benefit from the inclusion of:

- A thorough introduction to the development of regulatory guidelines for mutagenic and genotoxic impurities, including a historical perspective on the development of the EMEA guidelines and the ICH M7 guideline
- An exploration of in silico assessment of mutagenicity, including use of structure activity relationship evaluation as a tool in the evaluation of the genotoxic potential of impurities
- A discussion of a toxicological perspective on mutagenic impurities, including the assessment of mutagenicity and examining the mutagenic and carcinogenic potential of common synthetic reagents

Perfect for chemists, analysts, and regulatory professionals, *Mutagenic Impurities: Strategies for Identification and Control* will also earn a place in the libraries of toxicologists and clinical safety scientists seeking a one-stop reference on the subject of mutagenic impurity identification and control.

## ABOUT THE AUTHOR

**Andrew Teasdale** is a senior principle scientist within AstraZeneca, with 25 years experience in the industry. Andrew is also the inventor of the purge factor concept applied to the risk assessment of mutagenic impurities. Over the last 10 years he has been an author of over 30 papers relating to mutagenic impurities. Andrew is current an advisor to China FDA for ICH M7. Prior to entering the pharmaceutical industry Andrew obtained a degree BSc (Hons) in analytical chemistry from the University of Sunderland, followed by a PhD in organic chemistry from Durham University.

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