DESCRIPTION

This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics.

• Helps readers solve scientific, technical, and regulatory issues in preclinical safety assessment and early clinical drug development

• Explains scientific and philosophical bases for evaluation of specific concerns – including local tissue tolerance, target organ toxicity and carcinogenicity, developmental toxicity, immunogenicity, and immunotoxicity

• Covers the development of new small and large molecules, generics, 505(b)(2) route NDAs, and biosimilars

• Revises material to reflect new drug products (small synthetic, large proteins and cells, and tissues), harmonized global and national regulations, and new technologies for safety evaluation

• Adds almost 20% new and thoroughly updates existing content from the last edition

ABOUT THE AUTHOR

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