



Pediatric Non-Clinical Drug Testing: Principles, Requirements, and Practice

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This book explains the importance and practice of pediatric drug testing for pharmaceutical and toxicology professionals. It describes the practical and ethical issues regarding non-clinical testing to meet US FDA Guidelines, differences resulting from the new European EMEA legislation, and how to develop appropriate information for submission to both agencies. It also provides practical study designs and approaches that can be used to meet international requirements. Covering the full scope of non-clinical testing, regulations, models, practice, and relation to clinical trials, this text offers a comprehensive and up-to-date resource.

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