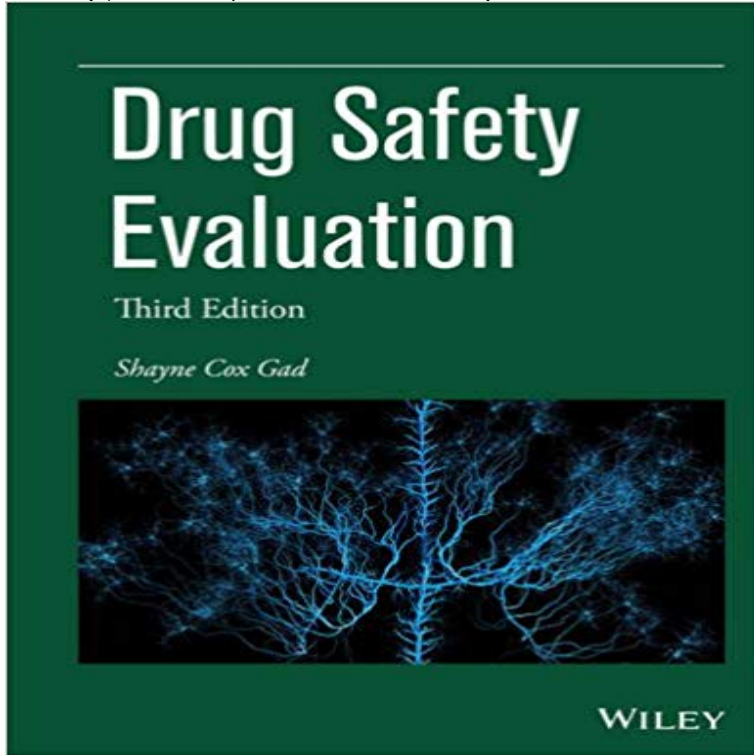


# Drug Safety Evaluation (Pharmaceutical Development Series)



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.

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