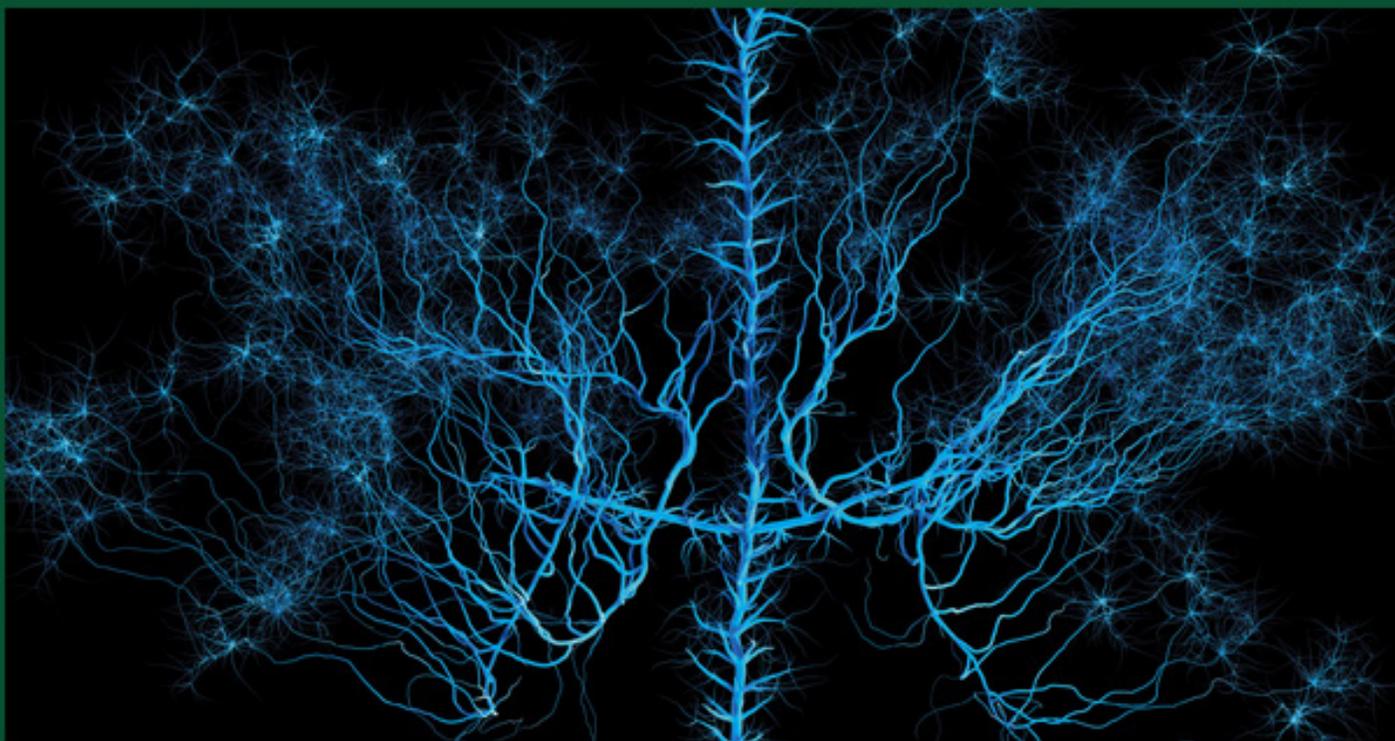

Drug Safety Evaluation

Third Edition

Shayne Cox Gad



WILEY

DRUG SAFETY EVALUATION

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3rd Edition

SHAYNE COX GAD

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To the memory of my mother Norma Jean Cox Gad, who crossed over nine years ago, and my brother Scott Michael Gad who joined her six years ago. I hope that all your beloved little friends are there with you. I will see you both again.

—Shayne Cox Gad

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PREFACE

The third edition of *Drug Safety Evaluation* is a complete revision of the second edition which maintains the central objective of presenting an all-inclusive practical guide for those who are responsible for ensuring the safety of drugs and biologics to patients and shepherding valuable candidates to market, healthcare providers, those involved in the manufacture of medicinal products, and all those who need to understand how the safety of these products is evaluated. The many changes in regulatory requirements, pharmaceutical development, and technology have required both extensive revision to every chapter and the addition of four new chapters.

This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics. Individual chapters also address specific approaches to evaluation hazards, including problems that are encountered and their solutions. Also covered are the scientific and philosophical bases for evaluation of specific concerns (e.g., carcinogenicity, development toxicity, etc.) to provide both understanding and guidance for approaching new problems. *Drug Safety Evaluation* is aimed specifically at the pharmaceutical and biotechnology industries. It not only addresses the general cases for safety evaluation of small and large molecules but also all of the significant major subcases: imaging agents, dermal and inhalation route drugs, vaccines, and gene therapy products. It is hoped that the approaches and methodologies presented here will show a utilitarian yet scientifically valid path to the everyday challenges of safety evaluation and the problem solving that is required in drug discovery and development.

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