Contents

List of Contributors vii
Preface ix

1 Introduction 1
   Elizabeth Kwong

2 Lead Identification/Optimization 9
   Mei Wong and Mark McAllister

3 Oral Drug Formulation Development in Pharmaceutical Lead Selection Stage 39
   Shayne Cox Gad

4 Bridging End of Discovery to Regulatory Filing: Formulations for IND- and Registration-Enabling Nonclinical Studies 89
   Evan A. Thackaberry

5 Planning the First Clinical Trials with Clinical Manufacturing Organization (CMO) 115
   Elizabeth Kwong and Caroline McGregor

6 Formulation Strategies for High Dose Toxicology Studies: Case Studies 139
   Dennis H. Leung, Pierre Daublain, Mengwei Hu and Kung-I Feng

7 Formulation, Analytical, and Regulatory Strategies for First-in-Human Clinical Trials 165
   Lorenzo Capretto, Gerard Byrne, Sarah Trenfield, Lee Dowden and Steven Booth

Index 243