## Contents

Forew Prefac Prefac	ributors  vord by Prof G D Gupta  ce to the Second Edition  ce to the First Edition  eviations	vii ix xi xiii xv
1.	Introduction Anoop Kumar	1
2.	History of Pharmacovigilance Ruchika Sharma, Shailesh Bhosale and Anoop Kumar	6
3.	Type and Source of Data Anoop Kumar, Gulam Navi Azad and Ruchika Sharma	23
4.	Case Processing Meenakshi Gupta, Vipin Bhati and Anoop Kumar	31
5.	Periodic Safety Updated Reports: An Overview Wimpy and Anoop Kumar	53
6.	Statistical Reasoning and Algorithms in Pharmacovigilance  Anoop Kumar	60
7.	Signal Management Process  Aakriti Garg and Anoop Kumar	63
8.	Periodic Benefit Risk Evaluation Report  Bivek Shah and Anoop Kumar	77
9.	Periodic Adverse Drug Experience Report Nidhi Sharma and Anoop Kumar	92
10.	Risk Management Plan and Risk Evaluation and Mitigation Safety of Medicinal Agents: An Overview Aakriti Garg and Anoop Kumar	100
11.	Addendum to Clinical Overview Riya and Anoop Kumar	111

XX	Global Pharmacovigilance	
12.	. Hemovigilance and Materiovigilance Rishabh Kumar, Nidhi Sharma and Anoop Kumar	119
13.	. Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy Drugs Anoop Kumar	130
14	Current Challenges and Future Perspectives of Pharmacovigilance	134
17.	Rishabh Kumar and Anoop Kumar	101
Glossary		143
Index		147