Drug Regulatory Affairs

is a compilation of fundamental concepts pertaining to pharmaceutical drug regulation. Governments protect public health by strictly controlling the safety and efficacy of human medicine, veterinary medicines, medical devices, cosmetics and complementary medicines. Companies responsible for the discovery, testing, manufacture and marketing of these products must ensure sale of safe and effective products. *Drug Regulatory Affairs* refers to fulfilment of all aspects of drug regulations within the pharmaceutical companies from development process to finished product marketing.

The book provides a sound basis on understanding of international drug regulatory guidelines controlling the quality, safety and purity of marketed drugs. The content of this book covers the syllabus of pharmacy undergraduate and postgraduate course content of drug regulatory affairs. The text focuses on delivering updated and reviewed up-to-date information on current global regulatory guidelines. The book contains information that is substantial to a comprehensive understanding of regulatory affairs and the practice in pharmaceutical industry.

Papiya Bigoniya MPharm, PhD
is currently Professor and Principal, DSKM College of Pharmacy, RKDF University, Bhopal. Earlier, she served as faculty at Department of Pharmacy, Barkatullah University, Globus College of Pharmacy, Bhopal, and Professor and Principal, Radharaman College of Pharmacy, Bhopal.

She completed her BPharm from Dr HS Gour University, Sagar, MPharm from Jadavpur University, Kolkata, and PhD from Dr HS Gour University, Sagar. She has to her credit 109 national and international publications in peer-reviewed journals, contributed in 10 book series and presented more than 98 papers at various conferences, workshops, seminars, SDPs and training programs.

Dr Bigoniya has 21 years of experience in research and teaching. She is the editorial board member, reviewer and referee in a number of journal. She has an Indian patent approved for innovation in skin cancer therapy, and working experience as principal investigator in research projects sponsored by various bodies like UGC, AICTE, MPCST and DRDO.

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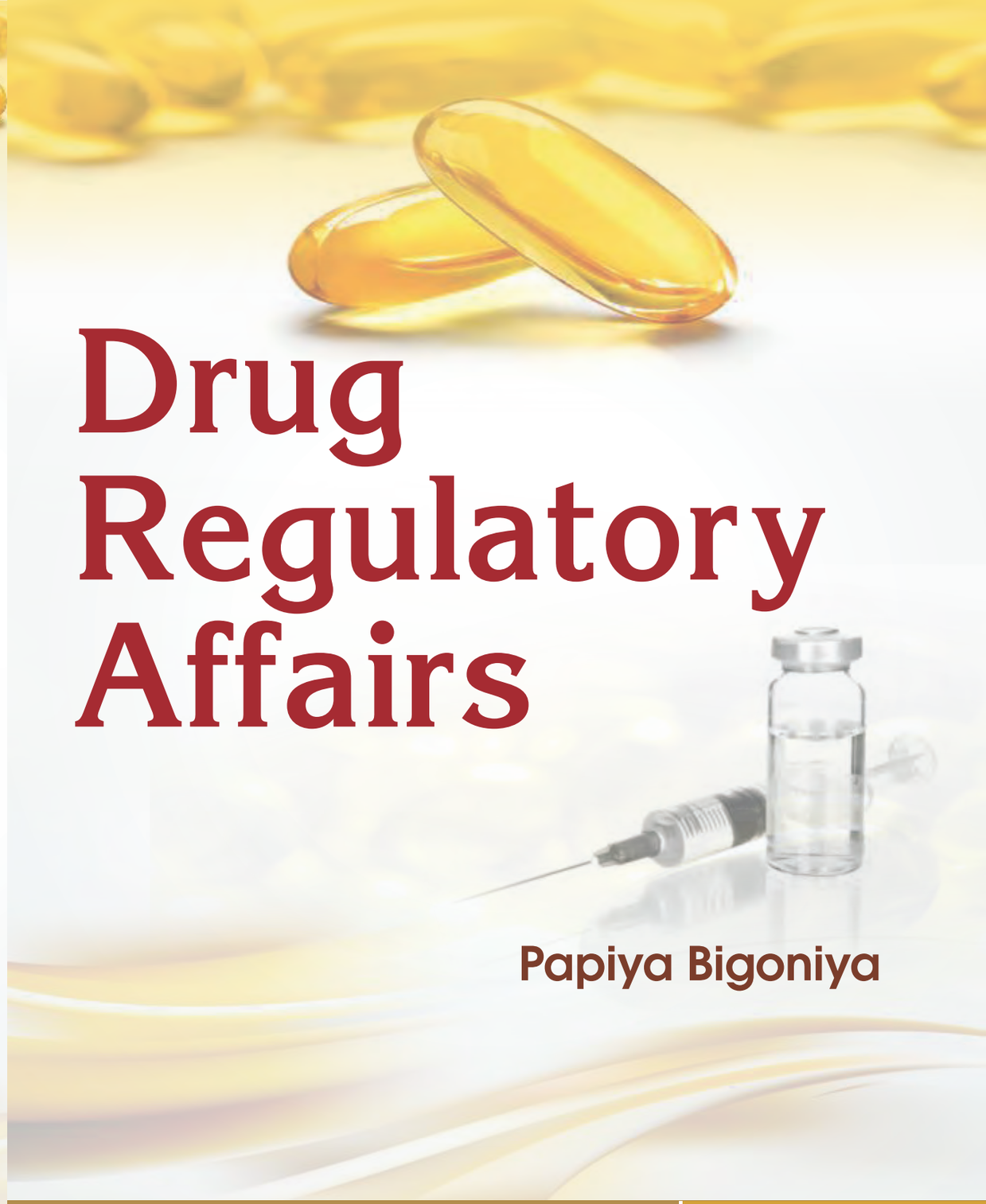

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Papiya Bigoniya
BPharm MPharm PhD

Professor and Principal
DSKM College of Pharmacy
RKDF University, Bhopal

former faculty at Department of Pharmacy, Barkatullah University, and
Globus College of Pharmacy, Bhopal, and

former Professor and Principal, Radharaman College of Pharmacy, Bhopal

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Ph: 23289259, 23266861, 23266867 Fax: 011-23243014 Website: www.cbspd.com

e-mail: delhi@cbspd.com; cbspubs@airtelmail.in

Corporate Office: 204 FIE, Industrial Area, Patparganj, Delhi 110 092

Ph: 4934 4934 Fax: 4934 4935 e-mail: publishing@cbspd.com; publicity@cbspd.com

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Preface

The regulatory affairs is a basic part of pharmaceutical science governing the ethical and legal issues that must be followed to safeguard public health. It implies with drug development, clinical trials, manufacturing, quality control, marketing authorization and sale of pharmaceutical products. Drug regulation is a multistep, multifunctional, interrelated practice that is to be adopted in three levels: Man, material, and method of a pharmaceutical organization. Understanding the impact of each level, proper coordinate functions are necessary to have an appreciable quality output, or it can result in dysfunctions with a quality defect. The overall aim of drug regulatory affairs is the integration of varieties of functions occurring at each level and to have a zero defect manufacturing mechanism. For example, when the quality of a vendor acquired material varies, the quality attributes of the final product will also vary despite the proper functioning of man and method.

In the current scenario, it is highly demanded to provide industry ready freshers who can quickly get a cohort in the assorted environment of a manufacturing firm. This requires the students to get exposed to theoretical concepts of drug regulation along with practical aspects of on-site implementation. As an author I have tried to make the content practical as much as possible, thus giving out this book with the abolition of the classical boundary between a textbook and a practical manual. Most of the pharmaceuticals, not all the personnel responsible for QC and QA related activities, belong to pharmacy background or had previous training. This was my endeavor to present this book in easily understandable verse that will be helpful for the persons of non-pharmacy background to relate with the subject comfortably and can effortlessly adopt in daily working. The book has been devised not only to give a detailed account of drug regulation but also has emphasized on the regulatory requirement of the agency like USFDA, WHO, EU, TGA, ICH, etc. The book contains information that I believe is essential to acquire a clear understanding of regulatory affairs and its practice in the industry.

This book contains tables, forms and lists apart from the text to provide with documentation and record keeping template that can be followed and further be adopted as per individual need. Concepts and processes are represented in the form of diagrammatic representations for easy understanding. As an integrated approach, the book is a step ahead by providing diagrammatic outlines and figures related to important drug regulatory concepts. Each chapter is provided with a chapter content list and key points to identify important subject matter and major issues covered. Basic terms in the text are displayed in bold or italic for easy recognition and memorization. The eight chapters contain information that is most relevant and applicable not only for students to gain knowledge but also for industries to apply in practice. The lists provide a list of important documents to be maintained by each section of the pharmaceutical

manufacturing firm with a representative format that will serve as a template. The content of all the chapters has strong relevance to the implementation of cGMP quality practices in pharmaceutical manufacturing unit.

The content of this book has been designed to match the syllabus of drug regulatory affairs in BPharm and MPharm courses of various universities. The chapters are divided to accommodate subject content that is most commonly covered in the postgraduate syllabus and has updated and reviewed content in context to current global regulatory guidelines. I have integrated the subject matter in the particular chapters that are taught in the pharmacy institutions at undergraduate and postgraduate levels. The subject spectrum of drug regulatory affairs is very vast to accommodate in one book, so this is the first title in a line. Drug regulatory affairs is a subject of continuous evolution and change, the students and professionals should continue to study throughout their career. The bibliography has been incorporated at the end of each chapter that is suggested for further detailed study.

Papiya Bigoniya

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