

Pharmaceutical Quality Assurance

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FOREWORD

Quality of a product is its fitness for purpose at minimum cost to the consumer. Pharmaceuticals being a vital sector of healthcare, a robust quality management system is an integral part of the operations in the pharmaceutical industry. Quality assurance plays a very crucial role throughout the lifecycle of a drug product by ensuring quality standards are being met at each of the stages of the lifecycle.

Quality assurance is one of the important subjects being taught in pharmacy colleges in India. However, there is lack of good quality text books, especially those written by Indian authors on this subject. I am happy to note that Dr. B. P. Nagori and his co-authors has made pioneering effort of bringing out this text-book on quality assurance for pharmacy students. The book is written as per the new syllabi of B. Pharm. introduced by PCI recently, that makes is very useful for the students of upcoming batches of B. Pharm. The content of the book is written in a lucid and illustrative manner so as to cater the needs of both UG and PG students. The core concepts of quality assurance, GMP, GLP and analytical method validation are described exhaustively that will help the students to grasp the subject effectively.

I am sure that this book would be very useful for both B. Pharm. and M. Pharm. students. Further, this would also serve as a valuable resource for industry personnel as well as for the students preparing for competitive exams.

I, congratulate and express my best wishes to the authors for bringing out this publication. I, expect that the team would bring many more editions of this volume in times to come incorporating the changing trends in the field.


Dr. B. Suresh
President

PREFACE

It is the prime obligation on each pharmaceutical manufacturer to meet the needs of its consumers in terms of safety, quality, efficacy, strength, and reliability of the products. Therefore, providing products matching the prescribed quality standards is one of the primary goals of each pharmaceutical company. Quality assurance is a wide-ranging concept which deals with all the aspects of quality. Quality assurance is a good practice that ensures no quality defects remains in the manufactured products, thus needs of the customers are satisfied fully.

With rising quality standards for pharmaceutical products globally and due to stricter regulatory requirements, need of qualified and trained quality assurance personnel in pharmaceutical industry has risen many folds in the last few years. To fulfill this need quality assurance as a separate specialization at M. Pharmacy level was introduced by Pharmacy Council of India (PCI) few years back. It is presently being taught by many pharmacy colleges in India. From the current academic session, i.e. 2017-2018 PCI has revised the syllabi of B. Pharmacy course, which is to be uniformly followed by all pharmacy colleges throughout country. The subject of quality assurance has now been introduced to B. Pharmacy students through this new syllabus. Looking at the industrial needs, it is a welcome step taken by PCI to incorporate the basic concepts of quality assurance even at B. Pharm. level.

There is lack of good quality text books on quality assurance subject for pharmacy students. This book is a sincere effort by the authors to provide comprehensive study material on this subject for the students and teachers of pharmacy. The content of the book is written in sufficiently exhaustive and illustrative manner so as to suffice the need of both B. Pharm. and M. Pharm. students.

The book consists of four chapters. The first chapter deals with the basic concepts of quality assurance. The second chapter explains the guidelines on Good Manufacturing Practices (GMP) for pharmaceuticals. The third chapter describes Good Laboratory Practices (GLP) guidelines useful in the testing of drugs and pharmaceuticals. Basic concepts of validation and calibration and detailed guideline on analytical method validation is presented in the fourth chapter. At the end of each chapter, question bank is provided which comprises of questions as per the pattern prescribed by PCI in the new B. Pharm. syllabi.

The authors gratefully acknowledge Mr. Tanay Sharma of M/S Scientific Publishers (India), Jodhpur for his keen interest and painstaking efforts in bringing out this book. We would welcome any suggestions, views and comments from the readers for future improvements.

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Dr. Renu Solanki
Dr. Vipin Mathur

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