# Industrial Pharmacy II

**As per the latest syllabus prescribed by Pharmacy Council of India for Bachelor of Pharmacy Course**

would help in bridging the existing gap of long needed demand for budding pharmacy technocrats, academicians and pharmacists, especially the budding professionals of pharmacy. It will serve as an excellent textbook for semester VII BPharm students.


Gaurav Agarwal MPharm, PhD is currently Dean, Faculty of Pharmacy, RP Indraprastha Institute of Technology (RP Educational Trust), Karnal. To his credit are numerous projects and publications. He has worked on taste masking techniques at F&D Department, IPCA Labs, Mumbai. He has an excellent track record in academic institutions of high repute like IFTM, Moradabad, and SGIT, Ghaziabad, and is actively engaged in teaching, research, administration and service to pharmacy profession. He has written well known textbooks like "*Pharmaceutics I, Pharmaceutics II, Pharmaceutical Technology I, Pharmaceutical Technology II, Pharmacy Practice* and *Drug Regulatory Affairs*, all published by CBSPD.

Jyoti Ghangas MPharm is currently Assistant Professor, Faculty of Pharmacy, RP Indraprastha Institute of Technology (RP Educational Trust), Karnal. During her research she has worked on generic drug approval submissions in ASEAN countries, and worked on various projects related to drug approval submissions in regulated and semi-regulated countries. She has won many awards in international and national conferences. She has field experience of working under NRHM for more than 3 years. She is actively engaged in review and research work related to drug regulatory affairs.



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Science and technology are constantly changing fields. New research and experience broaden the scope of information and knowledge. The authors have tried their best in giving information available to them while preparing the material for this book. Although, all efforts have been made to ensure optimum accuracy of the material, yet it is quite possible that some errors might have been left uncorrected. The publisher, the printer and the authors will not be held responsible for any inadvertent errors or inaccuracies.



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*to*
my father

Sh. Ram Kumar Ghangas

—Jyoti Ghangas

# Preface

The book *Industrial Pharmacy II* is designed specifically as per PCI (Pharmacy Council of India) B Pharmacy Seventh Semester students. The book covers the entire syllabus prescribed by PCI Course Regulation, 2014 in a very simple and precise manner to meet the demanding needs of the pharmacy aspirants. This book covers wide areas and contains a comprehensive description of current existing knowledge of drug regulatory affairs. The text not only deals with the basic concepts but also emphasizes technical and practical aspects of the subject. The book is primarily intended as a textbook for students of pharmacy for degree and masters courses in drug regulatory affairs. The book is also of great help for technocrats who want to pursue career in regulatory affairs department in pharmaceutical industry. Being an interdisciplinary subject, it is today covering a wide range of interest among the students, teaching and industry people. Taking this increasing interest into account, this book gives a comprehensive introduction to the subject.

The book contains numerous specimens, vivid illustrations, tables, diagrams and flow diagrams to present the ideas. The distinguishing feature is a summary of all the units at the end of each unit. The structure and the content of the book have changed to reflect modern thinking and current university curricula throughout the world. In spite of great care there might be some mistakes and deficiencies. We will be grateful for giving suggestions to improve. So go through the content and do mail to me at *gbitsian@rediffmail.com.*

**Gaurav Agarwal**
**Jyoti Ghangas**

# Acknowledgements

It is a moment of great pleasure and immense satisfaction for me to express deep gratitude and gratefulness to my father Er VK Agarwal and my mother Smt Asha Agarwal for inspiring me to bring out this book.

I am especially thankful to Shri RP Singal Ji, Chairman, RP Educational Trust, for his all time support and encouragement. My special thanks to Er Bharat Singal, and Anuj Singal, Secretary, RP Educational Trust, for inspiring me to bring out this book. I am indebted to Shri DL Mittal, Director, RPIIT Technical and Medical Campus, for his motivation.

I am also thankful to CBS Publishers and Distributors. I would like to put on record the sincere efforts of Mr YN Arjuna (Senior Vice President Publishing, Editorial and Publicity) and his team comprising of Ms Ritu Chawla (GM Production), Mr Parmod Kumar (DTP Operator) and Mr Rohan Prasad (Graphic Designer), for bringing out the book in the present form.

My completion of this project could not have been accomplished without the support of my loving daughter Shreya and son Vaidish who have allowed me time away from the writing and research work.

Last but not the least, I express my love to my wife Dr Shilpi for her caring, motivating and supportive nature. Her encouragement was always there when the times got rough. It was a great comfort and relief that she kept me away from our household activities during the entire tenure of writing and research work.

To my numerous students, whom I cannot possibly name individually, I thanks for their class interactions which have been the guiding spirit in selection of the subject matter and its logical arrangement.

**Gaurav Agarwal**

# Acknowledgements

I would like to express my gratitude to Dr Gaurav Agarwal, Dean, Faculty of Pharmacy, RPIIT, for believing in me and giving me this opportunity to create something which will help the students in the years to come. It would not have been possible without his constant motivation and support.

I express my gratefulness to CBS Publishers and Distributors for giving me this opportunity.

I shall always be thankful and indebted to all my teachers, especially Dr Upendra Nagaich and Dr Neha Jain, who gave me all that I have today. I would like to thank my colleagues for supporting me in this endeavour.

I would like to appreciate the critical eyes and viewpoints of my husband Sumit Anand for reading early drafts and advising me at every step. He equally deserves the credit for early and logical completion of this work. I convey my heartiest gratitude and thanks for always being so supportive.

Any attempt at any level cannot be satisfactorily completed without the support and guidance of family members. I would like to thank my mother-in-law Smt Anuradha Sharma who helped me a lot from time to time in making this project distinctive by imparting her teaching skills despite her busy schedules, my father-in-law Sh. Shyam Narayan Sharma who gave me different ideas in making this project unique.

Special thanks and gratitude to my mother Smt Premwati Ghangas for being the one who supports me, inspires me and loves me. I am grateful to my uncle Advocate Sh. Rajbir Ghangas for inspiring me. I extend my sincere word of thanks to Sujata Anand, Shobhit Anand, Pooja Anand and Aashish Ghangas who have always been a constant support. Last but not the least, I express profound love to sweet children of my family Shorya, Surya and Shakti who always act as stress reliever for me with their innocent smile.

I have learned a lot from my students, and they deserve an equal credit for the insights that helped create this book. I hope students will appreciate this book.

**Jyoti Ghangas**

# Syllabus Prescribed by Pharmacy Council of India for Bachelor of Pharmacy Course

## BP 702 T. INDUSTRIAL PHARMACY II (Theory)

**45 Hours**

**Scope:** This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

**Objectives:** Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

### Course Content

**UNIT 1** **10 Hours**

**Pilot plant scale up techniques:** General considerations-including significance of personnel requirements, space requirements, raw materials, pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

**UNIT 2** **10 Hours**

**Technology development and transfer:** WHO guidelines for technology transfer(TT): Terminology, technology transfer protocol, quality risk management, transfer from R & D to production (process, packaging and cleaning), granularity of TT process (API, excipients, finished products, packaging materials) documentation, premises and equipment, qualification and validation, quality control, analytical method transfer, approved regulatory bodies and agencies, commercialization—practical aspects and problems (case studies), TT agencies in India—APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TT related documentation—confidentiality agreement, licensing, MoUs, legal issues

**UNIT 3** **10 Hours**

**Regulatory affairs:** Introduction, historical overview of regulatory affairs, regulatory authorities, role of regulatory affairs department, responsibility of regulatory affairs professionals

**Regulatory requirements for drug approval:** Drug development teams, non-clinical drug development, pharmacology, drug metabolism and toxicology, general considerations of investigational new drug (IND) application, investigator's brochure (IB) and new drug application (NDA), clinical research/BE studies, clinical research protocols, biostatistics in pharmaceutical product development, data presentation for FDA submissions, management of clinical studies.

**UNIT 4** **08 Hours**

**Quality management systems:** Quality management & certifications: Concept of quality, total quality management, quality by design (QbD), six sigma concept, out of specifications (OOS), change control, introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

**UNIT 5** **07 Hours**

**Indian regulatory requirements:** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for new drugs.

**Recommended Books: Latest Editions**


1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http, //en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

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## UNIT 5: Indian Regulatory Requirements