

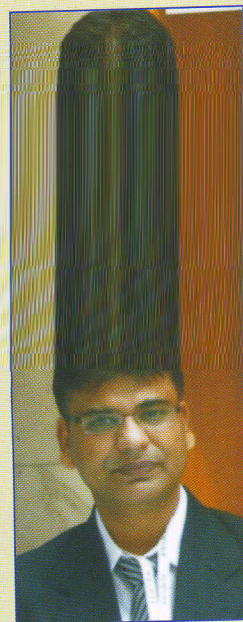
AN INTRODUCTORY APPROACH TO PHARMACEUTICAL REGULATORY AFFAIRS



- **Dr. Neeraj Upmanyu**
- **Dr. Gopal Garg**
- **Mr. Atul Tripathi**
- **Dr. Tripti Jain**

ABOUT AUTHORS

Dr. Neeraj Upmanyu completed Post Graduation in 2004 and Ph.D. in 2010 from Department of Pharmaceutical Sciences, Dr. H.S. Gour University, Sagar (M.P.) and presently working as Associate Professor, RKDF College of Pharmacy, Bhopal (M.P.). He has also author of one international book on "Dermo-Follicular Proliferation". He is research Guide for M. Pharm. and Ph.D. Students under the branch of Pharmaceutical Sciences. Dr. Upmanyu has presented one research paper at 13th International Tetrahedron Conference held at Amsterdam, Netherland, 2004.



Dr. Gopal Garg took his M.Pharm Degree from Department of Pharmaceutical Sciences, Dr. H.S. Gaur University, Sagar followed by Ph.D. from Pt. Ravishankar Shukla University, Raipur. He has published 58 research/reviews in International and National Journal of repute. His research interest extends from Analytical technique to phytochemical estimation. At present he is working as a Associate Professor in VNS Group of Institutions, Faculty of Pharmacy, Bhopal.



Mr. Atul Tripathi completed post graduation in 2011 from Rajeev Gadhi Prodyogiki Vishwvidyalaya and presently working as Assistant Professor, RKDF College of Pharmacy, Bhopal (M.P.) He has also author of one international book on "Dermo-Follicular Proliferation".



Dr. Tripti Jain is currently working as Drug Inspector, Food & Drug Administration, Raipur, Chhattisgarh, India. She completed her M. Pharm from Dr. Hari Singh Gour University, Sagar (M.P.) and Ph. D. Degree in 2013 from Vikram University Ujjain (M.P.). She is gold medalist in M. Pharm and recipient of M. L. Khorana Best Paper Award for year 2006. She has qualified GATE examination twice in 2000 & 2001. She has attended many conferences and having more than 20 international and national publications to her credit. Her areas of thrust includes Drug Regulatory Affairs, Phytochemistry, Tissue Culture & Standardization of Herbal Drugs.



CONTENT

- **CHAPTER- 1** -----01
Intellectual Property Right (Patent, Copy Right, Trade Marks and Design)
Processing and Its Application
- **CHAPTER- 2** -----29
Requirements Of GMP, CGMP, GLP, USFDA and ISO 9000 Series
- **CHAPTER- 3** -----61
Patent Documentation-Protocols, Forms and Maintenance of Records in
Pharmaceutical Industry
- **CHAPTER- 4** -----68
Concepts In Validation, Validation of Manufacturing, Analytical And Process
Validation And Its Application
- **CHAPTER- 5** -----92
Basic concept of quality control and quality assurance system, source and control of
quality variation of raw materials, containers, closures, personnel, environmental
etc.
- **CHAPTER- 6** -----130
Sewage Disposal and Pollution Control
- **CHAPTER- 7** -----137
In Process Quality Control Tests, IPQC Problems in Pharmaceutical Industries
- **CHAPTER- 8** -----144
Sampling Plans, Sampling and Characteristics Curves
- **CHAPTER- 9** -----153
Master Formula Generation and Maintenance, Standard Operating Procedure for
Different Dosage Forms
- **CHAPTER- 10** -----169
Bibliography