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S. No.	Name of the teacher	Title of the book/chapters published	Name of the conference
1	Dr. Bayya Subba Rao	Intellectual Property Rights in Pharmaceutical Industry:Theory and Practice	-
2	Dr. Bayya Subba Rao	Pharmaceutical Research Methodology and Biostatistics:	-

Total Books/Chapters/Conference : 02

PRINCIPAL
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(CC No: 1706)
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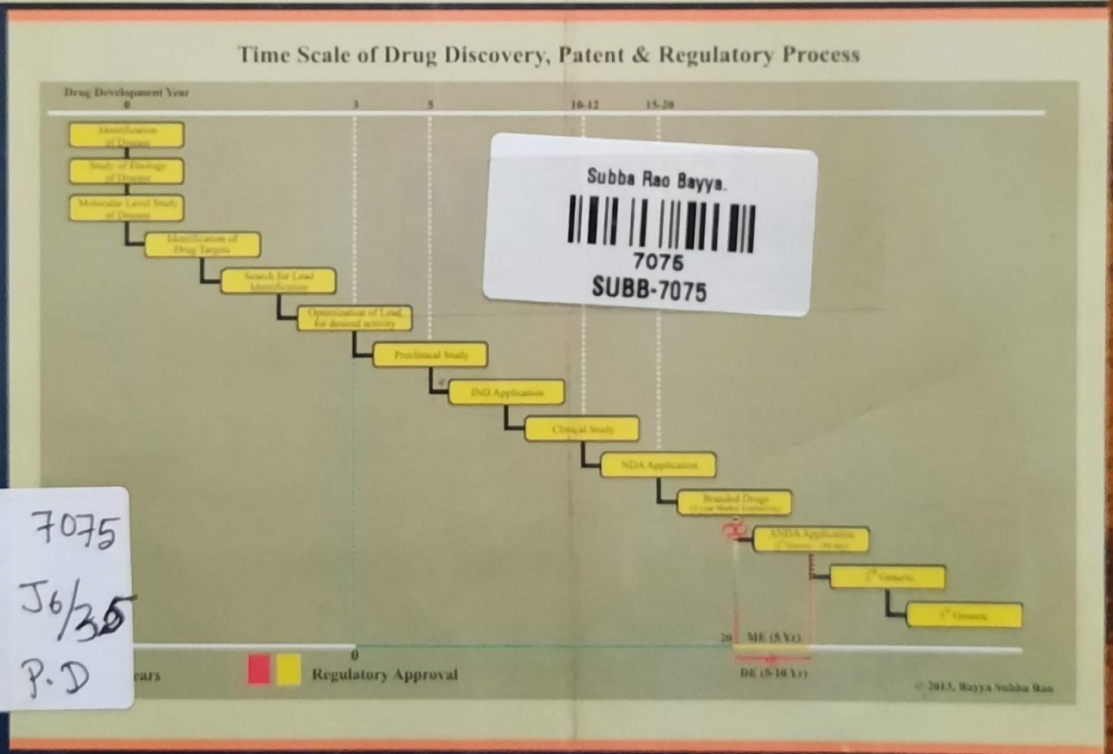
Intellectual Property Rights in Pharmaceutical Industry

Theory and Practice

(Appended with Validation, Audits, National Phase Entry and Prosecutions)

Second Edition

Bayya Subba Rao | P V Appaji



Intellectual Property Rights in Pharmaceutical Industry: Theory and Practice

(Appended with Validation, Audits, National Phase Entry and Prosecutions) Second Edition

This book is aimed at pharmaceutical fraternity involving as students, researchers, teachers, regulators, policy makers to understand key aspects of intellectual property matters. The book is planned for quick understanding of basic concepts leading to practice in pharmaceutical industry. The book provides clear cut understanding of national and international scenario of IPR matters.

Salient Features of the Book:

- Conventional English was used instead of legal language for the sake of initiators in learning IPR matters in pharmaceuticals.
- Major emphasis is relating to pharmaceuticals.
- History of IPR matters at global and national levels.
- International Conventions on IPR matters only relating to pharmaceuticals
- Introduction to every component of IPR with corresponding governing Acts, governing Ministry, and exclusivity periods with pharmaceutical related examples.
- Objective and role of GATT, WTO and TRIPS agreement.
- Introduction to The Patents Act, 1970 relating to inventions not patentable, types of patent applications, contents of a patent, patent office procedure timeline, PCT timeline, types of oppositions, types of infringement, expenditure incurred for filing and maintaining patents, rights of patentee, powers of controller of patents, compulsory licensing, and patent agents etc.
- How to do literature search relating to non-patented and patented information for innovation and patent mining.
- Comparison of principal The Patents Act, 1970 with three amendments.
- Administration structure, protocol to become a member of WTO and procedure to resolve disputes.
- Relationship of Drug Discovery, Drug regulatory and Market approval processes.
- Various disputes settled at WTO of India relating to pharmaceuticals.
- Judgments, case studies, notices relating to pre-grant opposition, post-grant opposition, compulsory licensing, infringements, working of patents, revoke of patents.
- Possible questions at end of every chapter.
- Above 100 frequently asked questions relating to Patents, Regulatory and Marketing relating to pharmaceuticals.
- Statistics relating to patent grants at IPO, USPTO, and DMFs at USFDA relating to India.

About the Authors

Bayya Subba Rao completed both B. Pharm and M. Pharm from College of Pharmaceutical Sciences, Manipal. He completed P. G. Diploma in Patent Laws from NALSAR University of Law, Hyderabad. He was awarded with Doctorate in Pharmaceutical Sciences degree from Andhra University, Visakhapatnam.

During his 19 years of career he was involved in basic research, process research, teaching, government service at various levels as scientist-II, research chemist, lecturer, associate professor, I/C Principal, patent analyst. He has to his credit over 35 research, review articles published in national journals and has five copyrights.

During his career he was involved in synthesis of new chemical entities, synthesis of drug metabolites and chemical process developments. He developed a process that were later patented.

He was involved in teaching intellectual property rights relating to pharmaceuticals to students at the B.Pharm and M.Pharm levels.

P. V. Appaji was Emeritus Director General at Pharmaceuticals Export Promotion Council of India (Pharmexcil), set up by Ministry of Commerce and Industry, Government of India. He has initiated his career as an officer at Drugs Control Department, Government of Andhra Pradesh and later as Deputy Commissioner in Department of Chemicals and Petrochemicals, as Director at National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. At Pharmexcil, as chief of organisation, he is actively involved in interacting with Government and the pharmaceutical industry to promote/resolve pharmaceutical export, policy issues and is actively involved in delegations abroad so that pharmaceutical trade barriers at the levels of transit, regulatory, policy making are effectively dealt with. At NPPA, He was actively involved as chief of evaluation of Drugs Price Control Order/Drug Pricing in the territory of India. He completed B.Pharm (1970), M.Pharm (1972) and Ph.D (1980) from Nagpur University. He has guided several Ph.D scholars. He has received Lifetime Achievement Award for his contribution to the pharmaceutical sector from Indian Pharmaceutical Association and others.

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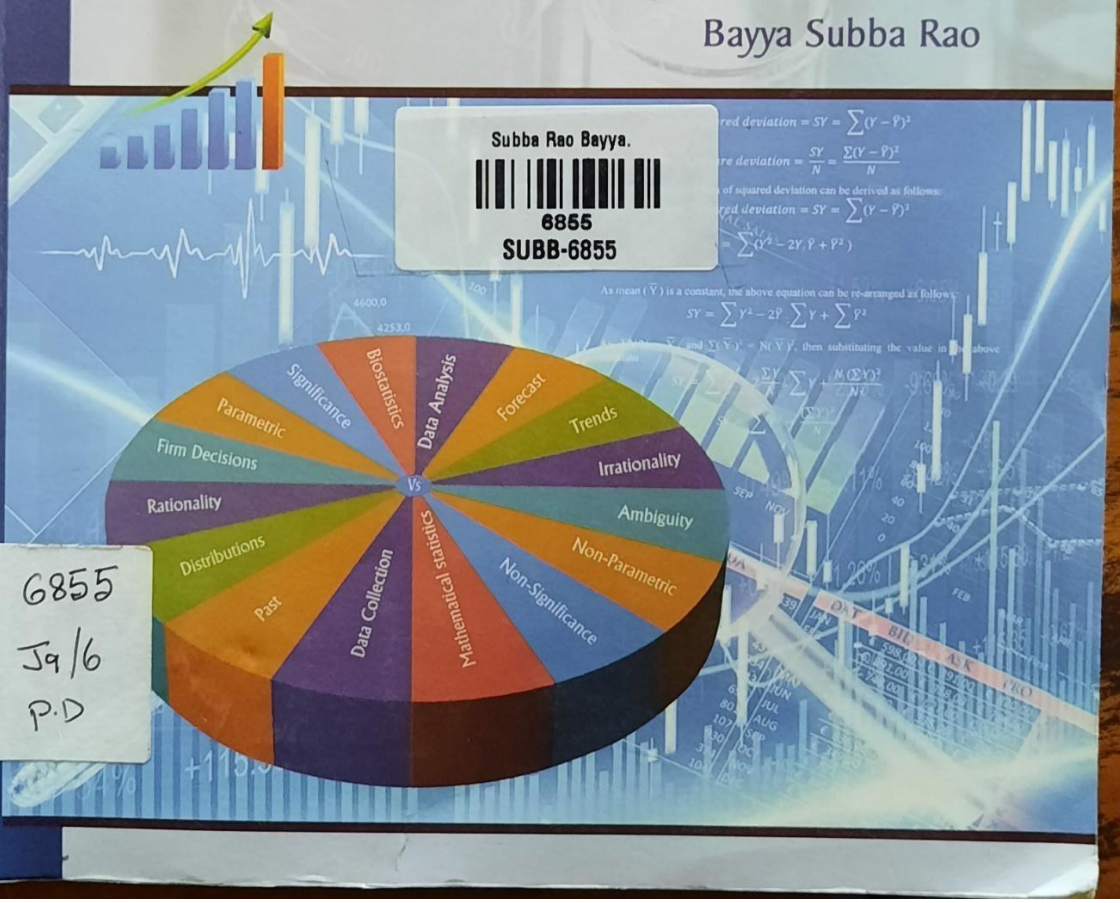
Pharmaceutical Research Methodology and Bio-Statistics

Theory and Practice

Bayya Subba Rao



Pharmaceutical Research Methodology and Bio-Statistics

Theory and Practice

"Pharmaceutical Research Methodology and Bio-Statistics: Theory and Practice" is aimed in understanding the fundamental concepts of developing a research bent of mind by careful planning, execution, collection of data and analyzing for statistical significance. The book is aimed at B. Pharm, Pharm D, Pharm D (PB), M. Pharm, allied course students, researchers at the academic and industry levels, Ph. D scholars, policy makers, regulators etc.

Key Features:

- Exclusively relating to pharmaceuticals
- Conventional English
- Distinguishing statistics and bio-statistics
- How to identify a problem, plan for research and execute the idea
- Chemical abstract literature search
- Anatomy of a research paper
- Compare and contrast of research proposal, research report, research paper, patent document, synopsis
- Concept of meta-analysis to resolve research ambiguities
- Classification of clinical study designs
- Approaches of developing a research methodology
- Abstract scaling concepts and techniques for developing questionnaire
- Data collection, cleansing, presenting
- How to overcome missing data
- Parametric distributions - binomial, poisson, normal, chi-square, student 't', F distributions
- Role of Type I and Type II errors, Power, sample size, confidence level, confidence interval, confidence limits
- How to judge whether data upon analysis is statistical significant or not
- Developing hypothesis as null, alternate and how to draw conclusion after conducting suitable statistical test
- Non-parametric statistical test - Run, Sign, Wilcoxon Signed rank, Wilcoxon rank sum tests
- Parametric, Non-parametric ANOVAs (1-way, 2-way, cross over, 3-way)
- Step wise Parametric and non-parametric problem solving
- Statistical softwares like SPSS, SAS, Minitab, Epi-Info with screenshots
- Applications of linear regression and correlation coef ficient relating to pharmaceuticals
- Fundamental concepts of book keeping, accountancy, emphasizing on making entries in journal and ledger
- Basic terminology of epidemiology
- Inventory control, role of computers, parenteral Admixture
- Developing a management report
- Question bank

About the Author

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During his 21 years of career he was involved in basic research, process research, teaching, government service at various levels as scientist-II, research chemist, lecturer, associate professor, I/C Principal, patent analyst. He has to his credit over 35 research, review articles published in National journals and has five copyrights.

During his career he was involved in synthesis of new chemical entities, synthesis of drug metabolites and chemical process developments. He developed a process that was later patent applied and abandoned.

He was involved in teaching Bio-Statistics and research methodology relating to pharmaceuticals to students at the B.Pharm, Pharm.D and M.Pharm levels.

The other academic related books authored were Practical Pharmaceutical In-organic Chemistry, Intellectual Property Rights in Pharmaceutical Industry: Theory and Practice.

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