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HEALTH TECHNOLOGY TRANSFER GUIDELINE (TTG)

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TEXT BOOK OF INDUSTRIAL PHARMAYCY-II Dr. Ritu Gulia, Ms Poonam Sandhu, Ms. Tilottama Bhattacharya, Dr. Viram Parmar, Ms. Aditi Sharma,2025-05-20 The Textbook of Industrial Pharmacy II is a comprehensive guide tailored for students researchers and professionals engaged in the pharmaceutical industry focusing on critical areas of drug manufacturing and regulation It delves into pilot plant scale up techniques highlighting key factors such as personnel and space requirements raw materials and process adaptation from laboratory to industrial scale for solids liquids and semi solids The book emphasizes the importance of proper documentation and introduces SUPAC guidelines and platform technologies which are essential for ensuring consistent quality and compliance It also offers an in depth discussion on technology development and transfer TT referencing WHO guidelines and addressing granular processes for APIs excipients packaging materials and finished products The documentation equipment qualification validation and regulatory agency roles are thoroughly covered including insight into Indian TT bodies like APCTD and NRDC A dedicated section on regulatory affairs explores their evolution functions and the responsibilities of professionals in the field It examines the steps involved in drug approval starting from preclinical development through IND and NDA submissions and stresses the significance of clinical protocols biostatistics and data presentation in gaining FDA approval Furthermore the book discusses quality management systems detailing modern quality tools like TQM QbD Six Sigma and standard systems such as ISO 9000 ISO 14000 NABL and GLP essential for ensuring regulatory compliance and product excellence Lastly it elaborates on Indian regulatory requirements shedding light on the organizational structure and role of CDSCO and State Licensing Authorities with a focus on obtaining the Certificate of Pharmaceutical Product COPP and navigating the approval procedures for new drugs This book is a valuable academic and practical resource for understanding the multidisciplinary scope of industrial pharmacy and its regulatory landscape **A Text Book of Industrial Pharmacy – II** Utkarsh Singh,2024-09-21 The vision to formulate a book on Industrial Pharmacy II is to assist the student of B Pharmacy and to fascinate their interest in gaining knowledge on Pharmaceutical Industry and different medical related concept In addition to it this book also provide the collective information on various aspects of Pharmaceutical Industry in easy language It is anticipated that this book will provide a favourable material to students as well as teachers to gather every information regarding this subject The objectives salient features of this book is that upon completion of this course the student should be able to gain knowledge regarding the following 1 Will have high consciousness of issues related to problems in Pharmaceutical Industry within the country and worldwide 2 Will have a grave way of thinking based on Industrial Design Development I am generously elated and thankful to My Father Mr Aniruddh Singh My Mother Mrs Sudha Singh Maternal Uncle Mr Ranjit Pratap Shahi and My Sister Ms Manshi Singh for always encouraging me to reach new heights I encompass and extend our deep sense of appreciation and gratitude to Dr Gulzar Alam Sir Mr Raj Vaibhav Sir and without their support it would not have been possible for me to write

this book I am also thankful to Dr Sashikant Tripathi Sir Dr Dhirendra Pratap Singh Sir Mr Rahul Gupta Sir who motivated me during this whole tenure I am keen to incorporate the constructive suggestions and feedback for development and upgrading in upcoming book Technical Report Series ,1950 *Industrial Pharmacy – II* Mr. Om Prakash Verma ,Mr. Raj Kumar Vishwakarma ,Mr. Sahil Akhtar, Industrial Pharmacy II stands at the gateway where classroom knowledge transforms into real pharmaceutical practice This subject connects theory with the living world of manufacturing plants validation floors quality control laboratories regulatory corridors and packaging lines Understanding these concepts is not merely for passing examinations but for shaping competent confident and industry ready pharmacists This book has been carefully designed as per the latest PCI syllabus for B Pharma 7th semester students covering every topic in a clear concise and systematic manner Each chapter follows a structured approach with simple explanations flowcharts tables figures and practical examples to make complex industrial processes easy to grasp and remember From GMP validation and documentation to packaging technology regulatory guidelines and quality assurance every concept is presented with precision and relevance The aim is straightforward if you study this book thoroughly you will not require any additional reference text It serves as both a learning guide and a quick revision companion May these pages help you think like an industrial pharmacist act like a professional and step confidently into the pharmaceutical industry of tomorrow Happy learning and best wishes for your success Om Prakash Verma Raj Kumar Vishwakarma Sahil Akhtar *INDUSTRAL PHARMACY-II* Dr. Dhananjay Macchindra Patil,Mr. Vineet Joshi,Dr Viswanadh Kunam,Ms. Sandhyarani Sagavkar.,Dr. Touseef Begum, TEXT BOOK OF INDUSTRIAL PHARMAYCY-II Dr. Ritesh Kumar, Dr. Devendra Kumar Bhopte, Dr. D. Akila Devi, Anjali Naharwal, Dr. Vivekanand Katare,2025-06-21 The Textbook of Industrial Pharmacy II provides a comprehensive and structured insight into the critical aspects of industrial pharmaceutical practices It begins with pilot plant scale up techniques highlighting the importance of scaling formulations from laboratory to production scale covering personnel space raw materials and regulatory documentation Special attention is given to scale up processes for various dosage forms such as solids liquid orals and semisolids including compliance with SUPAC Scale Up and Post Approval Changes guidelines and the emerging role of platform technologies The second unit Technology Development and Transfer TT outlines WHO protocols for transferring pharmaceutical technologies from R D to manufacturing It details the roles of quality risk management analytical method transfer and validation Important components such as API excipients packaging and documentation are discussed alongside legal frameworks including confidentiality agreements licensing and MoUs The section also explores Indian TT agencies like APCTD NRDC and BCIL Regulatory Affairs forms the third section offering a historical perspective and an overview of global regulatory bodies It emphasizes the function and responsibilities of regulatory professionals and the importance of their involvement across product lifecycle stages The fourth chapter details the regulatory requirements for drug approval addressing components such as INDs NDAs investigator brochures non clinical pharmacology toxicology and biostatistics It

also explains the management and design of clinical protocols BE studies and data presentation for FDA submissions In the fifth section Quality Management Systems are discussed extensively Topics include Total Quality Management TQM Quality by Design QbD Six Sigma Out of Specification OOS handling change control and compliance with ISO standards 9000 and 14000 series NABL and GLP practices This ensures students understand how to maintain and evaluate quality at every stage of product development and manufacturing Lastly the textbook addresses Indian Regulatory Requirements with a focus on the Central Drug Standard Control Organization CDSCO and State Licensing Authorities It covers their structure responsibilities and role in issuing Certificates of Pharmaceutical Product COPP along with procedures for new drug approval in India This well organized content makes the textbook a valuable resource for students educators and professionals bridging academic knowledge and industrial application **Intellectual Property Rights in Pharmaceutical Industry** Bayya Subba Rao,P. V. Appaji,2025-07-01 Intellectual Property Rights in Pharmaceutical Industry Theory and Practice is an exclusive book shedding light on the fundamental concepts of intellectual property protection with a special emphasis on pharmaceuticals The book explores how the importance of intellectual property rights has grown in the last few decades especially in India after signing the World Trade Organisation agreement The book explains how the Indian government has made necessary amendments in the intellectual property laws built infrastructure and even introduced topics related to intellectual property rights in the academic curriculum The book dives deeply into the Indian patent system with case studies from US and Indian courts serving as examples to provide a better understanding of the system The third edition is a result of the major administrative changes observed in the Indian government in recent years This book is aimed at students industry professionals scientists regulators and policymakers interested in the pharmaceutical industry This book serves as a valuable resource for B Pharm Pharm D M Pharm and Ph D level students along with other science educational programs in all the Universities of India On reading this book the pharmaceutical community will gain a better understanding of the intellectual property protection system leading to an orientation of research development to ensure intellectual property protection This book is a must have for anyone involved in the pharmaceutical industry who wants to understand the nuances of intellectual property protection in India Contents 1 Introduction and History of Intellectual Property Rights 2 International Agreements Treaties and Conventions 3 Introduction to Different Components of Intellectual Property Rights 4 Introduction to Traditional Knowledge and Biological Diversity 5 Introduction to WTO Agreement 6 Trade Related Aspects of Intellectual Property Rights Agreement 7 The Patents Act 1970 8 Surrender Revocation Lapse Restoration of Patent and Register of Patent 9 Expenditure for Application Follow Patent Office Procedure Grant of a Patent 10 Application Procedure and Time Line for Grant of Patent through PCT 11 Non Patented and Patented Literature Search 12 Comparison of the Principal The Patents Act 1970 with The Three Amendments 1999 2002 2005 13 Differences in The Patents Act 1970 with other Countries 14 Administrative Structure of WTO Membership and Dispute Settlement as per TRIPS Agreement 15 Technology Transfer

16 Hatch Waxman Act of United States A Relation to Drug Discovery Regulatory and Market Approval 17 Intellectual Property Validation 18 Intellectual Property Audits 19 National Phase Entry for IP Protection 20 Intellectual Property Litigation Prosecution 21 FAQ s in Pharmaceuticals on Patents Regulatory Marketing *Encyclopedia of Chemical Processing and Design* John J. McKetta,William Aaron Cunningham,1996 *Guidelines on Brazil's Foreign Investment Law* Attila de Souza Leão Andrade Júnior,1980 **Proceedings** ,2004 *Guide on Foreign Collaboration, Policies & Procedures, 1987-88* Rajiv Kumar Jain,1987 *The Journal of the American Chamber of Commerce in Japan* ,1978 **DNA Technology in Forensic Science** Committee on DNA Technology in Forensic Science,Commission on Life Sciences,Division on Earth and Life Studies,National Research Council,1992-01-15 Matching DNA samples from crime scenes and suspects is rapidly becoming a key source of evidence for use in our justice system DNA Technology in Forensic Science offers recommendations for resolving crucial questions that are emerging as DNA typing becomes more widespread The volume addreses key issues Quality and reliability in DNA typing including the introduction of new technologies problems of standardization and approaches to certification DNA typing in the courtroom including issues of population genetics levels of understanding among judges and juries and admissibility Societal issues such as privacy of DNA data storage of samples and data and the rights of defendants to quality testing technology Combining this original volume with the new update The Evaluation of Forensic DNA Evidence provides the complete up to date picture of this highly important and visible topic This volume offers important guidance to anyone working with this emerging law enforcement tool policymakers specialists in criminal law forensic scientists geneticists researchers faculty and students INIS Atomindex ,1984 **World Investment Report** ,2003 *International Technology Transfer* Howard V. Perlmutter,Tagi Sagafi-nejad,1981 **Lok Sabha Debates** India. Parliament. Lok Sabha,1903 Economic Review Ōsaka Shiritsu Daigaku. Keizai Gakubu,1987 *Key to Economic Science and Managerial Sciences* ,1978 **Toxicological Profile for Aldrin/dieldrin** ,2002

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