Who Guideline On Transfer Of Technology

Stewart Green,Paul Warren

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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   INDUSTRAL PHARMACY-II Dr. Dhananjay Macchindra Patil,Mr. Vineet Joshi,Dr Viswanadh Kunam,Ms. Sandhyarani Sagavkar.,Dr. Touseef Begum,   Technical Report Series ,1950   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   Industrial Pharmacy Dr Muralidhar, Dr Narmada,2024-02-03 Industrial Pharmacy From Pilot Plant to Market is a comprehensive guide that provides practical approaches to pharmaceutical product development With 37 exhaustive chapters it covers important topics such as pilot plant scale up techniques technology transfer protocols regulatory requirements quality management systems and Indian regulatory

requirements The book helps readers understand the significance of personnel requirements space requirements raw materials and relevant documentation for solids liquid orals and semi solids It also provides insights into WHO guidelines for technology transfer clinical research protocols quality management concepts ISO quality systems standards and Indian regulatory requirements This book is an essential resource for pharmaceutical professionals and students who seek to advance healthcare through innovative pharmaceutical product development   Codes of Conduct for the Transfer of Technology Jack N. Behrman,1976   Technology Transfer Stewart Green,Paul Warren,2002-08-14 This text is written by two leading quality specialists and serves as a quick guide reviewing the basic concepts associated with the transfer of product development between manufacturing sites often to different parts of the world where cultural and management differences abound It is a hot topic which is brought down to earth covering key activities documentation reporting and post transfer reporting for manufacturing professionals   *Guide on Foreign Collaboration, Policies & Procedures, 1987-88* Rajiv Kumar Jain,1987   **Technology Transfers and Licensing** John T. Ramsay,1996   **International Technology Transfer** Howard V. Perlmutter,Tagi Sagafi-nejad,1981   *Encyclopedia of Chemical Processing and Design* John J. McKetta,William Aaron Cunningham,1996   Guide to U.S. Government Publications Thomson Gale,2005-08   **Technology Transfer and the New EU Competition Rules** Steven D. Anderman,John Kallaugher,2006 The new Technology Transfer Block Exemption Regulation in force from May 1 2004 signals a profound change in the nature of the regulatory framework for technology licensing under EU competition law This book examines the new Regulation in detail placing it in the wider context of i the modernisation reforms of EC competition law and ii the treatment of IP rights over technology more generally The book also considers the approach to assessment of IP issues set out in the Guidelines that accompany the Regulation the authors discuss their legal basis and where appropriate criticise the approach taken by the Guidelines where the legal basis is unsure
    Guide to U.S. Government Publications ,2008-08 This comprehensive yet concise annual annotated reference source catalogs the important series periodicals and reference tools published by U S government agencies Over the years the index section of the Guide to U S Government Publications has expanded to more than 40 000 entries Agencies and titles are indexed followed by a keyword title index for quick and easy referencing No other single resource provides historical and current information on U S government publications in one place   *Guidelines on Brazil's Foreign Investment Law* Attila de Souza Leão Andrade Júnior,1980   **State and Local Initiatives on Productivity, Technology, and Innovation** Barbara J. Lipman,1990   Proceedings ,2004   *Managing International Technology Transfer* Min Chen,1996 As a result of the rapid globalization of business the subject of international technology transfer is now of importance to both scholars and practitioners of international business In drawing his examination from the fields of international studies international management and international law Min Chen provides a comprehensive consideration of the management and legal implications of international technology transfer The text is divided into four organically linked parts which discuss

comparative national policies on technology transfer the international protection of intellectual property international licensing and lastly international technology transfer via other major commercial channels This work should be of interest to students and academics in business and technology also to international executives and lawyers **Technology Transfer and Management in the Developing Countries** Harvey W. Wallender,Fund for Multinational Management Education,1979

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