

WHO guidelines for Technology Transfer (TT):

These guiding principles on transfer of technology are intended to serve as a framework which can be applied in a flexible manner rather than as strict rigid guidance. Focus has been placed on the quality aspects, in line with WHO's mandate.

1. Transfer of processes to an alternative site occurs at some stage in the life-cycle of most products, from development, scale-up, manufacturing, production and launch, to the post approval phase.

2. Transfer of technology is defined as “a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites”. It is a systematic procedure that is followed in order to pass the documented knowledge and experience gained during development and or commercialization to an appropriate, responsible and authorized party.

3. Literature searches revealed little information on the subject originating from national or regional regulatory bodies. Guidance on intra-company transfers was prepared by the International Society for Pharmaceutical Engineering (ISPE).

Who Guideline On Transfer Of Technology

Jack N. Behrman



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TEXT BOOK OF INDUSTRIAL PHARMACY-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

Industrial Pharmacy -II D. K. Tripathi, Ayushmaan Roy, Manindra Mahapatra, 2023-06-24 To ensure that the students can understand the concept and contents the book has been written in a clear language Each subject has been thoroughly explained However certain things that are significant and valuable are covered This will make it easier for the students to connect their theoretical learning to the real world needs of the pharmaceutical sector The course would make all the students understand at least the following Know the process of pilot planting and the scale of pharmaceutical dosage forms Understand the process of technology transfer from lab scale to commercial batch Know different Laws and Acts that regulate the pharmaceutical industry Understand the approval process and regulatory requirements for drug products

Contents

- 1 Pilot Plant Scale up Techniques
- 2 Technology Development and Transfer
- 3 Regulatory Affairs Regulatory Requirement for Drug Approval
- 4 Quality Management Systems
- 5 Indian Regulatory Requirements

Technical Report Series, 1950 **Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection** World Health

Organization,2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry

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 Dharendra 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

INDUSTRIAL PHARMACY-II Dr. Dhananjay Macchindra Patil,Mr. Vineet Joshi,Dr Viswanadh Kunam,Ms. Sandhyarani Sagavkar.,Dr. Touseef Begum, TEXT BOOK OF INDUSTRIAL PHARMACY-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

New Technologies and Human Rights Mr Mario Viola de Azevedo Cunha, 2013-10-28 Whilst advances in biotechnology and information technology have undoubtedly resulted in better quality of life for mankind they can also bring about global problems The legal response to the challenges caused by the rapid progress of technological change has been slow and the question of how international human rights should be protected and promoted with respect to science and technology remains unexplored The contributors to this book explore the political discourse and power relations of technological growth and human rights issues between the Global South and the Global North and uncover the different perspectives of both regions They investigate the conflict between technology and human rights and the perpetuation of inequality and subjection of the South to the North With emerging economies such as Brazil playing a major role in trade investment and financial law the book examines how human rights are affected in Southern countries and identifies significant challenges to reform in the areas of international law and policy

Pharmaceutical Regulatory Affairs Nimisha Srivastava, Neeraj Mishra, Sumel Ashique, Bharanitharan Rajendran, 2025-12-26 This book provides concepts procedures guidelines and regulatory affairs in drug development Pharmaceutical Regulatory Affairs Principles and Practices begins with a detailed overview of the drug development life cycle from initial discovery and preclinical research to clinical trials and market approval addressing scientific regulatory and ethical considerations at each stage The book covers the evolution of global trade agreements like the General Agreement on Tariff and Trades GATT and the World Trade Organization s WTO impact on pharmaceuticals highlighting issues surrounding pharmaceutical patents and intellectual property rights It discusses the importance of the Scale Up and Post Approval Changes SUPAC guidelines in ensuring quality and consistency in drug manufacturing post approval and examines the World Health Organization s WHO guidelines on technology development and transfer The fundamentals of regulatory affairs are covered emphasizing the roles and responsibilities of regulatory professionals The book provides an in depth look at

regulatory frameworks of major agencies worldwide including the Central Drugs Standard Control Organization CDSCO in India the Food and Drug Administration FDA in the US the European Medicines Agency EMA in the EU the Therapeutic Goods Administration TGA in Australia the Pharmaceuticals and Medical Devices Agency PMDA in Japan Health Canada and regulatory authorities in emerging markets It also addresses the international regulatory landscape for medical devices and reviews foundational pharmaceutical regulations Additionally the text explores regulatory guidelines for clinical testing including the roles and responsibilities under pharmaceutical legislation principles of bioethics and biosafety the digital transformation in clinical trials and the critical role of pharmacovigilance The book concludes with an examination of the global regulatory scenario for pharmaceutical excipients providing a detailed roadmap through the complexities of drug development regulatory compliance and global standards This book is valuable for professionals researchers and students of pharmaceutical sciences

Codes of Conduct for the Transfer of Technology Jack N. Behrman, 1976 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 **Scientific and Technical Books and Serials in Print**, 1984 **Technology Transfer and Management in the Developing Countries** Harvey W. Wallender, Fund for Multinational Management Education, 1979 Guide on Foreign Collaboration, Policies & Procedures, 1987-88 Rajiv Kumar Jain, 1987 *Promotion of Technology Utilization in Selected Asian Countries*, 1986 *White Paper on Small and Medium Enterprises in Japan*, 1985 International Technology Transfer Howard V. Perlmutter, Tagi Sagafi-nejad, 1981 INIS Atomindex, 1984 *Key to Economic Science and Managerial Sciences*, 1978

The Top Books of the Year Who Guideline On Transfer Of Technology The year 2023 has witnessed a remarkable surge in literary brilliance, with numerous captivating novels enthralling the hearts of readers worldwide. Lets delve into the realm of bestselling books, exploring the fascinating narratives that have captivated audiences this year. Who Guideline On Transfer Of Technology : Colleen Hoover's "It Ends with Us" This heartfelt tale of love, loss, and resilience has gripped readers with its raw and emotional exploration of domestic abuse. Hoover skillfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can succeed. Uncover the Best : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This spellbinding historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids captivating storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Who Guideline On Transfer Of Technology : Delia Owens "Where the Crawdads Sing" This evocative coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens spins a tale of resilience, survival, and the transformative power of nature, entrancing readers with its evocative prose and mesmerizing setting. These popular novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of captivating stories waiting to be discovered. The novel begins with Richard Popen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a masterful and suspenseful novel that will keep you wondering until the very end. The novel is a cautionary tale about the dangers of obsession and the power of evil.

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