

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).

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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, 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
4. Requirement for Drug Approval
5. Quality Management Systems
6. 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 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,

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 (CPP) 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 Tariffs and Trade (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

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