

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

**Dr. Ritu Gulia, Ms Poonam Sandhu,
Ms. Tilottama Bhattacharya, Dr. Viram
Parmar, Ms. Aditi Sharma**

Who Guideline On Transfer Of Technology:

WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2022-12-22 The WHO Technical Report Series 1044 presents the fifty sixth report by the WHO Expert Committee on the Specifications for Pharmaceutical Preparations It provides comprehensive standards and guidelines for the quality assurance of medicines developed through extensive international consultation The report includes new guidance on various aspects such as good manufacturing practices for sterile products technology transfer for medicinal gases and the stability studies of medical products The WHO s publications aim to support national health strategies and address pressing public health concerns by disseminating authoritative information and guidance globally This report reflects the collective views of international experts contributing to the WHO s mission to attain the highest possible level of health for all people

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

WHO Drug Information , 2021-04-08 *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 Technical Report Series ,1950 *INDUSTRIAL 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

The Transfer of Marine Technology to Developing Nations in International Law Boleslaw Adam Boczek,1982 State and Local Initiatives on Productivity, Technology, and Innovation Barbara J. Lipman,1990

WHO/FAO/OIE Guidelines for the Surveillance, Prevention and Control of Taeniosis/cysticercosis K. D. Murrell,P. Dorny,2005 **Official Export Guide** North American Publishing Company,1993

Technological Gap and Constraints in Agricultural Technology Transfer G. L. Ray,P. Chatterjee,S. N. Banerjee,1995

Environmental Technology Assessment ,1993 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

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 addresses 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

FAO Research and Technology Paper ,1986 **Toxicological Profile for Aldrin/dieldrin** ,2002

Technology, Employment and Basic Needs International Labour Office,1977 ILO pub WEP pub Draft position statement regarding the actual and future role of ILO and ILO Programmes relating to technology employment and basic needs emphasises the concept of appropriate choice of technology discusses new trends in international cooperation and describes ILO activities in the WEP the PIACT industrial committees and information retrieval

Technology Transfer A Complete Guide - 2020 Edition Gerardus Blokdyk, **Draft Toxicological Profile for Aldrin/dieldrin** ,2000

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