

## **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

**Huangqi Zhang**



## **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 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

**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

WHO/FAO/OIE Guidelines for the Surveillance, Prevention and Control of Taeniosis/cysticercosis K. D. Murrell,P. Dorny,2005

*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

**Economic Review** Ōsaka Shiritsu Daigaku. Keizai Gakubu,1987

**Lok Sabha Debates** India. Parliament. Lok Sabha,1903

**International Technology Transfer**

Howard V. Perlmutter,Tagi Sagafi-nejad,1981      **Current Literature on Science of Science** ,1995      The Trade-mark Reporter ,1979      *Joint Ventures in China* Mary L. Riley,1999      *Toxicological Profile for Aldrin/dieldrin* ,2002      China Business Strategies Nigel Campbell,Peter Adlington,1988 Based on a survey and research programme carried out in 1988  
*Industry/university/government Biomedical Research Alliances in the Public Interest* ,1991      *Official Report of the Debates of the House of Commons* Canada. Parliament. House of Commons,1995-11

Who Guideline On Transfer Of Technology: Bestsellers in 2023 The year 2023 has witnessed a remarkable surge in literary brilliance, with numerous compelling novels captivating the hearts of readers worldwide. Lets delve into the realm of bestselling books, exploring the engaging narratives that have enthralled audiences this year. Who Guideline On Transfer Of Technology : Colleen Hoover's "It Ends with Us" This touching 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 prevail. Uncover the Best : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This captivating historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids absorbing storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Discover the Magic : Delia Owens "Where the Crawdads Sing" This captivating 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 bestselling 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 compelling stories waiting to be discovered. The novel begins with Richard Papan, 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 an exceptional and gripping novel that will keep you guessing until the very end. The novel is a warning tale about the dangers of obsession and the power of evil.

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## Table of Contents Who Guideline On Transfer Of Technology

1. Understanding the eBook Who Guideline On Transfer Of Technology
  - The Rise of Digital Reading Who Guideline On Transfer Of Technology
  - Advantages of eBooks Over Traditional Books
2. Identifying Who Guideline On Transfer Of Technology
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Who Guideline On Transfer Of Technology
  - User-Friendly Interface
4. Exploring eBook Recommendations from Who Guideline On Transfer Of Technology
  - Personalized Recommendations
  - Who Guideline On Transfer Of Technology User Reviews and Ratings
  - Who Guideline On Transfer Of Technology and Bestseller Lists
5. Accessing Who Guideline On Transfer Of Technology Free and Paid eBooks
  - Who Guideline On Transfer Of Technology Public Domain eBooks
  - Who Guideline On Transfer Of Technology eBook Subscription Services
  - Who Guideline On Transfer Of Technology Budget-Friendly Options
6. Navigating Who Guideline On Transfer Of Technology eBook Formats
  - ePub, PDF, MOBI, and More
  - Who Guideline On Transfer Of Technology Compatibility with Devices
  - Who Guideline On Transfer Of Technology Enhanced eBook Features
7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Who Guideline On Transfer Of Technology
  - Highlighting and Note-Taking Who Guideline On Transfer Of Technology
  - Interactive Elements Who Guideline On Transfer Of Technology
8. Staying Engaged with Who Guideline On Transfer Of Technology

- Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Who Guideline On Transfer Of Technology
9. Balancing eBooks and Physical Books Who Guideline On Transfer Of Technology
- Benefits of a Digital Library
  - Creating a Diverse Reading Collection Who Guideline On Transfer Of Technology
10. Overcoming Reading Challenges
- Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
11. Cultivating a Reading Routine Who Guideline On Transfer Of Technology
- Setting Reading Goals Who Guideline On Transfer Of Technology
  - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Who Guideline On Transfer Of Technology
- Fact-Checking eBook Content of Who Guideline On Transfer Of Technology
  - Distinguishing Credible Sources
13. Promoting Lifelong Learning
- Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
- Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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