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## WHO GUIDELINE ON TRANSFER OF TECHNOLOGY

### DRAFT DOCUMENT FOR COMMENT

The need for new WHO guidance for transfer of technology was discussed at the forty-second meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2007. Colleagues from the WHO Prequalification Programme shared their experience of recently submitted dossiers by, and inspections carried out in, plants that had undergone technology transfer. Technology transfer is happening worldwide both within and between companies, and within the same country as well as between countries. The Expert Committee, therefore, recommended that WHO guidelines on transfer of technology be developed. This draft text was subsequently prepared by Mr John Startup, United Kingdom and by Dr Monika Zweygarth, South Africa. The document was then discussed during the consultation on WHO guidelines for medicines quality assurance, quality control laboratories and transfer of technology on 27-31 July 2009 and a revision prepared.

Please address comments on this proposal, by 10 October 2009, to Dr S. Kopp, Manager, Quality Assurance, Department of Essential Medicines and Pharmaceutical Policies, World Health Organization, 1211 Geneva 27, Switzerland, fax: (+41 22) 791 4730 or e-mail: [koppes@who.int](mailto:koppes@who.int) with a copy to [bonnyw@who.int](mailto:bonnyw@who.int).

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# Who Guideline On Transfer Of Technology

**Daniel F McAuley**



## **Who Guideline On Transfer Of Technology:**

**Global Manufacturing Technology Transfer** Adedeji B. Badiru, 2015-06-24 Global Manufacturing Technology Transfer Africa USA Strategies Adaptations and Management presents practical strategies for developing and sustaining manufacturing technology transfers It is particularly useful for helping developing nations achieve and sustain a solid footing of economic development through manufacturing The book examines Afr

**Codes of Conduct for the Transfer of Technology** Jack N. Behrman, 1976 *Research Handbook on Intellectual Property and Technology Transfer* Jacob H. Rooksby, 2020-02-28 Written by leading experts from across the world this Handbook expertly places intellectual property issues in technology transfer into their historical and political context whilst also exploring and framing the development of these intersecting domains for innovative universities in the present and the future

**Guidelines for Process Safety in Outsourced Manufacturing Operations** CCPS (Center for Chemical Process Safety), 2010-08-27 In today's competitive economy companies often augment in house production by outsourcing chemical reaction processes and distillation drying formulating blending and packaging operations While most of these tolling or contracted manufacturing services proceed without incident recent major accidents have pointed to weaknesses in some tolling arrangements such as reactivity of materials and processes This Guidelines book provides the reader with proven procedures to improve process safety throughout the life cycle of a contracted manufacturing operation Extensive checklists and examples used throughout the book make it a valuable learning tool and reference for companies conducting toll manufacturing or considering outsourcing manufacturing operations

*Technology Transfer in Biotechnology* Prabuddha Ganguli, Ben Prickril, Rita Khanna, 2009-04-22 Here the world's top experts impart their knowledge and experience many in print for the first time By considering developing country markets this book is the first truly global guide to technology transfer helping companies all around the world to avoid costly mistakes in product development and to recover investments quickly Individual sections treat trade related aspects of intellectual property rights technology transfer in health and healthcare as well as in agriculture and the environment

Triple C Model of Project Management Adedeji B. Badiru, 2008-04-18 A comprehensive guide to the implementation of the Triple C Model of project management this book presents the soft side of project management It deals with the fuzzy ambiguous people issues subject to emotional nuances and sentimental knee jerk reactions Offering practical steps for managing any project this book presents real world applications and case studies to illustrate the application of this model This text provides coverage of techniques for tracking managing and controlling project costs as well as implementing the project management body of knowledge PMBOK Schedule performance appraisals project performance appraisals and alternate project organization structures are also included

International Technology Transfer United States International Trade Commission, 1979

*WHO Drug Information*, 2021-04-08

**Sterile Product Development** Parag Kolhe, Mrinal Shah, Nitin Rathore, 2013-10-12 This comprehensive book encompasses various facets of sterile product development Key

concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book Formulation approaches that discuss a variety of dosage forms including protein therapeutics lipid based controlled delivery systems PEGylated biotherapeutics nasal dosage form and vaccines Process container closure and delivery considerations including freeze thaw process challenges best practices for technology transfer to enable commercial product development innovations and advancement in aseptic fill finish operations approaches to manufacturing lyophilized parenteral products pen auto injector delivery devices and associated container closure integrity testing hurdles for sterile product closures Regulatory and quality aspects in the areas of particulate matter and appearance evaluation sterile filtration admixture compatibility considerations sterilization process considerations microbial contamination investigations and validation of rapid microbiological methods and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development

**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 Managing Industrial Development Projects Adedeji Bodunde Badiru, 1993-07-07 Conventional

public management techniques in industrial management projects are often insufficient because they cannot respond or adapt to the dynamism of modern and global markets This guide shows how to overcome these problems by using project management techniques that expedite industrial development in regional national and global settings Using real world examples and a systems approach the author provides a project management model that accounts for all critical interfaces in industrial development projects He explores every aspect of project planning and organization as well as cultural and human resource issues Key areas discussed include how to Schedule and control projects Conduct and evaluate project feasibility studies Select a project manager and staff the project Secure the best experts for various project functions Expedite transfer of industrial technology from developed to developing nations Coverage of budgeting and cash flow analysis promotes understanding of the cost aspects of projects Readers are shown how to use the Critical Path Method and Program Evaluation and Review Techniques to streamline project scheduling They also find out how to use learning curve analysis to evaluate project performance Guidelines on managing multinational projects are supplemented with case studies that illustrate successful industrial development in different countries Appendices list numerous research industrial and economic resources as well as United Nations information sources Managing Industrial Development Projects paves the way for successful outcomes in countries that need them most It is a valuable reference for practitioners public administrators and national policy makers as well as students in industrial engineering industrial administration engineering management and public administration programs

*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

*TEXT BOOK OF INDUSTRIAL PHARMACY-II* Dr. Rajeev Kumar, Prof. (Dr.) Naresh Kalra, Prof. (Dr) Jitendra Singh Chaudhary, Kunal Agam Kanaujia , Dr. Manoj Kumar Katual, 2024-11-04 The Textbook of Industrial Pharmacy II covers a wide range of topics important for understanding the industrial and regulatory aspects of pharmaceutical manufacturing Here s an outline of the contents 1 Pilot Plant Scale Up Techniques o General considerations for personnel space and raw materials o Scale up considerations and documentation for solids liquid orals and semi solids o SUPAC guidelines and platform technology 2 Technology Development and Transfer o WHO guidelines for technology transfer

including terminology protocol quality risk management and processes from R D to production process packaging cleaning o Documentation premises qualification validation and regulatory bodies involved in TT o Indian TT agencies and relevant documentation including confidentiality agreements MoUs and legal issues 3 Regulatory Affairs o Overview of regulatory authorities and their roles o Responsibilities of regulatory professionals in drug development and approval 4 Regulatory Requirements for Drug Approval o Stages of drug development non clinical clinical IND and NDA applications clinical protocols and FDA submissions 5 Quality Management Systems o Concepts of quality management QbD Six Sigma ISO certifications NABL and GLP 6 Indian Regulatory Requirements o Overview of CDSCO and State Licensing Authorities COPP and procedures for new drug approvals This textbook provides a comprehensive guide to both the technical and regulatory challenges faced in industrial pharmacy

**Multinational Enterprises and the Law** Peter Muchlinski, 2021 Multinational Enterprises and the Law is the only comprehensive contemporary and interdisciplinary account of the techniques used to regulate multinational enterprises MNEs at the national regional and multilateral levels In addition it considers the effects of corporate self regulation and the impact of civil society and community groups upon the development of the legal order in this area The book has been thoroughly revised and updated for this third edition making it a definitive reference work for students researchers and practitioners of international economic law business corporate and commercial law development studies and international politics Split into four parts the book first deals with the conceptual basis for MNE regulation It explains the growth of MNEs their business and legal forms and the relationship between them and the effects of a globalized economy and society now increasingly challenged by recently revived nationalist economic policies upon the evolution of regulatory agendas in the field In addition the limits of national and regional jurisdiction over MNE activities are considered a question that arises throughout the specialized areas of regulation covered in the remainder of the book Part II covers the main areas of economic regulation including controls over and the liberalization of entry and establishment tax company and competition law and the impact of intellectual property rights on technology diffusion and transfer A specialized chapter on the regulation of multinational banks in the wake of the global financial crisis is new to this edition Part III introduces the social dimension of MNE regulation covering labour rights human rights and environmental issues Finally Part IV deals with the contribution of international investment law to MNE regulation and to the control of investment risks covering the main provisions found in international investment agreements their interpretation by international tribunals the process of investor state arbitration and how concerns over these developments are leading to reform proposals

*Innovation and Transfer of U.S. Air Force Manufacturing Technology* Committee on Computer-Aided Manufacturing, 1981-01-01

**Project Management for Scholarly Researchers** Adedeji B. Badiru, 2022-12-21 This book presents practical guidelines for university research and administration It uses a project management framework within a systems perspective to provide strategies for planning scheduling allocating resources tracking reporting and controlling

university based research projects and programs Project Management for Scholarly Researchers Systems Innovation and Technologies covers the technical and human aspects of research management It discusses federal requirements and compliance issues in addition to offering advice on proper research lab management and faculty mentoring It explains the hierarchy of needs of researchers to help readers identify their own needs for their research enterprises This book provides rigorous treatment and guidance for all engineering fields and related business disciplines as well as all management and humanities fields

**Method Validation in Pharmaceutical Analysis** Joachim Ermer, Phil W. Nethercote, 2025-03-06 New edition of the gold standard in the field of pharmaceutical analysis extensively updated to include the new ICH Guidelines Q2 R2 and Q14 Following a holistic lifecycle approach to analytical procedures Method Validation in Pharmaceutical Analysis provides hands on information for readers involved in development validation and continued maintenance and evaluation of analytical procedures in pharmaceutical analysis This newly revised and updated Third Edition includes much needed interpretation of the most recent ICH guidelines for validation and method development as well as recent publications of the USP on Analytical Procedure Lifecycle Management and the activities of the British Pharmacopeia AqBd Working Party It also addresses hot topics in the field such as data integrity and continuous monitoring of analytical performance Written by a team of highly qualified pharmaceutical professionals Method Validation in Pharmaceutical Analysis includes information on relevant topics such as Data governance data integrity and data quality as well as analytical instrument qualification and system validation lifecycle and continued HPLC performance qualification Analytical target profile decision rules and fitness for intended use and performance characteristics of analytical procedures Method selection development and optimization multivariate analytical procedures and risk assessment and analytical control strategy Implementation of compendial pharmacopeia test procedures transfer of analytical procedures and a lifecycle approach to transfer of analytical procedures Completely comprehensive in coverage Method Validation in Pharmaceutical Analysis is an essential reference for scientists researchers and professionals in the pharmaceutical industry analytical chemists QC and QA staff and public authorities tasked with relevant regulatory responsibilities

[Technical Report Series](#) ,1950 [OECD Guidelines for Multinational Enterprises on Responsible Business Conduct](#) OECD,2023-06-08 The OECD Guidelines for Multinational Enterprises on Responsible Business Conduct are recommendations addressed by governments to multinational enterprises

[OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations 2022](#) OECD,2022-01-20 In a global economy where multinational enterprises MNEs play a prominent role governments need to ensure that the taxable profits of MNEs are not artificially shifted out of their jurisdiction and that the tax base reported by MNEs in their country reflects the economic activity undertaken therein For taxpayers it is essential to limit the risks of economic double taxation

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