

## **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).

# Ispe Guidelines Technology Transfer

**European Commission. Executive  
Agency for Competitiveness and  
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## **Ispe Guidelines Technology Transfer:**

ISPE Good Practice Guide Ispe,2019-01-24

**ISPE Good Practice Guide** ISPE,2003-03-01

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

*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      Handbook of Pharmaceutical Analysis by HPLC Satinder Ahuja, Michael Dong, 2005-02-09 High pressure liquid chromatography frequently called high performance liquid chromatography HPLC or LC is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry Written by selected experts in their respective fields the Handbook of Pharmaceutical Analysis by HPLC Volume 6 provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques the book captures the essence of major pharmaceutical applications assays stability testing impurity testing dissolution testing cleaning validation high throughput screening A complete reference guide to HPLC Describes best practices in HPLC and offers tricks of the trade in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights current trends in HPLC ancillary techniques sample preparations and data handling      **Handbook of Analytical Validation** Michael E. Swartz, Ira S. Krull, 2012-04-24 Written for practitioners in both the drug and biotechnology industries this handbook carefully compiles the current regulatory requirements to correctly and properly validate a new or modified analytical method The Handbook of Analytical Validation is designed to teach readers how to fully and correctly adapt new or modified analytical methods to meet regulatory requirements The contents offer the latest regulatory requirements for submitting applications for new drugs or other applications as regards analytical method validation The chapters apply to both small molecules in the conventional pharmaceutical industry as well the biotech industry      **Regulatory Affairs in Industrial Pharmacy in India** Madhu Verma, Iti Chauhan, 2025-09-09 This book comprehensively explores the regulatory frameworks governing pharmaceutical manufacturing quality control and approvals in Indian pharmaceutical scenarios Tailored for industry professionals students and researchers it bridges the knowledge gaps in regulatory affairs in the pharmaceutical industry Covering key topics such as pilot plant scale up SUPAC Scale Up and Post Approval Changes technology transfer regulatory requirements and quality management systems it offers insights into navigating the complexities of Indian regulatory requirements A must read for those aiming to excel in pharmaceutical regulation the book serves as a roadmap for ensuring efficiency safety and compliance in pharmaceutical industries operating in India      Good Design Practices for GMP Pharmaceutical Facilities Terry Jacobs, Andrew A. Signore, 2016-08-19 This revised publication serves as a handy and current reference for professionals engaged in planning designing building validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U S and internationally The new edition expands on facility planning with a focus on the ever growing need to modify existing legacy facilities and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings All chapters have been re examined with a fresh outlook on current good design practices      **Technical Report Series** ,2007      **Chemical Engineering Progress** ,2004      **ISPE Good Practice Guide** Ispe, 2014-05-02      GEN Guide to Biotechnology Companies ,1995      **Information Control Problems in**

**Manufacturing Technology 1992** International Federation of Automatic Control,1993-04-13 These proceedings contain more than 80 of the best papers presented at the INCOM 92 Symposium and relate to the vast changes which are occurring worldwide in manufacturing technology Research oriented technical papers cover subjects such as simulation of manufacturing processes sensor based robots information systems general aspects of CIM and manufacturing networks

Proceedings of the ... ASME Design Engineering Technical Conferences ,2000      **Guidelines for Safe Handling of**

**Powders and Bulk Solids** Stanley S. Grossel,2005 Powders and bulk solids handled widely in the chemical pharmaceutical agriculture smelting and other industries present unique fire explosion and toxicity hazards Indeed substances which are practically inert in consolidated form may become quite hazardous when converted to powders and granules The U S Chemical Safety and Hazard Investigation Board is currently investigating dust explosions that occurred in 2003 at WestPharma CTA Acoustics and Hayes Lemmerz and is likely to recommend that companies that handle powders or whose operations produce dust pay more attention to understanding the hazards that may exist at their facility This new CCPS guidelines book will discuss the types of hazards that can occur in a wide range of process equipment and with a wide range of substances and will present measures to address these hazards      **The Illinois Engineer** ,1973      *Make Your Building Smile* European Commission. Executive Agency for Competitiveness and Innovation,2009 Renewable energy technology is a reality but has still not penetrated the building sector to the extent that it has become part of our everyday lives From photovoltaic panels to ground source heat pumps technology can help consumers save emissions while reducing their energy bills This brochure details 25 projects aiming to overcome the remaining hurdles renewable energy applications face in buildings both residential and commercial With a little push perhaps better marketing or a new approach from local authorities these applications can help change Europe s energy map definitively      **Technology Transfer** ,2003      *ISPE Good Practice Guide* Ispe,2011-11      ASHRAE Handbook ,1999

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