Technology Transfer And Pharmaceutical Quality Systems

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Technology Transfer in Pharmaceutical Industry The Potential of Technology Transfer | David Allen | TEDxTucsonSalon Technology Transfer Best Practices **Effective Tools in Technology Transfer Process (TTP) in Pharma Industry | Recorded Webinar | IChrom** *Scale up and Technology Transfer-An Overview* ~~Technology Transfer: Premises and Equipment's~~ ISPE Good Practice Guide: Technology Transfer 3rd Edition

Scaling the Science: Technology TransferEssentials of Technology Transfer Agreement What is TECHNOLOGY TRANSFER? What does TECHNOLOGY TRANSFER mean? TECHNOLOGY TRANSFER meaning *#Pharma information #Interview questions and answers #Technology transfer #FDA #Benefits Basics of Technology Transfer in Pharmaceutical Industry* ~~Process Validation in Pharmaceutical Manufacturing~~ ~~What is COMMERCIALIZATION? What does COMMERCIALIZATION mean? COMMERCIALIZATION meaning~~ Qualification and Validation **What is KNOWLEDGE TRANSFER? What does KNOWLEDGE TRANSFER mean? KNOWLEDGE TRANSFER meaning** ~~Out of the Box Thinking for Technology Transfer | Kirsten Leute | TEDxTucsonSalon~~ **What is Tech Transfer? Technology Transfer in the 21st Century | Helge Seetzen \u0026 Bob Lucky | TEDxNavesink** ~~Pilot Plant Scale Up Techniques (Pilot plant scale up techniques)~~ ~~Technology Transfer~~ **Quality by Design in Pharmaceutical Industry** *WHO guidelines for Technology Transfer | PART 1 | UNIT 2| INDUSTRIAL PHARMACY 2 | B.PHARM | 7th SEM* **Technology Transfer, Scale Up and Factors to Consider when Progressing from Discovery to Clinic** *About Technology Transfer* IPPCR: Technology Transfer *What is Technology Transfer? Meaning, definition and explanation | In pharma Technology transfer*

Technology development and transfer in short in english**Technology Transfer from R\u0026D to Production** TECHNOLOGY TRANSFER RELATED DOCUMENTATION, CONFIDENTIALITY AGREEMENT, LICENSING, MoU'S LEGAL ISSUES Technology Transfer And Pharmaceutical Quality

robust technology transfer commercialization. Developing a robust and continually improved process in conjunction with Pharmaceutical Quality Systems assures meeting or exceeding GMP requirements

Technology Transfer and Pharmaceutical Quality Systems

Technology Transfer in pharmaceutical manufacturing (WHO) Introduction Scope Glossary Organization and management Production: transfer (processing, packaging and cleaning) Quality control: analytical method transfer Premises and equipment Documentation Qualification and validation 1.1 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, …

Technology Transfer - Pharmaceutical Guidance

Technology Transfer Process: The drug quality is designed based on basic data concerning efficacy and safety obtained from various studies in preclinical phases and data concerning efficacy, safety and stability of drug products obtained from clinical studies. The quality of design will be almost completed in Phase II clinical study.

PHARMACEUTICAL TECHNOLOGY TRANSFER: AN OVERVIEW ...

Often, the technology required for local manufacturing is sourced from established technology providers. These already have ongoing programs for developing and updating products. Therefore, ensuring successful technology transfer from these partners is crucial in order to to quickly establish local pharmaceutical manufacturing.

Tackle pharma manufacturing with tech transfer |TechTalk

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Technology Transfer And Pharmaceutical Quality Systems ...

Technology transfer from R&D to manufacturing site is critical because of the scale-up of the product from pilot batch to large-scale commercial batch. A typical technology transfer process can be divided into production part, quality control part and documentation part.

Technology Transfer Guidelines for Pharmaceuticals ...

for Pharmaceutical Preparations, therefore, recommended in its forty-second report that WHO address this issue through preparation of WHO guidelines on this matter (2). 1.5 Transfer of technology requires a documented, planned approach using trained and knowledgeable personnel working within a quality system,

with

Annex 7 WHO guidelines on transfer of technology in ...
SOP on Technology Transfer of Drug Product Quality Assurance A blog about pharmaceutical quality control, quality assurance, microbiology, production and regulatory updates provided by regulatory agencies. Pharmaceutical Guidelines. A blog about Pharmaceutical Quality Control, Quality Assurance, Microbiology, Production and Regulatory updates provided by Regulatory agencies.

SOP on Technology Transfer of Drug Product ...
Technology transfers are frequently conducted throughout the product lifecycle. They require substantial resources, technical know-how, and organizational skills in both sending und receiving units. The transfer of biopharmaceuticals is particularly challenging and should be planned and executed by an experienced and skilled team.

Technology Transfer: What you need for a successful ...
Technology . Transfer. Investigational products. Management Responsibilities. ... The pharmaceutical quality system “assures that the desired product quality is routinely met, suitable

Pharmaceutical Quality Systems: US Perspective
According to the actualized GMP rules, the technology transfer is an essential part of pharmaceutical quality system at a modern pharmaceutical company. Key words: Medicine, life cycle, technology transfer, process scaling, pharmaceutical quality system, quality system procedures. 1.

Technology Transfer as the Process of Pharmaceutical ...
Technology transfer can and should involve development, CGMP, quality, and engineering groups. Do not rush things, which is by far the most common failing. Diligent planning and project management are key.

Modern Technology Transfer Strategies for ...
A technology transfer requires a planned approach by trained, knowledgeable personnel 118 working within a quality system, with documentation, data and information covering all aspects 119 of development, production and quality control (QC), as applicable.

WHO guidelines on the transfer of technology in ...
Transfer of manufacturing processes and analytical procedures between facilities or laboratories is a

necessary part of pharmaceutical development and commercialization. Technology transfers take the outputs of process or method development activities and transfers the knowledge to a different location where a process or analytical procedure will be operated.

What are Good Practices for Effective Technology Transfer ...

Transfer of pharmaceutical manufacturing processes and analytical methods between facilities or laboratories is an essential part of the pharmaceutical product lifecycle. The technology transfer must take place between development and commercialization.

Effective Pharmaceutical Technology Transfer - BII World

Technology transfer has various connotations in academia, law and business. In the pharmaceutical industry, the concept applies to the transfer of process technology from the R&D stage to a Contract Manufacturing Organization (CMO) for either clinical or full scale production of the Active Pharmaceutical Ingredient (API) or New Chemical Entity (NCE).

Transferring API Technology to a CMO? Use This Checklist

Knowledge Management (KM) is identified in ICH Q10, Pharmaceutical Quality System, as a key enabler to the Pharmaceutical Quality System (PQS). ICH Q8 (Pharmaceutical Development) ICH Q11, (Development and Manufacture of Drug Substances) and ICH Q12 (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management) each build on the expectation for knowledge to be ...

Knowledge Management as a Pharmaceutical Quality System ...

Gain a basic understanding of the technology transfer of analytical methods, active pharmaceutical ingredients, quality control standards, packaging components/operations and various pharmaceutical dosage forms from R&D to manufacturing. It is designed to provide an understanding of the issues affecting transfers within and outside a company.

Quality Systems and Control for Pharmaceuticals is an accessible overview of the highly-regulated area of pharmaceutical manufacture, the production of biomedical materials, and biomedical devices. Introducing the subject in a clear and logical manner it enables the reader to grasp the key concepts of

the multidisciplinary area of control science and specifically quality control using industrial and theoretical models. Taking a multidisciplinary approach to the subject the reader is guided through key topics such as product safety which takes into account aspects of analytical science, statistics, microbiology, biotechnology, engineering, business practice and optimizing models, the law and safeguarding public health, innovation and inventiveness and contemporary best practice. The author has both industry and academic experience and many ‘best practice’ examples are included throughout the text based on his own industry experience and current practicing industrial pharmacists. This is an invaluable reference for all students of pharmacy who may have little or no familiarity with industrial practice and for those studying BSc chemistry, biomedical sciences, process analytical chemistry and MSc in Industrial Practice.

This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters also discuss lessons learned from the FDA Office of Biotechnology Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small-scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation, mathematical modeling and monitoring, and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management. Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs.

Pharmaceutical process research and development is an exacting, multidisciplinary effort but a somewhat neglected discipline in the chemical curriculum. This book presents an overview of the many facets of process development and how recent advances in synthetic organic chemistry, process technology and chemical engineering have impacted on the manufacture of pharmaceuticals. In 15 concise chapters the book covers such diverse subjects as route selection and economics, the interface with medicinal

chemistry, the impact of green chemistry, safety, the crucial role of physical organic measurements in gaining a deeper understanding of chemical behaviour, the role of the analyst, new tools and innovations in reactor design, purification and separation, solid state chemistry and its role in formulation. The book ends with an assessment of future trends and challenges. The book provides a valuable overview of: both early and late stage chemical development, how safe and scaleable synthetic routes are designed, selected and developed, the importance of the chemical engineering, analytical and manufacturing interfaces, the key enabling technologies, including catalysis and biocatalysis, the importance of the green chemical perspective and solid form issues. The book, written and edited by experts in the field, is a contemporary, holistic treatise, with a logical sequence for process development and mini-case histories within the chapters to bring alive different aspects of the process. It is completely pharmaceutical themed, encompassing all essential aspects, from route and reagent selection to manufacture of the active compound. The book is aimed at both graduates and postgraduates interested in a career in the pharmaceutical industry. It informs them about the breadth of the work carried out in chemical research and development departments, and gives them a feel for the challenges involved in the job. The book is also of value to academics who often understand the drug discovery arena, but have far less appreciation of the drug development area, and are thus unable to advise their students about the relative merits of careers in chemical development versus discovery.

Quality, second edition, provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing. It is an excellent resource for practitioners, those pursuing pharmaceutical related certifications, and for students trying to learn more about pharmaceutical manufacturing. This book provides the background theory, applied descriptions of the guidelines and concepts, plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts. In this book the authors share their combined 60+ years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system. This book provides real-life examples from industry and guidelines for practical application of tools that can be referenced by operators, engineers, and management. This book is fully revised, updated, and expanded with new content in areas such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools. Fully revised, updated, and expanded new edition Features new topics such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools Includes end-of-chapter summaries and end-of-chapter question and/or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply

This book is a structured approach to designing a product and its associated manufacturing process. It shows pharmaceutical engineers and scientists involved in product and process development how to utilize QbD practices and applications effectively while complying with government regulations. Material includes discussion of how to utilize design space, models, process control methodology, and cumulative process knowledge to seek improvements in manufacturing, while maintaining and enhancing product performance. Edited by three renowned researchers in the field, this invaluable resource is an essential tool for all pharmaceutical professionals.

The development of a robust drug product requires juggling many competing priorities such as overcoming scientific challenges, following regulatory requirements, and managing business-related concerns. Unfortunately, despite large resources spent on R&D, multifactor productivity of pharmaceuticals is on the decline for several years now. Because of this business reality, pharmaceutical companies have seen a notable change in the traditional operating model and footprint over the past couple of decades. Outsourcing, in particular, has emerged as a successful business model for many pharmaceutical companies looking for ways to strategically increase their R&D capabilities and to augment their in-house resources. How to Integrate Quality by Efficient Design (QbED) in Product Development bridges the gap between theory and practice when it comes to strategic decision-making in a pharmaceutical research scenario. This book will introduce the concept of QbED and focus on various aspects such as patient-centric product designs, platform-based manufacturing technologies, business acuity, and regulatory strategies to balance the challenges in outsourcing with the need for strategic and statistically sound experiments rooted in good science. Detailed discussions will cover pharmaceutical business models, regulatory approval process, quality by design (QbD), business analytics, and manufacturing excellence specifically for small molecules and solid oral dosage forms. With the addition of case studies, flowcharts, diagrams, and data visualizations, How to Integrate Quality by Efficient Design (QbED) in Product Development will be a practical reference to help professionals working in the area of pharmaceutical drug development, strategy, and outsourcing management. Part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin Integrates pharmaceutical business models, economics, and outsourcing-related challenges into pharmaceutical product development Discusses relevant literature references in quality risk management, business strategy, QbD, and product development Provides decision-making flowcharts, conceptual diagrams, and data visualizations to make the book useful, easy to read, and to understand

A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry

offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product manufacturing. This revised second edition: Contains 21 new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.

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.

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies