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Technology Transfer Process In Pharmaceutical Industries

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ABSTRACT

The objective of this criticism is to review the method of however technology is transferred in pharmaceutical trade. This criticism is to debate its procedure for technology transfer method in pharmaceutical trade, the importance of technology transfer, reasons for use of this system, methods of technology transfer, aspects of technology transfer, organization of technology transfer, operate of technology transfer, steps concerned in technology transfer, few case of concerned within the technology transfer within the pharmaceutical trade and perceive the aspects connected with technology transfer. The article tries to debate the method of technology transfer within the pharmaceutical trade. the thought or method is advanced from a research- familiarized program to focus on toward development. The success of any program is extremely hooked in to the effectiveness of the communication preceding its implementation. the final word goal for flourishing technology transfer is to own documented proof that the producing processes for drug substances and drug product, severally, area unit sturdy and effective in manufacturing the drug substances and drug product yielding with the registered specifications and smart producing apply necessities. The Pharmaceutical Technology Transfer activities area unit to transfer product and method data between development and producing, and among or between producing sites to attain product realization.

Keywords: Technology Transfer, Technology transfer Dossier, Documentation, commercialization, manufacturing

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INTRODUCTION

Technology transfer may be a process of sharing skills, knowledge, technologies, method of producing, samples of producing and therefore the facilities among organizations. Technology transfer is the tactic by which basic research disciplines and foundation discoveries are developed into practical and profitably relevant applications and products. Technology Transfer cadre evaluate and oversee invention portfolios, dominate patent prosecution, negotiate licensing agreements and systematically review cooperative in situ research agreements. technology transfer process's some part embroil the prosecution of patents which is commanded by the national Patent and Trademark Office. Individuals with advanced degrees within the biomedical sciences are needed to review and process patents within the biotechnology field. [1-15]

TT Functions

1. Coordinate

Coordinating between technology users and developers, between researchers and manufactures may be a crucial element of technology transfer. Access to relevant internal and external resources to individual projects and enterprises has got to be enabled.

2. Nurture

A main ingredient for moving technology from a search laboratory to a replacement commercial enterprise successfully is an environment that's supportive of entrepreneurship. This must be encouraged by providing guidance, counseling and resources.

3. Link

Cataloging resources associated with business enterprises and connecting would-be entrepreneurs/researchers and other technology developers to outside groups and organizations which may help within the tactic of starting new products, companies etc. Such interdependence provide touchstone for individual business counseling, origin of funding or the link of community who can help with a specific facet of business advancement.

Facets of Technology Transfer [1-6]

Transfer of technology could happen in any of the subsequent ways

1. Government labs to private sector firms
2. Among the private sector firms of country itself
3. Among the private sector firms of distinctive countries.
4. From academics to private sector firms.
5. Academics, governments and industry collaboration• Developing innovative pharmaceutical and vaccine technologies;

Why Technology Transfer process is required in Pharmaceutical Industries:

Technology transfer is very much important in reference to pharmaceutical companies and industries .some reasons are mentioned here as:

- Developing innovative pharmaceutical and vaccine technologies;
- Continuing to deliver corporate social responsibility programs that provide a variety of products and therefore the transfer of specialized knowledge and skills, which contribute to public health and economic expansion and community health of the recipient's nation .
- Enabling access to appropriate therapies and technical know-how, by implementing programs to enhance the health of patients and build capacity round the world.
- Transferring not only manufacturing technology but also other sorts of acquired expertise, starting from good clinical and laboratory practices to innovative solutions for therapy adherence and health literacy.

Importance of Technology Transfer Process In Pharmaceutical Industries[15-20]

- Elucidation of necessary information to transfer technology to actual manufacturing from research and development by sorting variety of information gained during R&D.
- Explication of necessary information to existing product's technology transfer among multiple manufacturing places.
- Exemplification of specific procedures and points of perturb for the two sorts of technology transfer for contributing to the process within the above. This is pertinent to the technology transfer through R&D and drug production (chemically synthesized drug substances and products) and technology transfer in alliance with post-marketing amendments in manufacturing places

Technology Transfer Process[21-23]

Technology transfer is both integral and important to the drug discovery and development process for brand spanking new medicinal products. The decision to transfer products between manufacturing sites is usually driven by economics. Crucial moments of the process include data review, data assemblage , regulatory impact with particular insistence on any analytical validation, adjustment approvals, full-scale or pilot process batch, and if required stability set down . Typical technology transfer process was described .For a typical research-based pharmaceutical company, drug discovery and development can be broken down into distinct stages which were clearly described

1. Phases of technology transfer

1. Research phase.

a. Quality Design.

2. Development phase.

a. Research for Factory Production.

b. Consistency between Quality and Specification.

c. consistency affirmation through development and manufacturing.

d. Technology Transfer from R&D to Production.

3. Production phase.

a. Validation & Production.

b. assessment from marketed product's Production and Technology Transfer

Organization Of Technology Transfer Process:[5,21,22,23]

1 constituents of Technology Transfer Process are:

* Technology transfer
* Technology Promotion
* Technology Deployment
* Technology Innovation
* Technology Development
* Technology Research
* Technology Assessment
* Technology Information and communication
* Technology Investment
* Technology Collaboration
* Technology Commercialization

Effective Factors in Technology Transfer Process[24-28]

Critical factors in terms of making favorable conditions for pharmaceutical technology transfers are:

1. A viable and accessible local market
2. Political stability, good economic governance;
3. Clear development priorities;
4. Effective regulation;
5. Availability of skilled workers
6. Adequate capital markets
7. Strong property rights (IPR) and effective enforcement

Actually, scientific requirements, evaluation, and capacities, selection and acceptance of technology methods are significant within the technology transfer process . Thus, awareness regarding effective factors on technology transfer is of consideration for recipients of technology

Stages Of Technology Transfer[14,15,29,30]

Typically, technology transfer occurs during one among five stages within the product's lifecycle: early discovery, toxicological evaluation, clinical development, scale-up and commercial manufacturing, and in-line production. Each stage involves a special sort of transfer, rationale, and key participants. This transfer phases comprises of good-manufacturing practice guidelines and far- reaching templates that integrate the circumstantial transfer work streams of drug product, drug substance, thorough methods, and packaging compulsions.

The key activities for every of those work streams are aligned with good laboratory practices or current good manufacturing practices to make sure consistent and controlled manufacturing of a high-quality product. In addition, there are specific activities to deal with program management, documentation, and site readiness requirements. These phases help to optimize these deportation work streams and exercise by

- Addressing potential manufacturing equipment and processing constraints within the initial process design stages
- Ensuring that only the required transfer activities are going to be executed to avoid interfering with new product launches
- Managing compliance and regulatory activities designate assets more efficiently to reinforce both transfer activities and ongoing production .
- Implementing integrated plans like key activities, inputs/outputs, dependencies, and deliverables between the sending and receiving parties

Approaches to overcome barriers in Technology Transfer [31,32,33]

The Commercializing publicly funded technologies – The basic pattern envisioned is to give institutions receiving public research funds the right to obtain and exploit patents on inventions developed in the course of research. Research tool patents and freedom to work for the general public sector – The patents sometimes make it difficult for public researchers to hold out their research or to form the products of that research available it's intensified by the tendency of some publicly funded research laboratories to avoid use of a patented technology without permission even in nations where no relevant patent is effective. scientific publication and web approach –finite availability of scientific and technical journals led to enormous problems for developing nations scientists. National security issues and restrictions on exports of particular technology – International control designed to protect national security and to prevent the proliferation of important technologies also restrict the flow of technologies. Co-operative research agreements – The global support for public sector research might be encouraged is through co-operative research agreements designed to meet specific goals it would seem more feasible to focus efforts on technologies of serious

social benefit to the developing nations. Possible treaty on scientific access – There has also been a proposal for an international treaty on access to knowledge and technology negotiated on the basis of the type of reciprocity found in normal international trade negotiations.

Technology Transfer Documentation[34-38]

To properly transfer technology consistent with the above processes, documentation of technology transfer including appropriate procedures and technical documents is important. documentation and Procedures of technology transfer are indicated as following.

The data of the documents (such as development report) should be prepared and compiled consistent with purposes, and will be always readily available and traceable. For fruitful technology transfer, responsibilities and task assignments should be clarified, and acceptance precedent for the completion of technology transfer concerning of the very technology that has to be transferred.

According to doctrine , it's enticing to manage the product specification with thorough information of product including drug substances or products which is subject to transfer, and move forward with the technology transfer in accordance to the technology transfer plan established on the idea of this specification, and document the results because the technology transfer report. For that purpose, the subsequent technical information should be transferred.

- The Research &Development department should specify the necessary considerations of GMP in compliance specific to the subject drugs and manufacturing methods i.e., manufacturing processes, and present them to a department of facility and equipment.
- The power and equipment department should establish facilities and equipment's reflecting the above considerations, clearly details of the establishment and operational considerations of these facilities and equipment's, and present them to a drug manufacturing department.
- * The department responsible for drug manufacturing should entirely understand the above mentioned information, implement the validations, and execute appropriate operations and controls in conformity to the facilities and equipment's yet established, and record the results of operations and controls

Research and Development Report[39-42]

The research and development report (development report) is a file of technical information necessary for drug manufacturing, which is obtained from pharmaceutical development, and the research and development department is responsible of its documentation. This report is a crucial file to point rationale for the standard design of drug substances and drug products including information like raw materials, components, manufacturing methods, specifications

and test methods. The following exemplifies information to be contained within the development report

- Historical data of pharmaceutical development of latest drug substances and drug products at stages from early development phase to final application of approval
- Raw materials and components
- Synthetic route
- Rationale for formula designs and dosage form
- Rationale for design of manufacturing methods
- Rational and alter histories of important processes and control parameters
- Quality profiles of producing batches (including stability data)
- Test methods and specification of drug substances, reaction intermediates, final drug products, raw materials, and constituents , and their rationale that is the validity of specifications and range of important tests like content assay , impurities and dissolution profile , rationale for selection of test reagents, methods, and columns for chromatography , and traceability of data of these information.

Product Specification (Product Specification File) [43,44]**:**

The product specification is to compile information which enables the manufacture of the product, and to define specification, manufacturing and evaluation methods of the product and its quality, and therefore the transferring party is liable for documenting the file 14. The product specification file should be reviewed at regular intervals, and incorporate various information obtained after the beginning of production of the merchandise, and be revised as appropriate. The product specification file should contain the following.

- Information necessary for the start and continuation of product manufacturing
- Information necessary for quality assurance of the product
- Information necessary for assurance of operation safety
- Information necessary for environmental impact assessment
- Information of costs
- Other specific information of the product

Technology Transfer Plan[15,25,45]:

The technology transfer plan is to elucidate items and contents of technology to be transferred and detailed procedures of individual transfer and transfer schedule, and establish judgment criteria for the completion of the transfer. The transferring force should prepare the plan out before the implementation of the transfer process , and sign an agreement concerned with the contents with the transferred party.

Technology Transfer Report: [45.46]

The technology transfer report is to report the completion of technology transfer after data of actions taken according to the technology plan is evaluated and the information is confirmed pursuant to the fixed judgment criteria. Both , transferring group and transferred party can document the transfer report; however, they need to have an agreement on its contents that were being used.

Approval by Quality Assurance Department:

It is desirable that the quality assurance department should establish confirmation process for all kinds of technology transfer documentation, and should check and approve the documentation.

TECHNOLOGY TRANSFER DOSSIER[16,43.47,48]

The designee shall receive a Dossier that is also called as Technology Transfer dossier from R & D to another manufacturing station. The following items are included in the dossier.

* Molecule information
* Proposes Markets
* Master Formula Card
* Master Packaging Card
* Storage Requirements
* Expiry
* Raw Material/Packaging and labeling Specifications proposal
* Environmental, Health and safety requirements
* Proposed Master Formula
* Detailed description of the process
* Critical parameters of the process
* Shipping requirements
* Standard quality control procedures for Raw materials, in-process, packing materials and Finished product specifications.
* Finished Product Specifications
* Special Sampling requirements if any
* Stability testing requirement
* Product Development Report.

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