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Review Article

TECHNOLOGY TRANSFER IN PHARMACEUTICALS

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ABSTRACT
The Purpose of this review article is to discuss various critical paths for success of technology transfer. This article highlights the goal, methods, importance, facets and various models associated with technology transfer. A further detailed steps involved in technology transfer is described by understanding the problems associated during technology transfer. Licensing is one such phenomenon of technology transfer that has gained momentum in pharmaceutical industry where by pharmaceutical companies can contribute to research development. A major decision focuses on that point where the idea or process is advanced from a research-oriented program targeted toward commercialization. The three primary considerations to be addressed during an effective technology transfer are the plan, the persons involved and the process. Few cases of technology transfer in pharmaceuticals. In conclusion to technology transfer is a complex issue and should be deal with using holistic approach.
KEYWORD: Technology Transfer, Models, Research and Development, Commercialization.

INTRODUCTION

Technology transfer is the process by which a developer of technology makes its technology available to a commercial partner that will exploit the technology[1]. Pharmaceutical industry, "technology transfer" refers to the processes of successful progress from drug discovery to product development, clinical trials and ultimately full-scale commercialization[2]. There are two types of technology transfer, vertical or horizontal. Vertical technology transfer refers to transfer of technology from basic research to development and production respectively. Whereas, horizontal technology transfer refers to the movement and application of technology used in one place or context to another place[3]. The term technology transfer can be defined as the process of movement of technology from one unit to another. Commercial technology transfer may be defined as mutually agreed and goal-oriented. The transfer may be said to be successful if the receiving unit and the transferee can effectively utilize the technology for business gain. The transfer involves cost and expenditure that should be agreed by the transferee and transferor. Technology transfer is both integral and critical to drug development and development process[4]. The success of any particular technology transfer depends upon process understanding or the ability to predict accurately the future performance of a process (Figure 1)[5]. Technology transfer is a broad set of processes in which technology is transferred between different stakeholder such as governments, private sector, nongovernmental organizations NGO's and research institutions[6].

Methods of technology transfer

Licensing is the most common method of technology transfer. There are two strategies for licensing one is licensing-in and licensing-out[7]. In licensing-in strategy, companies that are small and lack facilities to do basic research and these facilities want to buy other research. In case of licensing-out strategy, company's right is given to another party[8].

Facets of technology transfer

The transfer of technology could happen in any of following ways:

1. Government labs to private sector firms.
2. Between private sector firms of same country.
3. Between private sector firms of different country.
4. From academia to private sector firms.
5. Academia, government and industry collaborations[9].

Importance of technology transfer

1. Demonstration of necessary information to technology transfer from research and development to actual manufacturing.
2. Demonstration of necessary information to technology transfer of existing product between various manufacturing places.
3. For the smooth manufacturing of commercialized products[10].
4. General impact of the technology transfer program.

i. Improvement of the research pertinence and its promotion in foreign countries.
ii. Contribution with the creation and consolidation of research groups and centers for technology development, involving the training of young research students.
iii. Promote interdisciplinary projects to be developed in the region of interest[11].

Reason of technology transfer

Many reasons exist why a company would like to transfer its technology to other parties:

1. Due to lack of manufacturing capacity, the developer of the technology may only have manufacturing equipment that suitable for lab and small scale operations and must partner with another organization to do large scale manufacturing.
2. Due to lack of resources to launch product commercially. The original inventor of technology may only have resources to conduct early-stage research and Phase-I and II clinical trials.
3. Due to lack of marketing distribution and distribution capability. The developer of the technology may have fully developed the technology and even have obtained regulatory approvals and product registrations, but it may not have the marketing and distribution channels and must collaborate with another organization that has the capability[12].

Effective factor in technology transfer

In the technology transfer process, the entire element of technology triangle (Figure 2) is to be transferred into organizations and not impose them exclusively into technology's hardware parts. They should be fully aware of

their capabilities and requirements before launching technology transfer. Actually, technological evaluation, requirements and capacities recognition and selection of technology methods are of vital importance in the technology transfer process (Aghyi, 1999). Thus, awareness of effective factors on technology transfer is of great importance for technology recipients[13].

Technology transfer problems commonly faced by Small and Medium Enterprises (SMEs)[14]

Jagoda and Ramanathan(2007), worked on the problems faced by SMEs in planning and managing technology transfer may be classified into three categories are: technology transfer process issues, corporate capability issues and operating environment and network information system issues. The problems are summarized below:

1. Problems during the technology justification and selection stage.
   i. Wrong selection of technology based on misjudgment when preparing a business case for a technology transfer project.
   ii. Cost of buying, installing, operating and maintaining the technology is also high.
   iii. The technology selected is also complex for easy understanding and assimilation of the transferee.
   iv. The technology needs extensive adaptation to suit local conditions.
2. Problems during the planning stage.
   i. Transferor (seller) underestimates the problems in transferring the technology to a developing country setting.
   ii. Transferor does not fully understand transferee needs.
   iii. Transferee managers are not involved in the planning which is carried out only by the transferor.
   iv. Too much attention is paid to the hardware to be purchased and not enough attention is paid to skills and information acquisition.
   v. Overestimation of the technological capabilities of the transferee by the transferor thereby leading to unrealistic expectations on how well the transferee can meet target dates.
   vi. Poor market demand forecasting by the transferee of the outputs to be produced by using the transferred technology.
   vii. The objectives of the transferor and transferee are not compatible.
   viii. Mechanisms chosen for implementing the transfer are not appropriate.
3. Problems during negotiations.
   i. Differences in negotiation approaches and strategies.
   ii. Lack of trust between the transferor and transferee.
   iii. Goal incompatibility during negotiations.
   iv. Inability to reach agreements on pricing, product, and marketing strategies.
   v. Both parties try to achieve results in an unrealistically short period of time.
4. Problems during technology transfer implementation.
   i. Shortage of experienced technology transfer managers.
   ii. Lack of trust in transferor developed systems by the transferee.
   iii. Inability to achieve quality targets.
   iv. Delay in obtaining supplementary materials, from the local environment, needed for quick implementation.
   v. High cost and poor quality of locally available materials needed to implement the technology transferred.
   vi. Inadequate tracking of the technology during implementation.
   vii. Cost overrun due to poor implementation[15].

Models of technology transfer

The difficulties and complexities faced by managers of technology transfer projects, researchers, consultants, and practitioners of technology transfer have been proposing models of technology transfer that could facilitate the effective planning and implementation of technology transfer projects. Two types of technology transfer models are qualitative and quantitative. Qualitative models often have as their objective the delineation of activities involved in managing technology transfer and the elicitation of factors and issues that can influence the success and/or effectiveness of technology transfer. Quantitative models, on the other hand, aim at quantifying parameters of significance in technology transfer and analyzing them with a view towards minimizing goal incompatibility between the transferors and transferees of technology.

Qualitative technology transfer models

The Bar-Zakay model: Bar-Zakay (1971) developed a technology transfer model based on a project management approach. Technology transfer process is divided into the Search, Adaptation, Implementation and Maintenance stages. Bar-Zakay Model disadvantage limited relevance today since many of the activities, terms and ideas expressed reflected the setting of the late 1960s to early 1970s, when buyers of technology were mainly passive recipients who depended greatly on aid programs for the purchase of technology.

The lessons that can be learnt from the Bar-Zakay model are the following:

i. There is a need for a comprehensive examination of the entire technology transfer process from "search" right through to "post-implementation" activities.
ii. The process approach must be adopted in planning and implementing technology transfer projects.
iii. Milestones and decision points are important so that activities can be strengthened, mistakes corrected, or even the project terminated at any point in time[16].

The Behrman and Wallender model: Behrman and Wallender (1976) have proposed a seven stage process for international technology transfer that may be more relevant to multinational corporations. The seven stages are:

i. Manufacturing proposal and planning to arrive at decisions regarding location and preparing a business case including good resource assessments.
ii. Deciding the product design technologies to be transferred.
iii. Specifying details of the plant to be designed to produce the product and other aspects related to construction and infrastructure development.
iv. Plant construction and production start-up.
v. Adapting the process and product if needed and strengthening production systems to suit local conditions.
vi. Improving the product technology transferred using local skills.
vii. Providing external support to strengthen the relationship between the transferor and transferee.

The weakness of this model is that, during the first three stages the transferor develops the technology transfer project with minimal involvement of the transferee thereby reinforcing dependency[17].

The Dahlman and Westphal model: Dahlman and Westphal (1981) model have proposed a nine stage process model as follows:

i. Pre-investment feasibility is carried out to gather information and establishing project viability that are carried out for techno-economic.
ii. On the basis of feasibility study there is a need to carry out a preliminary identification of technologies.
iii. Carry out basic engineering studies that involve the preparation of process flow diagrams, layouts, material and energy balances and other design specifications of the plant and machinery and the core technology to be transferred.
iv. To make the transfer effective carry out a detailed engineering study that involve the preparation of a detailed civil engineering plan for the facility, including construction and installation specifications and identification of the peripheral technology needed.
v. The subcontracting services are carried out for the selection of suppliers to assemble the plant machinery, equipment and plan for the co-ordination of the work among various parties.
vi. The education plan and training are executed in consultation with the suppliers of technology for the workers who would be employed in the technology transfer project.
vii. The plant is constructed.
viii. Operations are commenced.
ix. Develop trouble-shooting skills and put in place arrangements to solve design and operational problems as they arise, especially during the early years of operation.
x. Its major weakness is that it assumes that the transferee will have access to high-level engineering skills[18].

The Schlie, Radnor and Wad model: Schlie *et al.* (1987) propose a simple, generic model that delineates seven elements that can influence the planning, implementation and eventual success of any technology transfer project. These seven elements are listed below.

i. The transferor, which is the unit selling the technology to the recipient.
ii. The transferee, which is the unit buying the technology.
iii. The technology that is being transferred.
iv. The transfer mechanism that has been chosen to transfer the chosen technology.
v. The transferor environment is the immediate set of conditions, in which the transferor is operating. Attributes of the transferor environment that can influence the effectiveness of the transfer process include, among others, economic status, business orientation (inward versus outward), stability, attitude and commitment to the transfer project, and operating policies.
vi. The transferee environment is the immediate set of conditions under which the transferee is operating. Attributes of the transferee environment that can influence the absorptive capacity of the transferee include physical and organizational infrastructure, skills availability, attitude and commitment to the transfer project, technological status, business orientation (inward versus outward), economic status and stability.
vii. The greater environment which is surrounding both the transferor and the transferee. There may be layers of this environment that are sub-regional, regional and global. Even if the immediate operating environments of the transferor and the transferee are favorable to the technology transfer, if the layers of the greater environment are not supportive, then cross-border and international technology transfer could be adversely affected. Factors in the greater environment such as political relationships between countries, exchange rates, investment climates, trade negotiations, balance of trade, relative technological levels, and the status of intellectual property protection regimes could have a great influence on the success of a technology transfer project[19].

Lee et al. (1988) have developed a longitudinal model of technology transfer based on a study of developing and rapidly industrializing countries. The need of transferee firm to put in place strategies to be able to go through the stages of acquisition, assimilation, and eventual improvement[20].

The Chantramonklasri model: Chantramonklasri (1990) who proposes a five phase model as shown in (Figure 3). The five phases of this model are as follows:

i. Carrying out a pre-investment and feasibility study
ii. On the basis of feasibility study developing engineering specifications and design.
iii. Commence capital goods production based on the engineering specifications and designs that have been developed.
iv. Commissioning and start-u including comprehensive of the workforce.
v. Commercial production commences[21].

UNIDO (1996) model, in which endorsement of the Bar-Zakay approach, suggests that in the manufacturing sector, once the need for a technology transfer project is established the steps of search, evaluation, negotiation, contract execution, technology adaptation and absorption should be followed sequentially to ensure effectiveness[22].

Durrani et al. (1998) have proposed a generic model consisting of five steps:

i. Market-place requirements to be established.
ii. Identifying technology solutions.
iii. Classifying the identified technology solutions.
iv. Establishing sources from where the desired technology could be acquired.
v. Technology-acquisition decision was finalized[23].

Quantitative technology transfer Models

Sharif and Haq (1980) proposed the concept of Potential Technological Distance (PTD) between a transferor and transferee and argues that when the PTD is either too great or too small between the transferor and transferee, the effectiveness of the transfer is low. It suggests that when a transferee first looks for a potential transferor it is important to look for one with an "optimal" PTD[24].

Raz et al (1983) have presented a model of technological "catch-up" that shows how a technology leader, through technology transfer, can assist the rate of technological development of a technology follower. The model examines three phases of growth of a technology follower namely, the slow initial phase with high technological capability gap, the faster learning phase with the decreasing gap, and catch-up phase when the technological gap is very small or closed[25].

Klein and Lim (1997) have studied the technology gap between the general machinery and electrical and electronic industries of Korea and Japan. This model suggests that technology transfer from leaders can play a critical role in upgrading the technological levels of follower firms. Their study also shows that the followers should supplement the

transfer by independently putting in place measures to assimilate, modify, and localize the technology transferred from the leader[26].

Steps in technology transfer

During the development of a formulation, it is important to understand the procedure of operations used, critical and non-critical parameters of each operation, production environment, equipment and excipients availability should be taken into account during the early phases of development of formulation so that successful scale up can be carried out.

The steps involved in technology transfer are as follows –

Development of technology by research and development. (Research Phase)

i. **Design of procedure and selection of excipients by research and development:** Selection of materials and design of procedures is developed by research and development on the basis of innovator product characteristics.

ii. **Identification of specifications and quality by research and development**: Quality of product should meet the specifications of an innovator product.

Technology transfer from research and development to production (Development Phase): Research and development provides Technology Transfer Dossier (TTD) document to product development laboratory which contains all information of formulation and drug product as follows -

i. **Master Formula Card (MFC):** Master formula card contains product name along with its strength, generic name, MFC number, page number, effective date, shelf life and market.

ii. **Master Packing Card**: Master packing card gives information about packaging type, material used for packaging, stability profile and shelf life of packaging.

iii. **Master Formula**: Master formula gives information about formulation order and manufacturing instructions. (Process order and environment conditions)

iv. **Specifications and Standard Test Procedures (STP'S):** Specifications and standard test procedures are helps to know active ingredients and excipients profile, in-process parameters, product release specifications and finished product details.

Optimization and Production. (Production Phase)

i. **Validation studies:** Validation studies verify that process is stabilize the product based on transferred manufacturing formula and Production is implemented after validation studies. Manufacturing department is accepting technology and responsible for validation. The research and development department transferring technology should take responsibility for validation such as performance qualification, cleaning and process validation.

ii. **Scale up for production:** Scale up involves the transfer of technology during small scale development of the product and processes. It is essential to consider the production environment and system during development of process. Operators should concentrate on keeping these things in mind that their segment of the production process running smoothly if technology transfer is implemented thoughtfully. Effective technology transfer helps to provide process efficiency and maintain product quality.

Technology transfer documentation: Technology transfer document demonstrating the contents of technology transfer from transferring and transferred parties. Every step from research and development to production should be documented, task assignments and responsibilities should be clarified and acceptance criteria for completion of technology transfer concerning individual technology to be transferred. It is duty of Quality Assurance department to check and approve the documentation for all processes of technology transfer.

i. **Development report:** The research and development report is a file of technical development, research and development department is in-charge of its documentation. This report is an important file to show basis for the quality design of drug substances and its specifications and test methods. The development report is not prerequisite for the application for approval it can be used at the pre approval an inspection as valid document for quality design of new drug. The development report contains - (a) Data of pharmaceutical development of new drug substances and drug products at stages from early development phase to final application of approval. (b) Information of raw materials and components. (c) Design of manufacturing methods. (d) Change in histories of important processes and control parameters. (e) Specifications and test methods of drug substances. (f) Validity of specification range of important tests such as contents impurities and dissolution. (g) Verifications of results.

ii. **Technology transfer plan:** The technology transfer plan describe items and contents of technology to be transferred and detailed procedures of individual transfer and transfer schedule, establish judgment criteria for the completion of the transfer. The transferring party should prepare the plan before the implementation of the transfer and reach an agreement on its contents with the transferred party.

iii. **Report:** The Completion of technology transfer is to be made once data are taken accordingly to the technology plan and are evaluated to confirm that the predetermined judgment criteria are met. Both transferring and transferred parties should document the technology transfer report.

iv. **Exhibit:** After taking scale up batches of the product, manufacturing of exhibit batches takes place. In case of exhibit, batch sizes are increased along with equipments and their processes. This is done for filling purpose in regulatory agencies[27].

Few cases of technology transfer

In India technology transfer process is actively pursued through government laboratories, academic institutions and commercial entities such as companies. Government laboratories and institution are the frontrunner in creating and transferring the technology. The pharmaceutical company likes Cipla has technology transfer agreement with companies in Uganda, Nigeria, Egypt, Algeria. Themis laboratory has entered in technology transfer agreement with Aventis Pharma Ltd for the development of fixed dose combination of glibenaclamide and glimepride with metfomin technology patented by Themis[28]. Eli Lilly has entered in technology transfer agreement with Shasun Chemical and Drugs for the manufacturing of anti-TB drug, Cycloserine produced by Shasun to meet Eli Lilly global demand[29]. Local subsidiaries of foreign R&D-based pharmaceuticals such as Pfizer, Abbott, GlaxoSmithKline Beecham, Bayer, Boehringer Ingelheim, Aventis, Novartis, Merck, Sharp & Dohme, AstraZeneca, Schering Plough, Wyeth and Bristol-Myers Squibb bought local factories to

establish their operations, although it appears that some of these factories have been bought back by local firms. Laboratorio Elea (ELEA) also possesses licences to commercialize products made by Chiron Corporation (vaccines) and Novo Nordisk (hormone therapy) and a promotion agreement with Novartis for its line of transdermal patches in hormone therapy[30]. In 1999, the current provider of Velcade Millennium Pharmaceuticals, collaborated with DanaFarber cancer institute to study Velcade in multiple myeloma patients after the University of North Carolina achieved a complete response with the compound in the first multiple myeloma patient[31]. Indian pharmaceutical companies like Wockhardt ltd, Cipla ltd, Torrent pharmaceutical ltd, Dr Reddy's laboratories ltd, USV ltd have already signed in-licensing agreements with foreign drug markers. Ranbaxy is looking for in-licensing opportunities for novel drug delivery system[32].

CONCLUSION

A dedicated technology transfer organization is set up to facilitate and execute the process. Technology transfer can be considered successful if a receiving unit can routinely reproduce the transferred product, process or method against a predefined set of specifications is agreed with a sending unit and/or a development unit. Licensing is an important phenomenon of technology transfer that has gained momentum in pharmaceutical industry by which pharmaceutical companies can contribute to research and development. The three primary considerations to be addressed during an effective technology transfer are the plan, the persons involved and the process. The research and development centers should have their own model for the management and innovation to make them more versatile evaluating technical and commercial possibilities for new process or new services. Technology transfer is a complex issue and should be deal with using holistic approach.

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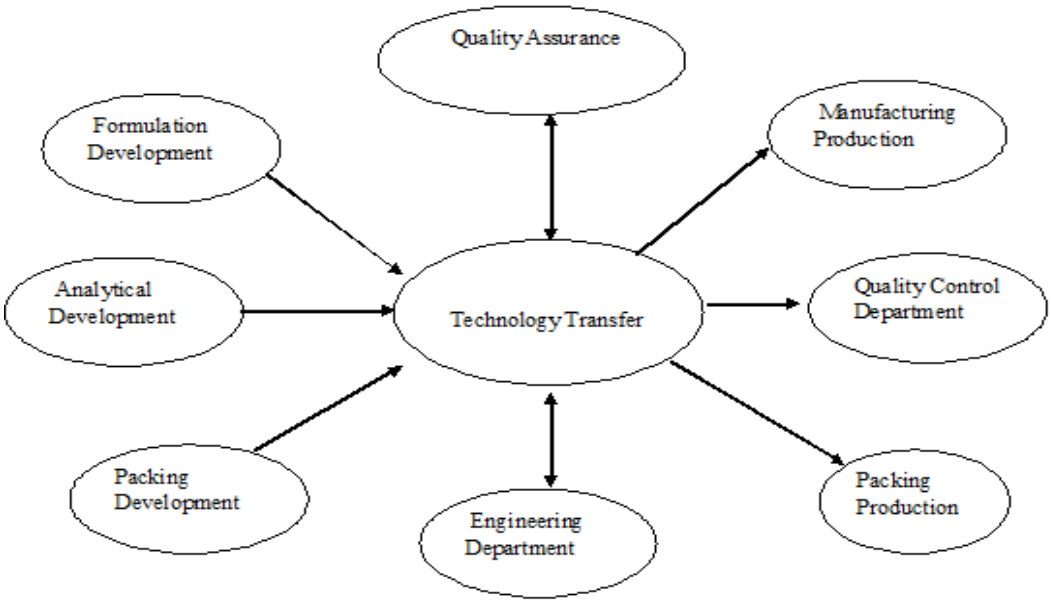

Figure 1. Process Development Work Flow in Pharmaceutical Industry.
Source (Yaswanth Allamneni).

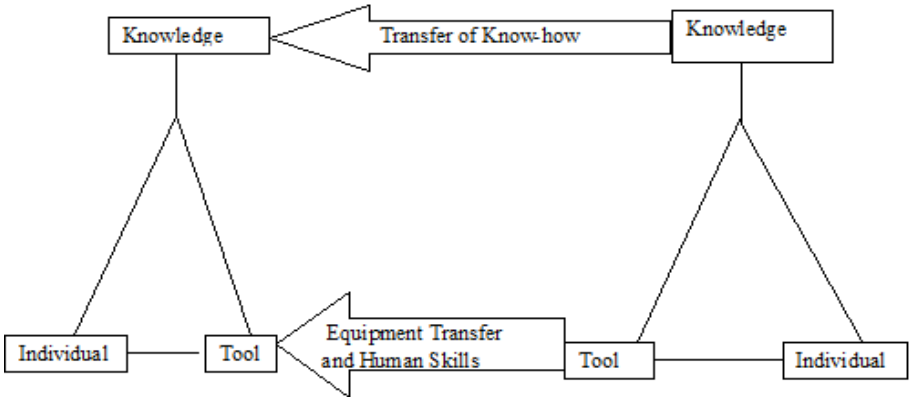

Figure 2. Technology Transfer Process. Source (Aghyi, 1999)

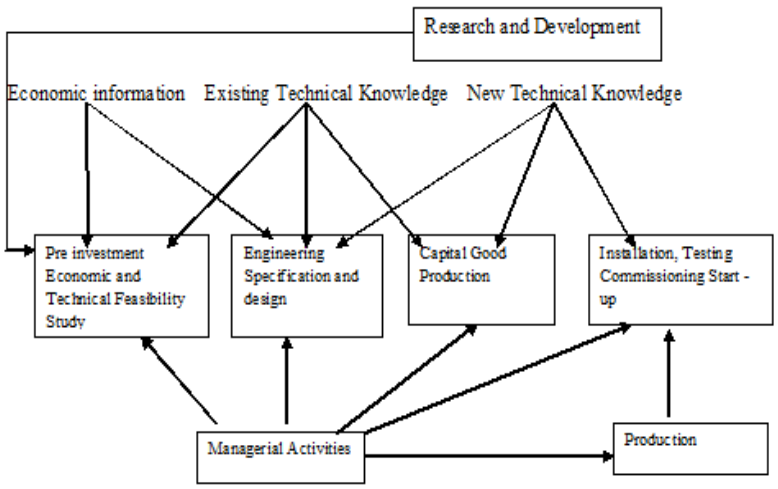

Figure 3 Five –Phase Model of International Technology Transfer.
Source (Chantramonklasri 1990).