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Review Article

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REVIEW ARTICLE ON TECHNOLOGY TRANSFER

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ABSTRACT

The purpose of this review article is to explore the meaning of technology, how technology is transferred in pharmaceutical as well as other industries. This article highlights goals, methods, importance of technology transfer world-wide, facets and various models associated during technology transfer. Productivity gains only result from the natural diffusion of innovation to the market place (technology transfer). In conclusion today's business setting, interest in the profitable exploitation of a firm's technological assets, through technology transfer, has intensified.

Keywords*: Technology Transfer, Models, Technology transfer offices.*

INTRODUCTION

In today's business setting, interest in the profitable exploitation of a firm's technological assets, throughtechnology transfer, has intensified. Factors that have facilitated international technology transfer includeglobalisation of business, liberalisation of the economic regimes of many countries, and the impetus given to the protection of intellectual property after the formation of the World Trade Organization (WTO). These factors have collectively resulted in commercial transfer of technology becoming an important element of the international business setting[3].The importance of technology and the management thereof is increasingly being recognised as an important strategic consideration by organisations. Technology used by organisationsshould enable them to be competitive in the global market. Organisations should thereforemanage technology and the aspects surrounding technology properly.One of the important aspects to be considered in the management of technology is the transfer of the most appropriate technology to the organisation. This necessitates the transfer of the technology from a developer environment to a user environment. Knowledge of the technologies used by an organisation, the technologies available to organisations as well as the technologies used by their competitors, may assist decision-makers in selecting the most appropriate technology. Technology resides in three key areas, namely those of skill, equipment and knowledge[1].

However, the importance of technology transfer from a development perspective is nothing new. More than three decades back, Mansfield (1975) pointed out that, "One of the fundamental processes that influence the economic performance of nations and firms is technology transfer.

WHAT IS TECHNOLOGY?

Past researchers have viewed and defined the term 'technology' from many perspectives and this has influenced the research design and results, negotiations around a transfer and government policies in general (Reddy and Zhoa, 1990).Thus, the term technology has been given various definitions by previous literatures. Technology consists of two primary components: 1) a physical component which comprises of items such as products, tooling, equipment, blueprints, techniques, and processes; and 2) the informational component which consists of know-how in management, marketing, production, quality control, reliability, skilled labor and functional areas.

Technology is defined as "specialised knowledge applied to achieve a practical purpose". In other words, scientific knowledge is applied to develop a product or service in order to satisfy an existing or new need. Technology is therefore the culmination of intellectual and physical ingenuity in order to augment human skill, according to Van Wyk[4].

TECHNOLOGY TRANSFER

Technology transfer is the process by which a developer of technology makes its technology available to a commercial partner that will exploit the technology. In pharmaceutical industry, "technology transfer" refers to the processes of successful progress

from drug discovery to product development, clinical trials and ultimately full-scale commercialization[5].

The term technology transfer can be defined as the process of movement of technology from one entity toanother (Souder *et al.* 1990; Ramanathan 1994). The transfer may be said to be successful if the receivingentity, the transferee, can effectively utilise the technology transferred and eventually assimilate it(Ramanathan, 1994). The movement may involve physical assets, know-how, and technical knowledge(Bozeman, 2000). Technology transfer in some situations may be confined to relocating and exchanging ofpersonnel (Osman-Gani 1999) or the movement of a specific set of capabilities (Lundquist 2003).Technology transfer has also been used to refer to movements of technology from the laboratory to industry, developed to developing countries, or from one application to another domain (Philips 2002). In a veryrestrictive sense, where technology is considered as information, technology transfer is sometimes defined as the application of information into use (Gibson & Rogers 1994)[2].

IMPORTANCE OF TECHNOLOGY TRANSFER

Commercialization of university-discovered technologies is a driver of economic growth and universities have played a major role in bringing innovative ideas and inventions to market. Technology transfer can potentially generate revenues for universities, create research connections between academia and industry, and enhance regional economic growth and development.(5) Therefore the development and transfer of knowledge and technology has been and will continue to be critical to success in all types of industries[9].

In recent years, there is a growing awareness that an appropriate transfer of manufacturing

technologies (technology transfer) is important to upgrade drug quality as designed during R&D tobe a final product during manufacture as well as assure stable quality transferred for many reasonsbetween contract giver and contract acceptor during manufacture[10].

REASONS FOR TECHNOLOGY TRANSFER

1. Lack of manufacturing capacity: The developer of technology may only have manufacturing equipment which is suitable for small scale operation, and must collaborate with another organization to do large scale manufacturing.

2. Lack of resources to launch product commercially: The original inventor of technology may only have the resources to conduct early-stage research such as animal studies and toxicology study, but doesn't have the resources to take technology through its clinical and regulatory phases.

3. Lack of marketing and distribution capability: The developer of 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.

4. Exploitation in a different field of application: Each partner may have only half of the solution i.e. the developer of the technology might be capable of exploiting the technology itself in the field of diagnostic applications and may grant exploitation right to commercial partner for the exploitation of therapeutics application[11,12].

GOALS OF TECHNOLOGY TRANSFER:

According to ICH Q10 guidelines

The goal of technology transfer activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realisation. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach and on-going continual improvement.

- Is a valuable step in the developmental life cycle leading to successful commercial manufacturing.
- To take all the gathered knowledge and use it as the basis for the manufacturing control strategy, the approach to process qualification and on-going continuous improvement.
- The transition of the product/process/analytical method knowledge between development and manufacturing sites.
- To ensure variability of process and parameters are controlled and sufficient in the face of the rigors of a commercial production environment. To verify parameters established during development are still within the determined design space and/or adjusted at scale-up[13].

MODELS FOR TECHNOLOGY TRANSFER

1. Qualitative Models-

a)The Bar-Zakay Model: Bar-Zakay (1971) developed a rather comprehensive TT model based on aproject management approach. He divided the TT process into the Search, Adaptation, Implementation, andMaintenance stages. He depicted the activities, milestones, and decision points (go or no-go) in each of thesestages as shown in Figure 1. The upper half of the figure delineates the activities and requirements of thetransferer (referred to as the "donor" by Bar-Zakay) and the lower half that of the transferee or the"recipient." The activities to be carried out are specified in detail in this model and the importance of boththe transferor and transferee acquiring skills to undertake technological forecasting, long-range planning,and gathering of project-related intelligence is emphasised. The model uses the term "donor" for thetransferor giving the impression that the owner of technology is giving away a valuable asset out of altruistic reasons! This is clearly not the case and the use of such terms must be avoided.The Bar-Zakay model also suffers from another disadvantage that, the model haslimited relevance today since many of the activities, terms, and ideas expressed reflected the setting of thelate 1960s to early 1970s, when buyers of technology were mainly passive recipients who depended greatlyon aid programs for the purchase of technology. It was also an era when government controls wereinstrumental in determining the rate, direction, and scope of technology flows.

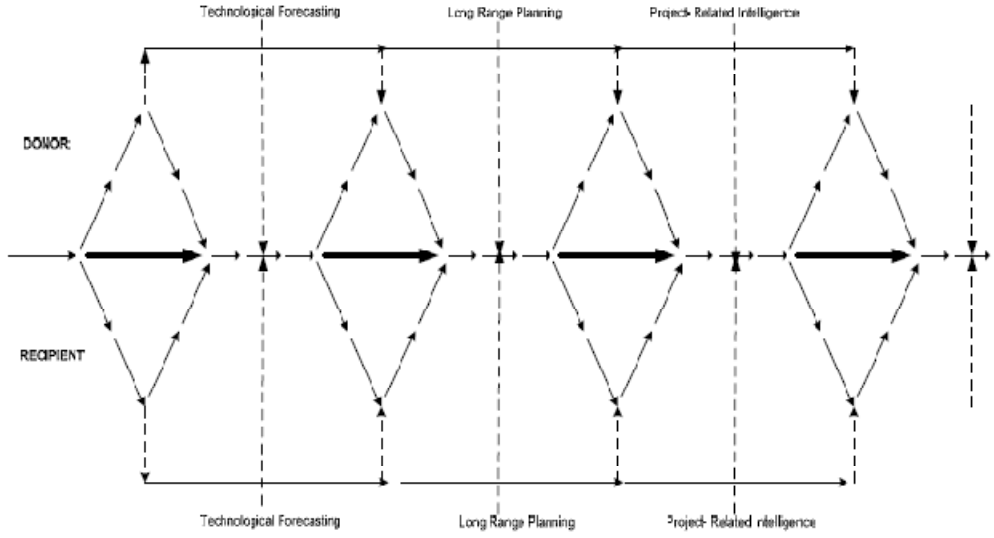
The lessons that can be learnt from the Bar-Zakay model are the following:

• There is a need for a comprehensive examination of the entire TT process from "search" rightthrough to "post-implementation" activities.

• A process approach must be adopted in planning and implementing TT projects

• It is important to have milestones and decision points so that activities can be strengthened, mistakescorrected, or even the project terminated at any point in time[14].

Fig. 1: Bar-Zakay model for technology transfer



(b) The Behrman and Wallender Model: Behrman and Wallender (1976) have proposed a seven stageprocessfor international technology transfer that may be more relevant to multinational corporations. Theseven stages are:

1. Manufacturing proposal and planning to arrive at decisions regarding location and preparing abusiness case including good resource assessments.
2. Deciding the product design technologies to be transferred.
3. Specifying details of the plant to be designed to produce the product and other aspects related toconstruction and infrastructure development.
4. Plant construction and production start-up.
5. Adapting the process and product if needed and strengthening production systems to suit localconditions.
6. Improving the product technology transferred using local skills.
7. Providing external support to strengthen the relationship between the transferor and transferee.One of the weaknesses of this model is that, during the first three stages, the transferor develops thetechnology transfer project with minimal involvement of the transferee thereby reinforcing dependency.

However, in the fifth and sixth stages there is considerable scope for the transferee to assimilate and improveboth product and process technology. This serves to emphasise the fact that technology transfer does notstop with commencement of production and unless there is a mechanism to foster assimilation the projectcannot be considered to have delivered.

The lessons that can be learnt from this model are the following:

- There is a need for the transferee to be involved right from the beginning in the planning andimplementation of a TT project.
- A technology transfer project does not end with commencement of production.
- Unless explicit measures are in place to ensure assimilation of the transferred technology, thetechnology transfer cannot be said to have been successful[15].

(c) The Dahlman and Westphal Model: Dahlman and Westphal (1981) carried out considerable work inthe Republic of Korea and, based on their experience in rapidly industrialising countries during the 1980s, inthe Far East, have proposed a nine stage process model as follows:

- Carry out pre-investment feasibility to gather information and carry out a techno-economic analysisto establish project viability.
- Carry out a preliminary identification of technologies needed, based on the feasibility study.
- 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 coretechnology to be transferred.
- Carry out a detailed engineering study that involve the preparation of a detailed civil engineeringplan for the facility, including construction and installation specifications and identification of theperipheral technology needed to make the transfer effective.
- Carry out the selection of suppliers for equipment and subcontracting services to assemble the plantand machinery and plan for the co-ordination of the work among various parties.
- Prepare and execute a training and education plan, in consultation with the suppliers of technology,for the workers who would be employed in the technology transfer project.
- Construct the plant.
- Commence operations.
- Develop trouble-shooting skills and put in place arrangements to solve design and operationalproblems as they arise, especially during the early years of operation.

This model may be regarded as an improvement of the Behrman and Wallender model with great emphasison transferee involvement at all stages of the TT project. Its major weakness is that it assumes that thetransferee will have access to high-level engineering skills. This may not be true in many developingcountries. It also pays very little attention to negotiation and post-implementation assimilation initiatives.The important lessons that this model presents include the following:

- A TT project is best studied using a sequential process perspective.
- Any TT project should not be commenced without a careful feasibility study since such projectsoften require heavy resource commitments.
- The transferee should be involved in the planning right from the beginning.
- It is important for transferees to develop sound engineering and project[18].

TECHNOLOGY TRANSFER AGENTS

1. **R &D UNIT**
   - Universities
   - Public Research Centres
   - Technology Institutes
2. **Companies**
   - Supplier of technology & R&D to third parties
   - Spin-off, start-ups
   - Large R&D department

Ways of "TECHNOLOGY" Transfer

• In print through technical journals
• In print through learned journals
• Scientific magazines
• Patents
• Orally at conferences
• Orally at learned societies
• In discussions with colleagues
• In discussions with acquaintances
• In discussion with consultants
• On television or radio
• Courses
• Service bulletins
• Data packs
• Specifications[1]

List of institutes in India assisting in Technology Transfer:

1. Asia Pacific Centre for Transfer of Technology
2. National Research & Development corporation
3. Technology Bureau for Small Enterprises
4. Foundation for Innovation & technology transfer

ORGNISATION OF TECHNOLOGY TRANSFER

Since a team concept is always the best approach to accomplishing a successful technology transfer project. The core technology transfer team should be commissions immediatelyfollowing the decision of executive management to pursue the drug candidate to commercialization.

Typical technology transfer core team will likely be comprised f individuals representive of different segments of the business.

1. **Project Manager**- For overall responsibility, coordination and progress communication to management. His or her role may be enhanced as necessary by additional staff & responsibility & authority delegated as appropriate.
2. **Regulatory Affairs**- For coordination of the appropriate regulatory filings, advice on approval timing, content of the filing documentation & response to regulatory inquiries.

3. **Engineering-** To coordinate associated capital projects & direct & control construction, equipment acquisition, installation & qualification.
4. **Material management-** To include those units responsible for pure chasing, Strategic planning, resource allocation & supply chain activities. This member (or members) will analyse & recommend the most favourable manufacturing strategy in consideration of internal capability, business partnership & tax advantages for the corporation.
5. **Manufacturing operations-** To represent the originating site and receiving location production activities. These representatives should have sufficient authority to commit the necessary personal & plant resource to accomplish the project within the defined cost & time limitations.
6. **Research and Development-** To support the technical issues and resolve problems. This group provides the process expertise and would be expected to train and direct the production trials at receiving site.

FUNCTION OF TECHNOLOGY TRANSFER TEAM

Coordinate- Coordinating between technology users and developer, between researcher and manufacturers is important element of technology transfer. Nurture- A main ingredient for moving technology from a research laboratory to new business enterprises successfully in an environment that is supportive for entrepreneurship. LINK- Cataloging resources related to business enterprises & connecting would be entrepreneurship / researcher and other technology developers to outside group & organization which can help in the process of starting new product, companies etc. such linkage provide referrals for individual business counselling, sources of financing.

STEPS INVOLVES IN TECHNOLOGY TRANSFER PROCESS-

During 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 excipient availability should be taken into account duringthe early phases of development of formulation.

(A) Development of technology by R&D. (Research Phase)

(a) Design of procedure and selection of excipients by R&D – Selection of materials anddesign of procedures is developed by R&D on the basis of innovator product characteristics. (b) Identification of specifications and quality by R&D – Quality of product should meet the specifications of an innovator product.

(B) Technology transfer from R&D to production (Development Phase) – R&Dprovides technology transfer dossier (TTD) document to product development laboratory, which contains all information of formulation and drug product as follows -

(a) Master Formula Card (MFC) – Includes product name along with its strength, genericname, MFC number, page number, effective date, shelf life and market.

(b) Master Packing Card – Gives information about packaging type, material used forpackaging, stability profile and shelf life of packaging.

(c) Master Formula – Describes formulation order and manufacturing instructions. (Process order and environment conditions.

(d) Specifications and Standard Test Procedures (STP'S) – Helps to know activeingredients and excipients profile, in-process parameters, product release specifications and finished product details.

(C) Optimization and Production. (Production Phase)

(**a) Validation Studies –** Production is implemented after validation studies that canverify that process is able to stabilize the product based on transferred manufacturingformula. Manufacturing department accepting technology is responsible for validation and the R&D department transferring technology should take responsibility for validation such as performance qualification, cleaning and process validation.

(b) Scale up for production – Involves the transfer of technology during small scaledevelopment of the product and processes. It is essential to consider the productionenvironment and system during development of process. Operators should concentrate on keeping their segment of the production process running smoothly.

(D) Technology Transfer Documentation –Generally interpreted as document indicating contents of technology transfer for transferring and transferred parties. Each step from R&D 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.

(a) Development Report – The R&D report is a file of technical development, and R&Ddepartment is in-charge of its documentation. This report is an important file to indicaterationale for the quality design of drug substances and its specifications and testmethods. 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 – (1) Data of pharmaceutical development of new drug substances and drug products at stages from early development phase to final application of approval. (2) Information of raw materials and components. (3) Design of manufacturing methods. (4) Change in histories of important processes and control parameters.

(5) Specifications and test methods of drug substances. (6) Validity of specification range of important tests such as contents impurities and dissolution. (7) Verifications of results.

(b) Technology Transfer Plan – The technology transfer plan is to describe itemsand 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.

(c) Report – Completion of technology transfer is to be made once data are takenaccordingly to the technology plan and are evaluated to confirm that the predeterminedjudgment criteria are met. Both transferring and transferred parties should document thetechnology transfer report.

(E) 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.

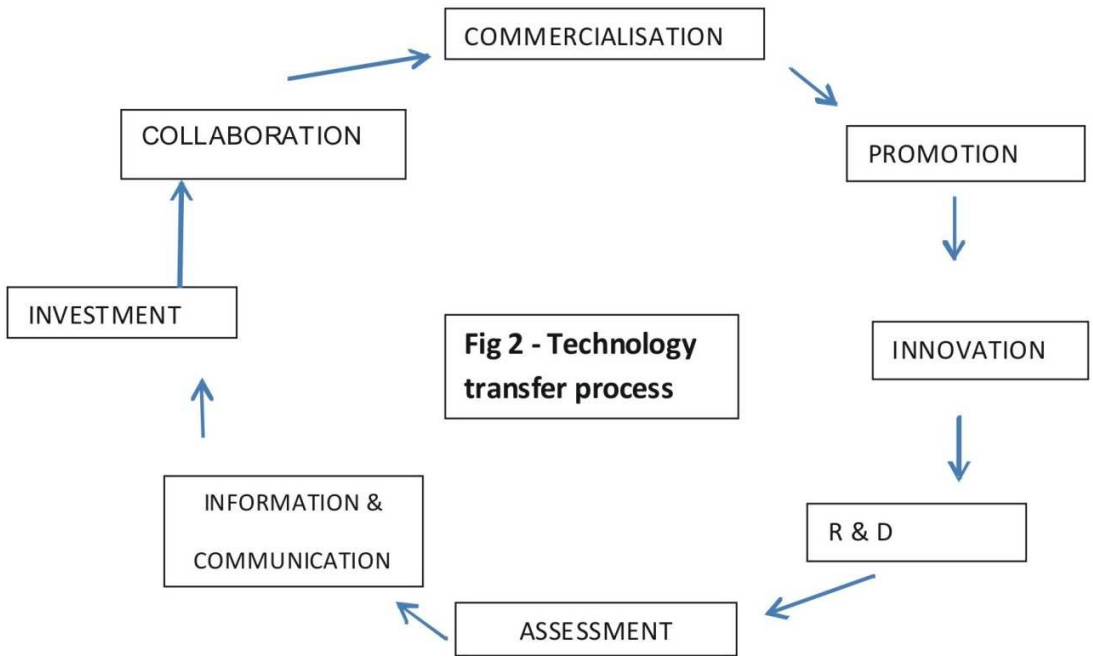
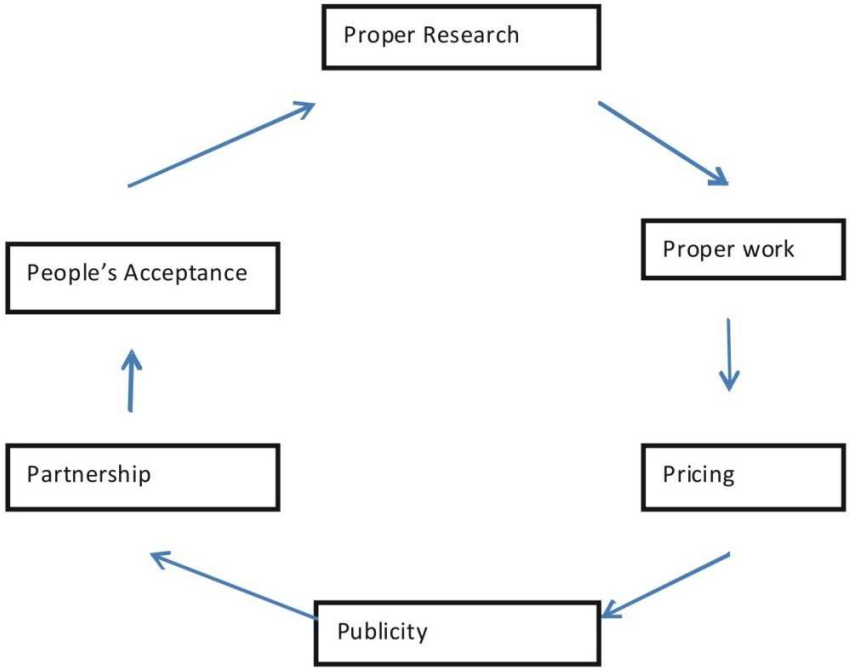


Fig 2 - Technology transfer process

CONTENTS OF TECHNOLOGY TRANSFER-

Fig. 3: 6P's of perfect technology transfer



Proper Research – By proper research we mean firstly that in which the result are reproducible and issues such as scale up, stability etc and other practical now has been addressed, also that in which problem were taken up in first place.

Proper work- This refers to institutional and guidelines regarding IP Protection licensing modalities etc. which must be in place beforehand. In the absence of these, decision get delayed, lack of fairness in decision e.g. case of X institute, which came up with good technology but since no guidance were there, kept running around for two years and then gave up.

Pricing – most difficult and critical area of Transfer of technology. - Too high price can put off buyer, leaving the technology unsold. - Too price a result in revenue loss. - There are basically two model regarding pricing Price charged for a technology should depend upon market force i.e. impact of the technology irrespective of amount spent on developing it. Price charged should include all expenses involved in developing it.

Publicity – It is important to identify and then approach buyer i.e. adopt targeted Publicity and not blanket publicity. Specific journal, website, letters to manufacturer, personal selective visit etc. are some common approach which help in locating buyer.

Partnership – this means working along with industry. Industry takes it up, manufacturer and makes available to society. Partnerships are important to ensure your technology is successfully adopted simply conveying the details may not be sufficient.

People's Acceptance – It is no use trying to develop a technology which people will not accept e.g. due to religious reason/social concern etc. genetically modified food, irradiated vegetables processed beef in India, improved capsule made of non-vegetarian material

CONCLUSION

Appropriate technology transfer is important to upgrade the quality of design to be the quality of product, and ensure stable and high quality of the product. The technology transfer does not mean onetime actions taken by the transferring party toward the transferred party, but means continuous information exchange between the both parties to maintain the product manufacturing. . 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 agreed with a sending unit and/or a development unit.

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