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A REVIEW ON TECHNOLOGY TRANSFER IN PHARMACEUTICAL INDUSTRY

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Abstract: Technology Transfer is the process to transfer the information and technologies that are necessary to manufacture the quality drug product consistently. This review mainly represents various reasons for technology transfer, various methods of technology transfer, various steps involved in technology transfer, necessary factors for effective technology transfer process, different models of technology transfer and organization of technology transfer. The critical path for success is dependent on completion of technology transfer to the production site at an affordable cost.

Keywords: Technology Transfer, Factors for effective technology transfer, Models



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INTRODUCTION

In the pharmaceutical industry, “technology transfer” means the processes of successful progress from drug discovery to product development, clinical trials and ultimately full-scale commercialization. [1,2] The technology transfer is the process by which the developer of technology makes his technology available to the commercial partner that will exploit the technology.[3] There are 2 types of technology transfer vertical and horizontal. The vertical technology transfer means to transfer of the technology from basic research to the development & production respectively. The horizontal technology transfer means the movement and application of used in one place or the context to another place.[4] It is the process by which an original innovator of the technology makes its technology available to commercial partner that will exploit the technology. Technology transfer is very helpful to develop the dosage forms in different ways as it provides efficiency in the process, maintains the quality of the product, helps to achieve the standardized process which facilitates the cost effective production. The commercial technology transfer can be defined as the mutually agreed & goal oriented. The transfer can be said to be successful if the receiving unit and the transferee can effectively utilize the technology for the business gain.[5] The success of any technology transfer depends upon the process understanding or the ability of predicting accurately the future performance of the process. The cost of the product development raises during the pilot scale-up and initial the production batch that is the critical path for the success is dependent on the completion of technology transfer to the production site at an cost that is affordable.[6]

Reasons for technology transfer

1. Due to lack of manufacturing capacity: The developer of technology may only have the manufacturing equipment which are suitable for small scale operations, so he must collaborate with another organization to do large the scale manufacturing.
2. Due to lack of resources for launching of product commercially: The original inventor of the technology may only have the resources to carry out early-stage research such as studies on animals and toxicology studies, but he doesn't have the resources to take the technology through its clinical phase 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 registrations of products, but it may not have the channels of marketing and distribution.
4. Having exploitation in a different field of application: Each partner may have only half

of the solution that is the technology developer might be capable of exploiting the technology itself in the field of diagnostic applications and may grant exploitation right to the commercial partner for the exploitation of its therapeutics application.[6,7]

Why technology transfer in pharmaceutical industry?

In the pharmaceutical industry the technology transfer refers to the processes that are needed for successful progress from drug discovery to development of product, to the clinical trials to the full scale commercialization or in other words it is a process by which a developer of technology makes its technology available to commercial partner that will exploit the technology. In the pharmaceutical industry preparation of dosage form needs scale up in or at various stages, such as the small scale lab development from the 0.5-2kg batch can be scaled up to the 5-10 kg & then to 20-100 kg on the pilot scale. The production scale can typically range from 200 kg to greater than 1000 kg. Technology transfer involves the manufacturing of drug products with the increasing batch sizes on larger equipment or using continuous processing on pilot scale equipments. Usually the scale up involves the transfer of technology and the transfer of knowledge that has been accumulated during the small scale development of the product and processes. It is also important to realize that good communication is critical for the formulation and process transfer to be successful. It is essential for the researcher or the developer of technology to make available this technology to another person to exploit for the progress of development of technology and for exploitation of a technology in the different fields of applications and to make it use with another organization that may have the better marketing capability, manufacturing capability and commercial capability. In the pharmaceutical industry, technology transfer by collaboration with other departments and other organizations to commercialize a pharmaceutical product is the common process[8-10].

STEPS INVOLVES IN TECHNOLOGY TRANSFER PROCESS

During formulation development, it is necessary to understand the operating procedures used, production environment, critical and non-critical parameters of each operation, availability of excipient and equipment should be taken into account during the early phases of formulation development.

(1) Technology development by Research and Development. [Research Phase]

(i) Procedures design and excipients selection by R&D – Proper selection of materials and design of procedures is developed by R&D based on characteristics of innovators product. (ii) Specifications and quality identification by R&D – The products quality should meet the innovators product specifications.

(2) Technology transfer from Research and Development to Production [Development Phase]
– R&D provides TTD document [technology transfer dossier] to product development lab, which contains all the information of formulation and drug product as follows:

(i) Master Formula Card [MFC] - It includes name of product along with its strength, its generic name, effective date, MFC number, page number, and market and shelf life.

(ii) Master Packing Card -It gives information about type of packaging, the packaging material used, stability profile and the shelf life of packaging.

(iii) Master Formula -It describes order of formulation and also manufacturing instructions. [Order of process and environment conditions].

(iv) Standard Test Procedures (STP'S) and Specifications – It helps to know the profile of active ingredients and excipients, in-process parameters, specifications of product release and details of finished product.

(3) Optimization and Production. [Production Phase]

(i) The Validation Studies - After validation studies the production is implemented which can verify that based on transferred manufacturing formula the process is able to stabilize the product. For validation manufacturing department accepting technology is responsible and for validation such as performance qualification, cleaning and process validation R&D department transferring technology should take the responsibility.

(ii) Scale up for production – It involves the transfer of technology during small scale development of the processes and product. It is important during development of process to consider the production environment and system. The operators should concentrate on keeping their segment for the smoothly running of production process.

[4] Documentation of Technology Transfer –Generally interpreted as document indicating contents of technology transfer for transferring and transferred parties. Each and every step from R&D to production should be documented, responsibilities and task assignments and should be clarified and the acceptance criteria for completion of technology transfer concerning individual technology to be transferred. Checking and to approve the documentation for all processes of technology transfer is duty of Quality Assurance department

(i) Report of Development- The R&D report is the file of technical development and in-charge of its documentation is R&D department itself. This report is the important file to indicate rationale for the quality design of the drug substances and its specifications and test methods. For the application for approval the development report is not prerequisite; it can be used at the pre-approval an inspection as valid document for the quality design of the new drug. The report of development contains – (a) The data of pharmaceutical development of new drug

substances and drug products at the stages from early phase of development to final application for the approval. (b) The information of raw materials and the components. (c) The design of manufacturing methods. (d) The change in histories of important processes and control parameters. (e) The specifications and test methods of drug substances. (f) The validity of specification range of important tests such as dissolution and contents impurities. (g) Results of Verification.

(ii) Plan of Technology Transfer- The technology transfer plan is to describe items and the contents of technology to be transferred and detailed procedures of transfer schedule and individual transfer, to establish judgment criteria for the completion of the transfer. The plan should be prepared by the transferring party before the implementation of the transfer and reach an agreement on its contents with the transferred party.

(iii) The Report- Once the data are taken accordingly to the technology plan the completion of technology transfer is to be made and are evaluated to confirm that the predetermined judgment criteria are met. The technology transfer report should be documented by both transferring and transferred parties.

(iv) Exhibit -The manufacturing of exhibit batches takes place only after taking scale up batches of the product, In the case of exhibit, along with equipments and their processes batch sizes are increased. This is done for filling purpose in regulatory agencies. [11]

Necessary factors for effective technology transfer process

The selection of methods of technology, technological evaluation, requirements and capacities recognition has the most importance in the technology transfer process [12]. The effective factors of technology transfer processes are:

- i. Investment in R&D, development of proper managerial and organizing skills in organizations that have a long-run strategic planning in technology development.
- ii. Establishment of the proper relationship between production and research, training of individual related to technology also must be provided along with interactions with various international centers in the technology cooperation areas.
- iii. Development of information in the field of technology transfer methods, modification of cultural value systems in the organizations, and diffusion of scientific attitude in the organizations.
- iv. The employment of the entrepreneur managers and the creations of standards and capabilities in the companies.
- v. The infrastructure related to equipment, organization, information and human.

vi. The training in international companies and the employment of international specialist in the technology field.

vii. Various technological factors such as the degree of achieving the technology, its simplicity, its price, and technology development and complicity of technology [13].

Various methods of technology transfer

[a] By the Transfer of technology or by sale:

In an agreement when the transfer of rights is carried out with a contract is known the sale of technology. The inclusive control and management is handed over to the buyer who pays the price that is [sales price]. A high and fixed price for full transfer of the rights to the buyer is demanded by the owner but the buyer will not easily agree unless the buyer is convinced of the economic value & the potentiality of the patent utilization.

Reasons for transfer of technology or sale arises where

1. Sales companies and sales by the specialized technology development are in the ordinary course of their business.
2. The patents owner does not have the capability to execute and there are hindrances in licensing to the third party.
3. Based on partial patent, it is difficult to produce the finished goods,
4. Problems in developing a basic patent into a commercial product.
5. Research & invention funds is raised by an individual inventor for this kind of technology transfer a contractual agreement between the 2 parties is required but this is only possible when the patent is registered with IPR organization [Intellectual Property Rights].

[b] By licensing of technology

The Licensing covers the broad spectrum of permissions that are granted for the use of technology, trademarks and patents. Different methods through which technology is transferred internationally, among those the most versatile method is licensing. Licensing offers flexibility in technology choice and the opportunity for the source and the receiving institution to negotiate. The Technology license agreements also enable a foreign licensor to reap profits from the transfer of technology without risking the capital in a sometimes volatile foreign market

Amongst the various forms of transferring the technology internationally, the licensing method is the most versatile and it offers the flexibility in choice of technology. The licensing means granted permissions for the execution of technology, trademarks and patents. Both the parties that give and take the execution & usage of the rights enter into the licensing contract under

specified conditions including the payment of technical fees for a specified period. After the period is over, the execution and the usage becomes invalid. The commonly used methods in technology transfer are the sales and licensing method. In the sales method the technology transfer is mainly conducted because the licensing method of technology transfer is not properly recognized. So, there is the need for the spread of recognition as well as the development & propagation of the transfer techniques

[c] By combination of management, know-how and capital:

The success of commercialization is not guaranteed in case of highly advanced and improved technology, so the technology is transferred together along with the capital, management and knowhow and the core components.

[d] By the sale of technology data such as microfilms, plans etc

In case of small scale projects for solving simple technological problems by using a part of technology information.

[e] Using the technical personnel as the medium

In this the technical personnel is involved directly in the technology transfer through deployment and invitation of technical personnel, the resolution of technological issues through the employment.[14-16]

Facets of Technology Transfer

1. Govt. Laboratories to Private sector.
2. Between Private sectors of same country.
3. From Academics to private sectors.
4. Between Academy, Private and Government sectors

Government laboratory to private sectors

These type of Technology Transfer is advantageous as the Government laboratories can get good financial support and funds from the government for their research work and the technology developed by them reaches the private sector.

Between the Private sectors of same country

These type of Technology Transfer generally occurs due to inadequate knowledge of the regulatory requirements, inappropriate financial resources. Hence the private sector that develops the technology is paid by the other sectors that absorbs the technology[17].

From Academics to private sectors

The Academic sectors that are actively involved in the research develop the technology and make it available to the private sectors. By collaboration of private sectors with the institutions, saving of money can be done.

Between Academic, Private and Government sectors

The government provides necessary funds to the academic institutions in developing technology that can be further transferred to the industry [18].

MODELS FOR TECHNOLOGY TRANSFER

1. Qualitative Models

a) The Bar-Zakay Model: Based on a project management approach Bar-Zakay in 1971 developed a rather comprehensive model of Technology Transfer. Bar-Zakay divided the Technology Transfer process into the 4 stages as Search, Adaptation, Implementation, and Maintenance stages. Bar-zakay depicted the activities, milestones, and the decision points [go or no-go] in every of these stages. The upper half delineates the activities and requirements of the transferer [which is referred as the “donor” by Bar-Zakay] and the lower half that of the transferee or the “recipient.” In this model the activities to be carried out are specified in detail and the importance of both the transferor and transferee acquiring skills to undertake technological forecasting, gathering of project-related intelligence and long-range planning is emphasized. The model uses the term “donor” for the transferor giving the impression that the owner of technology is giving away a valuable asset out of unselfish reasons. This is clearly not the case and the use of such terms should be avoided. This model also shows another disadvantage that, this model has limited relevance today as many of the terms, activities and ideas that are expressed reflected the setting of the late 1960s to early 1970s, when the buyers of the technology were mainly passive recipients who depended greatly on aid programs for the purchase of the technology. It was also an era when government controls were the instrumental in determining the direction, the rate, and the scope of the technology flows.

The points that can be learnt from this model are as follows:

- It is necessary to have milestones and decision points so that the activities can be strengthened, Mistakes can be corrected, or even the project terminated at any point in time.
- The process approach should be adopted in the planning and implementing technology transfer projects
- There is the need for the comprehensive examination of the entire technology transfer process from “search” right through to the “post-implementation” activities.[19]

(b) The Behrman and Wallender Model: A seven stage process for international technology transfer have been proposed by Behrman and Wallender (1976) that may be more relevant to multinational corporations.

The seven stages are as follows:

1. The manufacturing proposal and planning to arrive at the decisions regarding location and preparing the business case including the good resource assessments.
2. The product design technologies to be transferred have to be decided.
3. Aspects related to construction and infrastructure development and specifying details of the plant to be designed to produce the product.
4. Production start-up and plant construction.
5. Strengthening production systems to suit Local conditions and if needed adapting the process and product.
6. By using local skills the product technology transferred can be improved.
7. To strengthen the relationship between the transferor and transferee by Providing external support. One of the disadvantages of this model is that, during the first 3 stages, the technology transfer project developed by the transferor with the minimum involvement of the transferee thereby reinforcing the dependency. Hence, in the 5th and 6th stages to improve both product and process technology there is considerable scope for the transferee. This gives an importance to the fact that technology transfer does not stop with commencement of production and unless there is a mechanism to foster the assimilation the project cannot be considered to have delivered.

From this model following points can be learnt:

- Involvement of the transferee is necessary right from the beginning in the planning and implementation of the Technology Transfer project.
- With commencement of production the technology transfer project does not end.
- The technology transfer is not to be said to have been successful unless the explicit measures are in place to ensure the assimilation of the technology transferred [20]

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

- To carry out pre-investment feasibility by gathering information and carrying out a techno-economic analysis to establish the project viability.

- Based on the feasibility study to carry out the preliminary identification of technologies needed.
- To carry out basic engineering studies that involves the preparation of process flow diagrams, material and energy balances, layouts and other design specifications of the plant and machinery and the core technology to be transferred.
- To carry out the detailed engineering study that involves the preparation of the detailed civil engineering plan for the facility, which includes construction and installation specifications and identification of the peripheral technology needed to make the transfer effective.
- To carry out the selection of suppliers for the equipment and subcontracting services to assemble the plant and machinery and plan for the co-ordination of the work among the various parties.
- To prepare and execute a training and education plan, by consulting with the suppliers of technology and for the workers who would be employed in the technology transfer project.
- To construct the plant
- To commence operations.
- To develop trouble-shooting skills and put in place arrangements to solve design and operation related problems as they arise, specially during the early years of the operation.
- This model can be regarded as an improvement of the Behrman and Wallender model with the great emphasis on transferee involvement at all the stages of the Technology Transfer project. The major disadvantage is that it assumes that the transferee will have to access to high-level engineering skills. In many developing countries this may not be true.
- A very little attention is paid to negotiation and post-implementation assimilation initiatives. A important information that this model presents include the following:
 - By using a sequential process perspective the Technology Transfer project is best studied.
 - Without a careful feasibility study any of the Technology Transfer project should not be commenced as such projects often require the heavy resource commitments.
 - Right from the beginning the transferee should be involved in the planning.
 - For transferees it is important to develop project and sound engineering [21]

The Schlie, Radnor and Wad model: proposed a seven elements simple, generic model that can influence the eventual success, implementation and planning, of any technology transfer project. These seven elements are as follows:

- The unit selling the technology to the recipient is the transferor.
- The unit buying the technology is the transferee.
- The technology which is being transferred.
- The mechanism of transfer that has been chosen to transfer the chosen technology.

- A 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 skills availability, physical and organizational infrastructure, technological status, attitude and commitment to the transfer project, business orientation, economic status and stability.
- A transferor environment is the immediate set of conditions, in which a transferor is operating. Attributes of the transferor environment that can influence the effectiveness of the transfer process include, among others, business orientation, economic status, stability, attitude and commitment to the transfer project and operating policies.
- The greater environment which is surrounding both the transferor and the transferee. There may be the layers of this environment that are sub-regional, regional and global. If the layers of the greater environment are not supportive even if the immediate operating environments of the transferor and the transferee are favourable to the technology transfer, then cross border and international technology transfer is adversely affected. The factors in the greater environment such as political relationships between countries, investment climates, exchange rates, balance of trade, trade negotiations, relative technological levels, and also status of intellectual property protection regimes could have the great influence on the success of a technology transfer project.[22]

Lee et al (1988)

Based on the study of developing and rapidly industrializing countries Lee et al developed the longitudinal model of technology transfer. The need of the transferee firm to put in place the strategies to be able to go through the stages of the assimilation, acquisition and eventual improvement.[23]

The Chantramonklasri Model:

He Proposes a 5 phase model. The five phases of this model are:

- To carry out a pre-investment and feasibility study.
- Based on feasibility study developing design and engineering specifications.
- Based on the engineering specifications and design to commence capital goods production that have been developed.
- By commissioning and start-up including comprehensive of the workforce.
- By Commercial production commences.[24]

UNIDO (1996): This model suggests that once the need for the technology transfer is established in the manufacturing sector, the steps of evaluation, search, contract execution, negotiation, technology adaptation and absorption should be followed sequentially to ensure the effectiveness. [25]

Durrani et al (1998)

He proposed a generic model which consists of 5 steps:

- Requirements of market place to be established.
- To identify the technology solutions.
- To classify the identified technology solutions.
- To establish the sources from where the desired technology would be acquired.
- To finalize the technology acquisition decision.[26]

The Quantitative technology transfer Models:

Sharif and Haq (1980): They proposed the concept of PTD (potential technological distance) between a transferor and transferee and argue that the effectiveness of the transfer is low when the PTD is either too great or too small between the transferor and transferee. It suggests that when the transferee looks first for a potential transferor it is necessary to look for one with a “optimal” PTD.[27]

Raz et al (1983)

Have presented a model of technological “catch-up” that shows how the leader of the technology, through the technology transfer, he can assists the rate of the technological development of the technology follower. This model examines 3 phases of growth of a technology follower which are, the slow initial phase with an high technological capability gap, the faster learning phase with an decreasing gap, and catch-up phase when an technological gap is closed or very small.[28]

Klein and Lim (1997)

The technology gap between the general machinery and electrical and electronic industries of korea and japan have been studied by Klein and Lim. This model suggests that leaders of the technology transfer can play a critical role in upgrading the technological levels of the follower firms. The study also shows that by independently putting in place measures to assimilate, modify and localize the technology transferred from the leader the followers should supplement the transfer.[29]

ORGANISATION OF TECHNOLOGY TRANSFER

As the team concept is always the best approach to achieve a successful technology transfer projects. The core technology transfer team must be commissions immediately following the decisions of the executive management to pursue the drug candidate to commercialization. A typical technology transfer core team will likely be comprised of individuals representatives of the different segments of the business.

1. **The Project Manager-** The overall coordination , responsibility and communication progress to the management. His or her role may be enhanced as necessary by the additional staff and responsibility and authority delegated as appropriate.
2. **Regulatory Affairs-** For the coordination of the appropriate regulatory filings, advice on the timing of approval , filing documentation contents and response to the regulatory inquiries.
3. **Engineering-** For coordination of associated capital projects and direct and equipment acquisition, control the construction, installation and qualification.
4. **The Material management-** Those units responsible for strategic planning, pure chasing, supply chain activities and resource allocation are included. These members will analyse and recommend the most favourable manufacturing strategy in consideration of partnership in business, internal capability, and advantages of tax for the corporation.
5. **The Manufacturing operations-** Receiving location of production activities and to represent the originating site. These representatives should have the sufficient authority to commit the necessary personal and plant resource to achieve the project within the defined time and cost limitations.
6. **Research and Development [R&D]-** To support the technical issues and resolve problems. These groups provides the expertise process and would expect to direct and train the production trials at the receiving site. [30]

CONCLUSION

The technology transfer in the pharmaceutical industry means the actions taken to transfer the information and the necessary technologies to realize the quality of design of drugs during the manufacturing. The technology transfer is considered to be successful if the transferred product, process or method against a predetermined set of specifications is agreed with the sending unit or the development unit is routinely produced by the receiving unit. The technology transfer does not mean a one time action taken by the transferring party toward the transferred party, but it means the continuous information exchange between both the parties to maintain the product manufacturing. The 3 primary considerations to be addressed during the effective technology transfer are the plan, the persons involved, and the process. The licensing is the important phenomenon of the technology transfer that has got a lot of appreciation in pharmaceutical industry by which the pharmaceutical companies can contribute to the research and development.

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