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Review Article

Review on Technology Transfer in Pharmaceutical Industry

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ABSTRACT

The purpose of this review article is to discuss different ways for success of technology transfer. This article highlights the goal, methods, importance and various models associated with technology transfer and steps involved in the process of technology transfer. This is an attempt to understand the aspects related with technology transfer. 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. The success of any particular technology transfer depends upon process understanding or the ability to predict accurately the future performance of aprocess.

Keywords: Technology transfer, pharmaceutical production, Research and development

INTRODUCTION

A proper technology transfer (TT) is both essential and important to drug discovery and development for new medicinal products. It is also required to upgrade drug quality planned during research development and to final product during manufacturing as well as to guarantee that stable quality is transferred.

Technology-The application of scientific knowledge for practical purpose, especially in industry.

Technology Definition

(techne-"art, skill, cunning of hard" and logy –speak)

The term "technology transfer" it's very difficult to define precisely.

"It is the collection of techniques, methods or processes used in the production of goods or services or in the accomplishment of objectives, such as scientific investigation. It can be the knowledge of techniques, processes etc. The term technology transfer refers to the activity of movement of technology from one development to another. The process is said to be the completed successfully if the receiving unit and the transferee should constructively utilize the technology for the improvement of business[1].

World Intellectual property organization (WIPO)

Defines"A series of processes for sharing ideas, knowledge, technology and skills with another individual or institution (eg: a company, a university or a governmental body) and of acquisition by the others such ideas, knowledge, technologies and skills .

Goals of technology transfer[2]

It is to transfer product and process knowledge bet ween and manufacturing, and within or between manufacturing sites to achieve product realization. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach, and ongoing continual improvement.

Reasons to participate receiver in the process of TT[3]

The main reason for a receiver is to get access to new, helpful technology for production. Such access helps to decrease the time and cost of developing the products.

To improve the general skill level of employees.

It includes for a broader distribution area and new business opportunities.

For similar enterprises, joining hands with well-known multi-national companies can also bring reputational benefits.

Popular Technology Transfer Models[4]

Since the early 1970s, considering 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. Both qualitative and quantitative models have been proposed. Jagoda (2007) points out that, "Qualitative models often have as their objective the delineation of activities involved in managing TT and the elicitation of factors and issues that can influence the success and/or effectiveness of TT. Quantitative models, on the other hand, aim at quantifying parameters of significance in TT and analyzing them with a view towards minimizing goal incompatibility between the transferors and transferees of technology." In this paper, emphasis will be on the qualitative models. The mathematics involved in the quantitative models will not be elaborated upon and only their major findings will be presented.

A Brief Overview of Some Qualitative TT Models

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The Bar-Zakay Model: Bar-Zakay (1971) developed a rather comprehensive TT model based on a project management approach. He divided the TT process into the Search, Adaptation, Implementation, and Maintenance stages. He depicted the activities, milestones, and decision points (go or no-go) in each of these stages as shown in Figure 1. The upper half of the figure delineates the activities and requirements of the transferor (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 both the transferor and transferee acquiring skills to undertake technological forecasting, long-range planning, and gathering of project-related intelligence 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 al truistic 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. Jagoda points out that, "The model has 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. It was also an era when government controls were instrumental 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" right through 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, mistakes corrected, or even the project terminated at any point in time.

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:

Manufacturing proposal and planning to arrive at decisions regarding location and preparing a business case including good resource assessments.

Deciding the product design technologies to be transferred.

Specifying details of the plant to be designed to produce the product and other aspects related to construction and infrastructure development.

Plant construction and production start-up.

Adapting the process and product if needed and strengthening production systems to suit local conditions.

Improving the product technology transferred using local skills.

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 the technology 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 improve both product and process technology. This serves to emphasize the fact that technology transfer does not stop with commencement of production and unless there is a mechanism to foster assimilation the project cannot 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 and implementation 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, the Technology transfer cannot be said to have been successful.

The Dahlman and Westphal Model

Dahlman and Westphal (1981) carried out considerable work in the Republic of Korea and, based on their experience in rapidly industrializing countries during the 1980s, in the 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 analysis to 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 core technology to be transferred.

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 to make the transfer effective.

Carry out the selection of suppliers for equipment and subcontracting services to assemble the plant and 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 operational problems 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 emphasis on transferee involvement at all stages of the TT project. Its major weakness is that it assumes that the transferee will have access to high-level engineering skills. This may not be true in many developing countries. It also pays very little attention to negotiation and post-implementation assimilation initiatives.

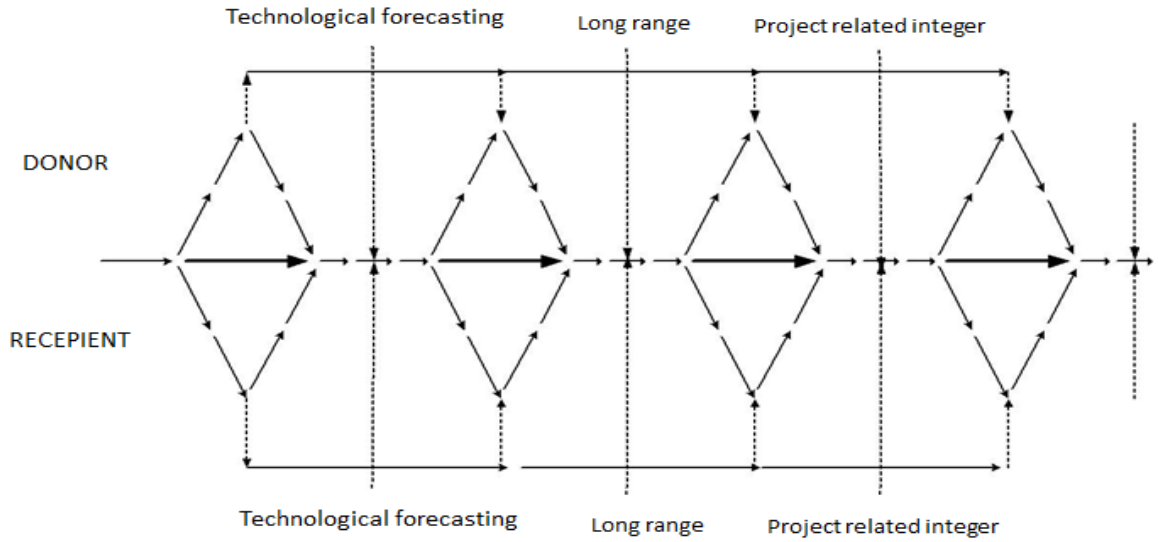

Figure 1: The Bar-Zakay model of technology transfer

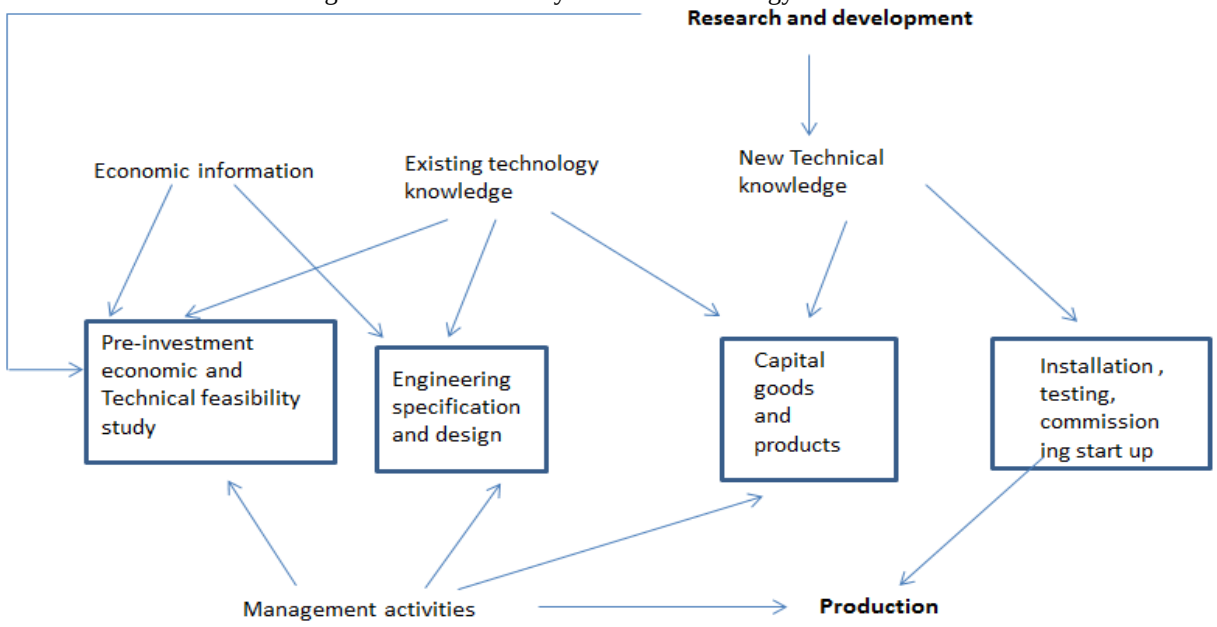

Figure 2: The Five-phase model of international technology transfer

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 projects often 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 management skills without which the TT process cannot be managed effectively.

The Schlie, Radnor, and Wad Model

Schlie (1987) proposes a simple, generic model that delineates seven elements that can influence the planning, implementation, and eventual success of any TT project. These seven elements are listed below.

The transferor, which is the entity selling the technology to the recipient.

The transferee, which is the entity buying the technology.

The technology that is being transferred.

The transfer mechanism that has been chosen to transfer the chosen technology.

The transferor environment which 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 out ward), stability, attitude and commitment to the transfer project, and operating policies.

The transferee environment which 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.

The greater environment which is that 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 TT project. The seven elements of this model are valid even in today's business setting. The way that they manifest themselves can however change with time. The weakness of this model is that it offers no guidelines as to what a transferee should do. The valuable lessons that emerge from this model are as follows:

The many changes that have taken place and are taking place in the global business setting today have made it imperative for managers of technology to gain good insights into the transferee environment, transferor environment, and the greater environment when planning and implementing a TT project.

The choice of the technology transfer mechanism should be based on a sophisticated understanding of the other six elements.

The Chantramonklasri Model

The Dahlman and Westphal Model has been further improved by Chantramonklasri (1990 who proposes a five phase model as shown in Figure 2

The five phases of this model are as follows:

Carrying out a pre-investment and feasibility study

Developing engineering specifications and design based on the feasibility study

Commence capital goods production based on the engineering specifications and designs that have been developed.

Commissioning and start-u including comprehensive of the workforce

Commence commercial production

While the first two phases of this model are valid it is not clear whether the required capital goods can be produced within the transferee setting unless the transfer arrangement also includes the transfer of technology needed to manufacture these. While this may be valid in large, technologically advanced countries such as China and India, it may not be so in other smaller developing countries. As in the Dahlman and Westphal Model the negotiation and assimilation elements are missing. The lessons that maybe learnt in this case are similar to those of the Dahlman and Westphal Model.

Other Qualitative Models of Technology Transfer

There are several other models that have been developed. However, due to limitations of space these will only be described briefly.

Lee (1988) has developed a longitudinal model of technology transfer based on a study of developing and rapidly industrializing countries. They point out that transferee firm need to put in place strategies to be able to go through the stages of acquisition, assimilation, and eventual improvement. As the firm advances technologically, it needs to choose appropriate mechanisms of transfer, depending on the stage of the life cycle of the technology and their own technological capability profile. They also note that the mechanisms chosen by the transferor to transfer technology will depend on the relative newness of the technology, its strategic importance to the transferor firm, and the level of intellectual property protection needed.

Reddy and Zhao (1990), in a model similar to that of Schlie (1987) state that any international technology transfer (ITT) project should examine three main components, which they refer to as the home country component, host-country component, and transaction component. The home country is that of the transferor and the host country is that of the transferee. The home-country component involves an examination of issues such as home-country government policies on technology transfer (restrictions etc.), the role and strategy of transferring firms from a foreign direct investment point of view, the nature and importance of technology to be transferred, and the firm's global R&D investment strategy. The host country component involves issues such as host-country government policies related to foreign investment and technology transfer, the relative suitability of the technology being considered for transfer, the technological capability of the transferee and the scope for upgrading, mechanisms of transfer being considered, and the scope for assimilation of the transferred technology. The transaction component consists of important business issues such as the pricing of technology, intellectual property protection, payment modalities, potential conflicts, and measures for ensuring effective transfer.

Keller and Chinta (1990) argue that effective technology transfer would be determined by the extent to which the transferor and transferee manage the barriers that impede transfer and strengthen initiatives that facilitate it. The facilitating initiatives refer to the willingness of the partners to adapt their respective strategic and operational postures to ensure a "win-win" outcome. The barriers could be political, legal, social, cultural, economic, and technological. They also stress the importance of selecting the correct mechanism to transfer the technology.

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

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

Establishing market-place requirements

Identifying technology solutions

Classifying the identified technology solutions

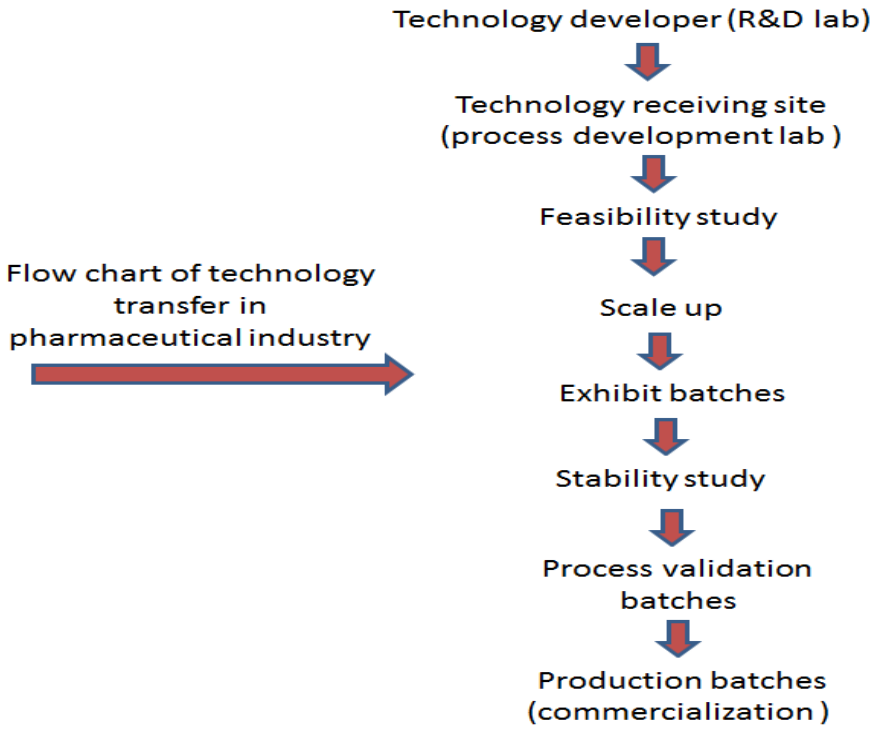

Figure 3: Flow chart of technology transfer in pharmaceutical industry

Establishing sources from where the desired technology could be acquired

Finalizing the technology-acquisition decision

This model stops with the technology acquisition decision. Its major lesson is that it stresses the importance of establishing the need for a technology transfer project and the need for identifying multiple sources of technology for enabling a better choice of transferor.

Bozeman (2000) has proposed a contingent effectiveness model of technology transfer. While the emphasis is on technology transfer from universities and government laboratories to industry, the model is also relevant to inter-firm technology transfer. In this model, the key elements of the transfer process are:

The transfer agent (the transferor)

The transfer mechanism

The transfer object (the content and form of the technology being transferred)

The transfer recipient (the transferee)

The demand environment (market and non-market factors vis-à-vis the need for the technology).

This model also stresses importance of establishing the need for a technology transfer project and the need for identifying multiple sources of technology for enabling a better choice of transferor. Six "out-the-door" measures are proposed. These are market impact, economic development, political benefits, opportunity costs, and development of scientific and human capital as a result of the transfer. The importance of impact assessment is a valuable lesson that this model imparts.

A Brief Overview of Some Quantitative TT Models

The literature is sparse when it comes to quantitative models of technology transfer. Some of the more important models are described briefly. For the sake of brevity, the mathematics has been left out and the interested reader may wish to refer to the original publications. Perhaps, the earliest quantitative model is due to Sharif and Haq (1980). This model proposes 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. From a practical point of view, a potential transferor at the firm level may not be willing to easily divulge information that could enable an assessment of the PTD. The greatest value of the model is that it draws attention to the need for incorporating the concept of a PTD in deciding the transferor.

Raz (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. They argues that this type of analysis would enable technology leaders to develop clear policies, based on considerations of competitiveness, security, and other related issues, when entering into technology transfer agreements.

Using an econometric model**,** Klein and Lim (1997) have studied the technology gap between the general machinery and electrical and electronic industries of Korea and Japan. Their findings suggest 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. This model thus emphasizes, based on empirical evidence, the need for post-implementation activities that facilitate assimilation and modification of the transferred technology. It also clearly delineates the need for a firm, as it grows technologically, to link its technology transfer activities with internal R&D. It may be said that the main contribution of the quantitative models is their emphasis on the need for partners in technology transfer projects to develop skills to be able to use formal, analytical approaches that can generate needed information for better technology transfer planning. An examination of the models of technology transfer shows that there are several valuable lessons that they convey. These are summarized below.

It is important to expend comprehensive analytical effort in establishing the need for a technology transfer project prior to the commencement of a TT project.

A TT project should not be commenced without a careful feasibility study since such projects often require heavy resource commitments.

A process approach must be adopted in planning and implementing TT projects and to ensure effective technology transfer there is a need to comprehensively examine the entire process from "technology search" right through to "post-implementation" activities.

The many changes that have taken place and are taking place in the global business setting today have made it imperative for managers of technology to gain good insights into the transferee environment, transferor environment, and the greater environment when planning and implementing a TT project.

Multiple sources of technology must be identified to enable a good choice of transferor.

The transferee must be involved right from the beginning in the planning and implementation of a TT project.

It is important for transferees to develop sound engineering and project management skills without This the technology transfer process cannot be managed effectively.

Partners in TT projects need to develop skills to be able to use formal, analytical approaches that can generate needed information for better technology transfer planning.

It is important to have milestones and decision points so that activities can be strengthened, mistakes corrected, or even the project terminated at any point in time.

The mechanisms chosen by a transferor to transfer technology will depend on the transferor and transferee setting, the technological capability of the transferee, the relative newness of the technology, its strategic importance to the transferor firm, and the level of intellectual property protection needed.

As a transferee firm advances technologically, it needs to choose appropriate mechanisms of transfer, depending on the stage of the life cycle of the technology and its own technological capability profile.

A technology transfer project does not end with commencement of production. Unless explicit measures are in place to ensure assimilation of the transferred technology the technology transfer cannot be said to have been successful.

The success of a technology transfer project would be determined by the extent to which the

Transferor and transferee manage the barriers that impede transfer and strengthen initiatives that facilitate it. However, what may also be noted is that there is no model that tries to capture all of these important considerations. An eclectic model that presents all this wisdom in a process-oriented approach would be very useful to managers of technology transfer project. Such a model must also have the capacity to address many of the problems faced by firms, especially small and medium enterprises (SMEs), when planning and implementing technology transfer. The next part will first present a summary of common problems faced by SMEs in planning and implementing technology transfer and then propose an eclectic, process model called, "the Life-cycle Approach for Planning and Implementing Technology Transfer" that tries to incorporate the Wisdom of the models discussed. It is envisaged that the adoption of this process model will enable SMEs to manage the common problems they face in planning and implementing TT projects.

Steps in technology transfer[5]

The quality of design will be almost completed in phase II clinical study. Various standards for manufacturing and test will be established in process of reviewing factory production and phase III study to realize the quality of design, if design will be verified in various validation studies will be upgraded to be the quality of product and the actual production will be started. Technology transfer consists to action taken in these flows of development to realize through the quality as designed during the manufacture. Even if the production starts, the technology transfer will take place in process such as changes in manufacturing places. The processes are classified into the three categories**:**

Research Phase

Development Phase

Production Phase

Research Phase

Design of method and selection of excipients by R&D

Selection of materials and design of procedures is development by R&D on the basis of innovator product characteristics. Compatibility different studies and stability studies will be done for this.

The design-to-design properties and functions of drug products corresponds to such as elimination of adverse reaction, improvement of efficacy, assurance of stability based on various data such as chemical and physical properties, efficacy, stability and safety obtained from preclinical studies. Quality design for a drug substance is used to determine starting materials their paths and basic specification of drug.

Identification of specification and quality by R&D

Quality product which is developed should meet the specification of innovator products for this different stability studies are carried out for innovator product and for product which is to be manufactured.

Development Phase (Technology transfer from R&D to production)

R&D provides technology transfer dossier (TTD) document to product development laboratory which contains all information of formulation and drug product as given below *Technology Transfer Dossier (TTD)*TTD contained all the information of drug product as given below:

Master formula card (MFC)
Master Packaging Card (MPC)
Master formula
Standard Test Procedures
Specifications
Development report
Packaging development report

Master formula card (MFC)

MFC included Product name along with its Strength, Generic name, MFC number, Page number, Effective date, shelf life, market, packaging details, storage conditions, precautions for personnel safety as well as for the product safety. Ingredients details with pharmacopoeial status along with the specifications numbers, brand names / grades along with approved vendors label claim and a brief manufacturing detail.

Master packaging card

It gives information about packaging type, material use for packaging, stability profile of packaging and shelf life of packaging.

Master formula

It describes formulation order and manufacturing instruction. Formulation order and manufacturing instruction gives idea of process order, environment condition required and manufacturing instruction for dosage form development.

Specification and standard test procedure (STPs)

It helps to know active ingredients and excipients profiles, in process parameter and specification, product release specification and finished product detail.

Research for factory production

To manufacture drugs with qualities as designed, it is required to establish appropriate quality control method and manufacturing method, after detecting variability factors to secure stable quality in the scale up validation that is performed to realize factory production of drug designed on the basis of result from small scale experiments.

Consistency between quality and specification

When product specification is established on the basis of the quality of product determined in the above, it is required to verify that the specification adequately specifies the product quality. In short, the consistency between quality and specification is to ensure in the products specification that the quality predetermined in the quality design is assured as the manufacture quality and the product satisfies the quality of design.

Assurance of consistency through development and manufacturing

To make developed product have indications as predetermined in clinical phases, quality of design should be reproducible as the quality of product (assurance of consistency). For this purpose, transferring party in charge of development should fully understand what kind of technical information is required by the transferred party in charge of manufacturing and should establish an appropriate evaluation method to determine whether a drug to be manufactured meets the quality of design

Technology transfer from R&D to production

Transfer of the technical information is necessary to realize manufacturing formula and actual production facility. Technical information to be transfer should be compiled as R&D report.

Production Phase

Validation studies

Production is implemented after various validation studies verify that, it is able to consistently manufacture product based on transferred manufacturing formula with a higher degree of stability. Research and development department transferring technology should take responsibility for validation such as performance qualification, cleaning validation and process validation unique to subject drugs.

Scale-up

Scale up followed after getting all information from R&D. It involved the transfer of technology and the transfer of knowledge. From sifting to film coating each process had its own set of challenges. The development of robust formulation and process through the use of Design of Experiments (DoE) as well as understanding the critical v/s non-critical parameters for each operation were be major determining factors for success v/s failure on scale-up. The following chapter focused on the same of the scale-up issues and considerations for several unit operations that may be utilized during the manufacture of solid dosage forms. Full scale commercialization includes: Active Pharmaceutical Ingredient(API), Drug product (dosage form or delivery system), analytical methods.

Considerations of different parameters for scale-up

Before starting scale-up, we also considered different parameters that should be optimum for successful technology transfer. These were: Flexibility, Cost, Dependability, Innovation and Product Quality. It was important to realize that good communication was critical for formulation and process transfer to be successful.

Selection of method

The method for batch fabrication was selected on the basis of data given from R&D. Granulation, Blending, compression and coatings are critical parameters for technology transfer. Technical information of developed products is obtained from data of a limited amount of batches. Various standards have been established from the limited data and quality evaluation method established in development phase is not always sufficient for factory production. It is highly desired to feedback and accumulates technical information obtained from repeated production. In addition, it is important to appropriately modify various standards established before based on this information. Accountability and responsibility for design and manufacturing should be executed.

Technology transfer documentation

Technology transfer documentation is generally considered as document indicating content 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 the duty of quality assurance department to check and approve the documentation for all processes of technology transfer.

Development report

The ultimate goal for successful technology transfer is to have documented evidences. The development report contains data of pharmaceutical development of new drug substances and drug product at stages from early development phase of finale application of approval, information of raw materials and components, rational for dosage form and formula designs and design of manufacturing methods, change in histories of important processes and control parameters, stability profile, specification and test methods of drug substances, intermediates, drug products, raw materials, which also includes validity of specification range of important tests such as contents impurities and dissolution, rational for selection of test methods, reagents and columns, and traceability of raw data of those information. This report contained the method of development as well as process development. Process development and commercial production were on critical path because of compressed time-to market expectations.

Packaging development report

This information provided details about packaging development to the concerned technology transfer person for executing the function.

Technology transfer plan

The technology transfer plan is to describe items and content of technology to be transferred and detailed procedure of individual transfer and transfer schedule, and to establish judgement 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.

CONCLUSION

In pharmaceutical industry, technology transfer is very important for the better growth of the firm by setting business, interest in the profitable exploitation, through technology transfer, the knowledge increases by transferring the technology between department inside a firm and firm to firm (small scale to large scale). Successful transfer needs a good relationship between transfer and receiver. It is a continuous information exchange between both the parties to maintain the product manufacturing.

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