

Translation and Commercialization of Pharmaceutical scientific Innovations: An Overview

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ABSTRACT

Economic and social transformation of a country depends on adopting advanced technology. The rightful usage of the later leads to a significant improvement in quality of production, export efficacy, and ultimately results in improving living standards of the people. Generally, scientific innovations are converted into technology helps in every area. The promise of technology transfer is recognized as a key consideration for the present globalized world irrespective of the countries with different income strata. The process of technology transfer in the field of medicine and pharmaceuticals helps to face the crucial challenges and leads phenomenal improvement in the field of global health. This can create necessary conditions for global economic growth and poverty reduction. Most of the research based pharmaceutical industries engaged in unique type of technology transfer which are the part of today's business practice. For the authorities responsible for public health policy making, technology transfer in medicines and pharmaceuticals is of major importance in order to upgrade the public health. To contribute to these discussions and with a view to share the knowledge, we have attempted to narrate the various steps involved in pharmaceutical technology transfers.

Key words: Technology transfer, Economy, Research and development, Global health.

INTRODUCTION

Technology transfer (TT) is a process, which includes mutual exchange of scientific findings from one organization to another with the intention of developing new products such as medicines, educational tools, electronic devices, safety equipment and health services for the better public use.[1,2] Pharmaceutical TT is helpful, for example, to develop new drug delivery systems with improved efficiency, maintains quality of product and helps to achieve standardized process that facilitates cost effective production.[3,4] Successful results of scientific research are generally utilized to develop practical applications with an intention to produce useful products for society and this process is well recognized as technology transfer (TT). Thus, TT is anything that facilitates to yield economic and social

benefits to the people from scientific innovation. Due to its complexity TT is an expensive and long term process of R&D derived from basic research, applied research and commercial development. TT process generates new products, services, jobs and has impact on the economic well-being of a society either directly or indirectly. It is almost proved and accepted that TT affects the economic status of countries that already have promoted it through their active innovative systems. The success of TT in western countries such as the United States is well attracting and influencing to create interest from several other countries to change or modify their laws/policies which can help them in better management and transfer of successful results of innovations. A key example is three tier R&D process based on TT, which can be found in the invention and development of drugs in pharmaceutical industry. For them, TT helps for successful progress from drug discovery through product development, clinical trials and full-scale commercialization of a product. Thus, TT is a process of making availability of advanced innovations from one party to another commercial partner to exploit

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the technology in enhancing the value of their product. TT is a legal as well as an economic concept, follows an investment climate which is determined more by economic considerations such as market nature, business competitiveness and factors of production parameters than anything else. To provide better global health facilities, as health is a fundamental human right of the common public, there is an obvious need to intensify increase in the resources required for health care R&D. However, TT has become a key driver of health care R&D. The importance of pharmaceutical TT for developing countries with respect to health and economic improvement has been recognized as the highest priority. This paper was prepared with the aim to discuss trends or advancements of TT since its historical conception. An attempt was also made to initiate the awareness about this novel policy which is considered most useful for global health improvement.

Conceptual origin and historical milestones:

Concept of TT is not a new thing as per many researchers. The conceptual origin of TT can be traced back to the pre-history of human species where it largely involved tacit knowledge which is evolutionary prior to explicit knowledge.[5,6] Until 3000 BC there were no written languages reported to be utilized in the TT process. And during this period TT had mainly occurred through languages, which were supplemented by equations and diagrams constituted as the major means of explicit transfer of technological knowledge. TT process was explicitly done in friendly encounters mainly through the spoken language and gestures without the support of any written literatures. However, much of pre-historic TT occurred between people when they assimilated superior agricultural technologies and eliminated those which could not reproduce as rapidly.[7] It was traced from the Neolithic times to the role that Arabs played in transferring technologies from East to West and the transfer of English textile expertise to the American textile industry in the eighteenth and nineteenth centuries.[8] In the

eighteenth Century, France managed to import English workers through industrial espionage, despite the English law preventing knowledge migration. American textile industry became successful in the eighteenth and nineteenth centuries through transfer of knowledge and expertise by the English textile industry. [9,10] Few TT models were developed after the World War II to govern the implementation of TT activities and their application to market place.[11,12] Four important TT models that developed over the period can be named as the appropriability model, dissemination model, knowledge utilization model, and communication model. In studies carried out in 1970 “the economic international trade approach” was adopted in developing a linear model.[13] In the 1980s research on TT emphasized on the effectiveness of the specific technology being transferred which in general was within a broader context of economic development.[14] Strategic management researchers have further contributed to the development of TT frameworks based on knowledge-based view (KBV) and organizational learning (OL) perspectives, as these were found to have quite similar dimensions such as outcomes, processes, barriers and facilitators. These perspectives have significantly contributed to the expansion of TT models since literatures from both KBV and OL perspectives appear to subsume most of the contributions.[15] The development, transfer of knowledge and technology has been and will continue to be critical to the success of pharmaceutical industry. World Health Organization (WHO) has framed global strategy and plan of action on public health, innovation and intellectual property rights, accordingly importance of TT for medicines is recognized with an agreed action to promote TT in developing countries.

Benefits of technology transfer:

TT is one means by which developing countries can accelerate the acquisition of knowledge, experience and equipment related to advanced, innovative industrial products and processes. It has been

credited with the potential to develop improved health care products, increase the reliability of supply and decrease reliance on imports, raise the competence of local workforce and reverse the “brain drain” from developing countries, by increasing local employment opportunities. Over and above the beneficial impact on economic and social development normally credited to technology transfer. TT is also useful in improvement of the health of people of the recipient country by increasing access to innovative medicines. Thus, TT is essential for economic development and can help the pharmaceutical industries in the following ways.

- TT establishes innovative research and development activity. The needful information can be elucidated from research and development activities. That information can be further transferred to actual production.[16] Ultimate goal for successful TT is to have documented evidence that the manufacturing process for drug substances/drug products is robust, effective, complying with the registered specifications and Good Manufacturing Practice requirements.[17]
- TT extends the benefits of R&D to the society especially in developing countries. Research is carried out in laboratories on an experimental scale in small batches before it could be produced for commercial use at large batches. TT is important for such research results to materialize on a larger scale for commercialization especially in the case of products which are being developed. TT includes not only the patentable aspects of production but also includes the business processes, such as knowledge and skills.[18,19]
- TT provides an opportunity to reduce cost on drug discovery and development, thus major pharmaceutical companies look for technology transfer opportunities to reduce the risk, cost and rate of failure.
- TT elucidates necessary information of existing product between various manufacturing places; to develop new, more effective compounds, delivery

systems, and medical devices, to ensure safety, purity, and effectiveness of drug products.

- TT helps in compliant and effective commercialization to bring new, more effective products to market faster, to interpret the consistent good manufacturing practice (GMP) regulations, to adhere to all applicable regulations and guidelines, to establish cost-effective production/ distribution and achieve superior return on investment to shareholders as well as stakeholders.
- TT provides safe and effective treatments to patients and achieves affordable healthcare cost.

Need for the technology transfer [20, 21] :

An organization develop the technology comes forward to transfer it to the other organization instead of self exploitation for numerous reasons. Technology is transferred between two parties. Some of the reasons why TT is done are as follows.

- **To establish alliance with the partners for clinical and regulatory studies.**

The original inventor of technology have resources only to conduct early-stage research activities such as animal and toxicology study, but doesn't have the resources to take technology through its clinical and regulatory phases must collaborate with another organization to complete the entire phases which are required to launch the product commercially.

- **To establish alliance with partners having manufacturing capability.**

Here, the developer of technology has small scale manufacturing equipments and does not have extended facility for large scale manufacturing. Under such circumstances the developer of the technology must establish the alliance with a partner belonging to another organization that does have that capability. These kinds of alliances are some time also named by the term ‘contract manufacturing’.

- **To establish alliance with partners having marketing and distribution capability.**

Here, the organization is able to develop the technology till getting regulatory approvals and product registration for sale but it is not capable to

distribute its product successfully for marketing and must collaborate with the organization that does have that capability.

• **To establish multiple exploitation partnership**

If the technology is developed with multiple intentions such as diagnostic and therapeutic applications, the developer may like to establish partnerships with different organizations to exploit the technology for different applications so that he can create multiple streams of income.

• **To establish collaboration between research institutes and commercial organizations.**

Most of research organizations/universities develop the technology, but do not have capability of exploitation required to collaborate with commercial organization have it. This kind of industry-institutional collaborations can bring many better pharmaceutical products in to the market.

Various stages of new drug development and TT [16, 20]:

TT is not a single stage process; it involves the transformation of a pharmaceutical prototype into a

successful product and requires the cooperation and active involvement of many individuals. The classic view of a flow from basic to applied technology is a great over simplification sometimes, for instance, problems or insights arising at the production level give rise to new ideas that contribute to fundamental basic advance. During development of a formulation, care should be taken to understand operational procedure used, critical and non-critical parameters of each operation, production environment, equipment and excipient availability, which should be taken into account during the early phases of development of formulation, so that successful scale up can be carried out. Appropriate care during TT is important to enhance drug quality as developed by R&D in final formulation as well as to assure quality for predetermined period of time. The various stages involved in new drug development are depicted in the below figure and stages of TT are given below:

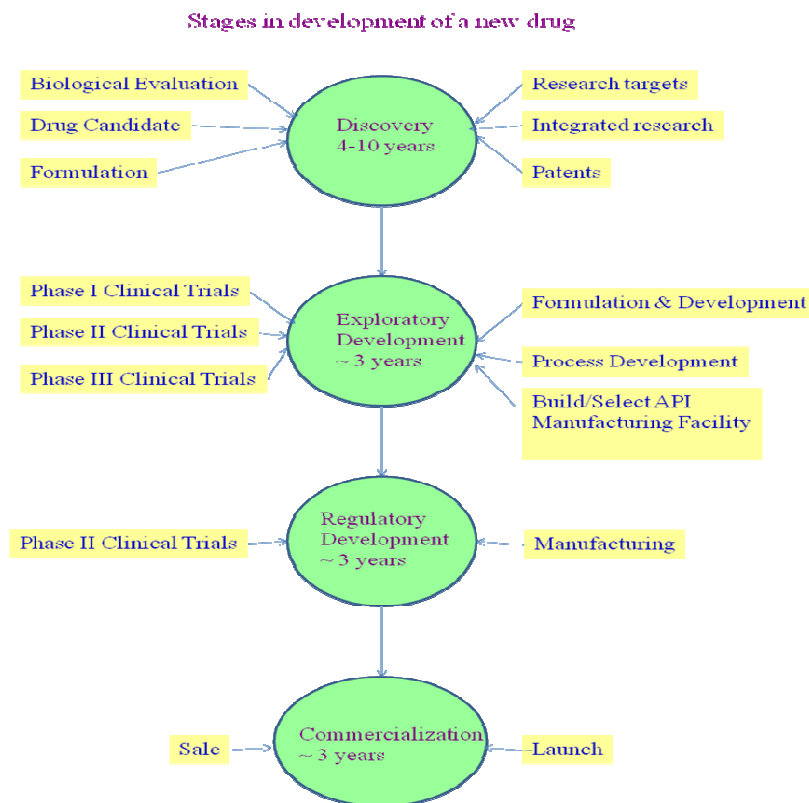


Figure 1: Stages involved in the development of a new medicine

- **Design of procedure and selection of excipients**

Prior to start with further steps, it is very essential task to design the proper procedure and select the right excipients. To begin, R & D does some exercise to select the excipient materials required for the proposed production and design the correct procedure based on innovator product characteristics by carrying out different tests and compatibility studies.

- **Identification of specification and quality**

As innovator products should meet certain quality specifications, R & D conducts stability studies for innovator product and for product which is to be manufactured.

- **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 processes and drug product that include master formula record (MFR) contains product name along with its strength, generic name, MFR number, page number, shelf life and intended market. Master packaging record gives information about type of packaging, material used for packaging, stability profile, and shelf life of packaging materials. Specifications and standard test procedure (STPs) helps to know active ingredients, excipients profiles, critical in-process parameters, specifications, and finished product details. The flow chart of TT can be depicted as below:

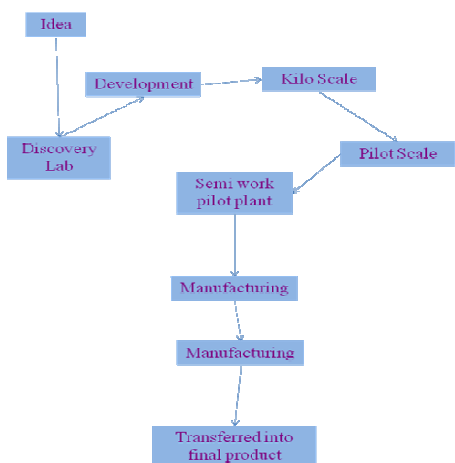


Figure 2: The flow chart of technology transfer

Different ways of technology transfer:

Transfer of technology usually happens in different ways between government laboratories to private sectors, between the private sectors of the same country, between academic and private sectors, between academy, government and private sectors of different country.

- **Between government laboratories and private sectors**

Government laboratories usually avail plenty of research grants under various heads from statutory and other funding agencies. The technology developed by government laboratories reach the private sectors through TT. The main advantage of this type of TT is that there is no added financial burden on government laboratories, because they get additional financial support and funds from government.

- **Between private sectors of the same country**

TT takes place between two private sector organizations of the same country mainly in the situations such as lack of commercialization ability, financial constraints, inadequate knowledge of regulatory requirements, and lack of sufficient human resources. Here, the developer of technology gets money against the transfer of technology.

- **Between academia and private organizations**

Such TT takes place between academic/research institutes and private organizations. The academic/research institutes develop the basic technology that can be further developed and commercialized. Many academic/research institutes are actively involved in research and significantly contribute to the development of technology. The basic technology of drug discovery, developed by research institutions, is absorbed for commercialization by private organizations.

- **Between private organizations of different countries**

TT takes place between private organizations of different countries and it is particularly beneficial for organizations that belong to developing countries in strengthening of their economic status. The developed

country would get incentives for development and the absorber country can commercialize the technology, thereby it can build its economic status.

- **Between government, academics and private organizations**

In this process, government can act as a facilitator in developing the technology, the technology developed by the academic institutions can then be transferred to industry.

Types of Technology Transfer Models:

Traditional Models

- **The Appropriability Model**

This model was developed between 1945-1950s, which suggests that no special efforts are being infused for the sale of goods or quality technologies, which sell themselves due to their better attributes.[22] Also this model put light on the need of quality research, highlights the importance of competitive market pressure in gaining TT and promoting the use of research findings.[11,12,22] As per this model, TT happens only when a customer is available as a user or market creates a new user. According to this model, once a technology has been developed as an end product of research process, it is made available as technical report through professional journals which implicitly attract the user to establish communication with technology developers. Moreover, earlier reports have revealed that technologies thus developed without being reported or published have never gained importance by the users.[23]

- **The Dissemination Model**

This model was developed in between 1960-1970s and subsequently popularized.[24,25] The dissemination approach describes about the significance of technology and innovations to be introduced to the customers by the experts[26] and presumes that the expertise professionals share the knowledge with the willing user. Once the communications are established, the new technology will move like water through a pipe line, once the channel is opened to the user. The main drawback of

this model is its often unilateral communication characteristics with non participation of users.

- **The Knowledge Utilization Model**

The knowledge utilization model was derived in late 1980s and has a significant influence on TT literature.[27,28] This model stresses on the cardinal role of interpersonal communication between the technology developers/researchers and users, also on the importance of organizational barriers or facilitators of TT. This approach indicates an evolutionary step which describes on how to organize scientific knowledge for proper use in the technology user's setting.[29,30] The important assumption of this model is that technology drives directly from one party to another in a single direction, unilaterally from the experts to the users and tries to ease the complexities involved in the TT process.[31] All the aforementioned models still exhibit the linear bias and show limitations in terms of their narrow applications in TT.[12]

The Communication Model

This model has been considered to be the alternative model to previous three models [26,32,33] and works on perceiving TT as communication and information flow process with full exchange and sharing of meanings. According to this model, the technology is an on-going process, which consists either two-way or nonlinear interaction by continuous and simultaneous sharing of ideas among the participants. The advantage of two way interactive communication is that it overcomes the barriers existing between the developers and the end users.[33,34] With all of its appreciations as highlighted by this model it failed to explain the intricacies with respect to the issues such as knowledge transferred through collaborative learning, the subjectivity of knowledge, the need for contextual adaptation, assumption, and beliefs that takes on more acute proportions with soft or disembodied technologies.[12]

Advanced Models Developed After 1990s

A thorough review of literature reveals that apart from the above traditional models many researchers

have attempted to develop new TT models distinguishing from the traditional models. The later models developed by researchers attempted to address the limitations that arise from the traditional models in terms of the application in contemporary high-tech industries. [35] Several models developed after 1990s have emphasized on the important elements of communication between the technology developer and the receiver or between different organizations, the different levels and the factors which influence TT process.

• Knowledge-Based View Related Models (KBV)

Kogut and Zander are among the first researchers who established the foundation for knowledge based theory of a firm when emphasizing the strategic importance of knowledge as a source of competitive advantage.[36] Their work is focused on the idea that role of firms in creation and transfer of knowledge within the organization is to do better than other market leaders. This view was further articulated and empirically tested to assert that the firms are efficient means by which knowledge is created and transferred. [37] A common understanding is developed by individuals and groups in a firm through repeated interaction to transfer knowledge from ideas into production and markets. As firms provide a normative territory to which members identify, costs of coordination, communication, and learning within firms are much lower which allow more knowledge to be shared and created within firms.

• Organization Learning Related Models (OL)

This model explains the ability of an organization about learning and focusing on the sources of knowledge. The model describes that an organization learns through hired individuals because of their specific competencies or knowledge which may be gained through on the job training or formal training. Learning is an individual phenomenon, which benefits the organization entirely through the individuals. OL should involve systemizing knowledge into its practices, processes, and procedures. When an individual fails to use knowledge or resign, it will still

remain with the organization. If an organization acquires or merges with other organization, OL occurs when the acquiring organization absorbs the acquired organization practices and procedures, or adds to its personnel the knowledge embodied in the acquired organization's processes and personnel.[38] A three-fold typology of organizational learning was developed which contain single-loop, double-loop and triple-loop learning.[39] Single-loop learning is described as the error detection and their appropriate corrections in order to allow an organization to change its methods and rules to improve what is being done within existing programs or policies. As a result, the organization achieves its current objective more efficiently. In addition to the error detection and correction, double-loop learning involves change of the value of existing theory-in-use of an organization. Triple-loop learning is "learning how to learn" and also a process how to execute single and double-loop learning. A three stage model of OL was also proposed based on the concept of knowledge acquisition, knowledge sharing and knowledge utilization. Knowledge acquisition refers to the development or creation of skills, insights, and relationship, whereas, knowledge sharing relates to the dissemination of knowledge that has been learned and knowledge utilization is the integration of learning to make it widely available; where it can be generalized to new environments. Knowledge and skill acquisition occur not only through acquisition but also through knowledge sharing and utilization.[40]

Anatomy/Channels of Pharmaceutical Technology Transfer[41]:

The transfer of pharmaceuticals technology occurs through many channels, all of which result in improving the economic capabilities of the recipient organization or an individual. What is transferred may be a physical object or pure knowledge. Following one definition, the following elements are identified:

• "Techno-ware"

This element comprises the transfer of some physical objects such as equipments needed for use in research

laboratories or equipment required for manufacture of pharmaceutical ingredients, or equipments essential for packaging of the final products.

- **“Human-ware”**

This includes transfer of skills and expertise in the form of human resources required for technology management and learning. This can be exemplified with conduct of a training course for researchers or general practitioners across the world.

- **“Info-ware”**

TT can also create positive spillover effects into associated industries and into the supporting public sector research infrastructure; all techniques related to knowledge, information and technology; in the form of a technology license.[42]

- **“Orga-ware”**

This includes transfer of organizational and procedural knowledge needed to operate a given technology relating to a chemical or biological compound, manufacturing of a particular drug product, evaluation and optimization of the procedures etc.

Role of Foreign Direct Investment (FDI) system on TT:

Foreign Direct Investment (FDI) is by far the main channel of TT, but other market mechanisms such as licensing agreements, royalties and joint ventures are necessary channels for transferring pharmaceutical technologies. Through regulation and investment, governments can help to create the right conditions for technology markets to function. The research-based pharmaceutical industry, like most other industries, is seeing the newly industrialized countries and other middle-income countries increasingly relying on TT to access advanced foreign technologies and grow their domestic capabilities. The research-based pharmaceutical industry's track record is proof that in the public health arena, the historical demarcation lines such as “North-South” are being replaced by more complex networks of TT. The above trend is not always shared by low income countries, and is therefore sometimes characterized by an

exposure to foreign technologies and weak absorptive capacity. This creates a particular challenge for pharmaceutical TT and means that those parts of the world least equipped to benefit today from TT are among those who need its products the most.

The Favorable Conditions for Pharmaceutical TT:

Paramount commercial opportunities are available for the private sector with respect to TT, but if the basic conditions are right, non-commercial reasons may also play a part. This is particularly true in advanced technology sectors, especially when this might provide an opportunity to open a market to a specific technology. Many countries are already well positioned in terms of pharmaceutical TTs. With respect to potential TT ventures for pharmaceutical and vaccine manufacturers a variety of factors are considered. Many of these are influenced by government policy decisions. However, the political stability and rule of law are prerequisites for all the investors. Research-based pharmaceutical companies are looking for in prospective recipient countries. For this purpose, eight critical factors are considered in terms of creating favorable conditions for pharmaceutical TTs, which are; a viable and accessible promising local market, political stability with good economic governance, clear development priorities and effective regulation, availability of skilled workforce and clear economic priorities, adequate capital markets, innovation-friendly environment with strong intellectual property rights (IPR) with effective enforcement, quality of the relationship between industry and government, proper access to information, adherence to high regulatory standards, and the extent they are able to work together effectively for long periods of time. The government has effective role in creating optimal enabling conditions to attract TT based on overall economic policy objectives of the country, and its willingness in this respect is a strong determinant of whether transfers will be directed towards their domestic industrial sector. Indeed today, some governments are taking an active role in encouraging

the TT. However, for low income countries, it is still difficult for their domestic industry to meet the above conditions and hence attract TT. In these cases, the role of government and international development institutions is greater and policy will play an important role in determining the potential for TT in the future.[43]

Role of Technology Transfer in the Improvement of Global Health:

Low and middle income countries can accelerate the acquisition of knowledge, experience and equipment related to advanced, innovative industrial products and processes. TT has been credited with the potential to improve the health, increase reliability of supply, decrease reliance on imports, and raise the competence of local workforce. Over and above the beneficial impact on economic and social development normally credited to TT. In the field of pharmaceuticals, TT can help to improve the health of people belonging to recipient country by increasing access to innovative medicines and vaccines. Research-based pharmaceutical companies, members of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), can make a unique contribution to improve global health through the innovative medicines that they develop. In addition, they have a strong track record of sustaining programs to improve the health of patients in low and middle income countries, by strengthening local healthcare capacity, by educating patients and by involving in R&D activities especially on the diseases of developing world. Many research-based pharmaceutical companies with their programs have built up a credible track record using TT in improvement of public health and country's ability to use innovative medicines, by strengthening the expertise of the local scientific and medical communities with the goal of improving the health infrastructure. The rewards to companies transferring pharmaceutical technology to emerging countries are often reputational as well as commercial. Global Strategy and Plan of Action on Public Health,

Innovation and Intellectual Property Rights of the World Health Organization (WHO) has recognized the importance of transferring technologies for medicines. An agreed action is to promote transfer of technology and creation of health products in developing countries through identification of best practices, investment and capacity building provided by developed and developing countries where appropriate⁴⁴. While many newly industrialized countries and other middle-income countries are developing a strong experience and expecting the benefits that access to advanced foreign technologies and growing their domestic capabilities can bring; low income countries may not always be able to offer the preconditions required for successful uptake of TT. In these circumstances, following are the conditions based on IFPMA member companies' experience of TT: the governments can encourage TT by focusing on attracting technology for which there is already a demand from local companies, that which can help to increase the local market and/or reduce regulatory barriers. High income countries can help by giving experts to low and middle income countries for greater access to international standard setting bodies, which will help to increase individuals' technical expertise and familiarity with such standards. Public sector institutions can also increase technical and financial assistance to low and middle income countries to strengthen local technical competence.

CONCLUSION

Transformation of knowledge is in other words extension of existing knowledge and the creation of new knowledge. Thus, transformation is defined as the integration, application and leveraging of contributed knowledge, and the creation of new knowledge as a result of R&D activities. The cumulative commercialization of TT depends on the success of creation, sharing and implementation. This study contends that TT does not only require transmission of knowledge but also knowledge

absorption and use. Effective adoption of the technology, system, or management practices or all of them to the local environment is the key factor for the successful exploitation of an advantage of TT internationally. In this view, a significant amount of progress has been made towards achieving successful pharmaceutical technology transfer that can effectively help in improvement of global health. This review significantly contributes to the existing technology transfer literature by reviewing the historical evolution and development in addition to the comparative description on the traditional technology transfer models with newly developed models and could help to shape the direction of future strategies on technology transfer specifically for low and middle income countries.

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