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## Technology transfer in pharmaceutical industry

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### Abstract

In today's business setting, interest in the profitable exploitation of a firm's technological assets, through technology transfer, has intensified. Factors that have facilitated international technology transfer include globalisation of business, liberalisation of the economic regimes of many countries, and the impetus given to the protection of intellectual property after the formation of the World Trade Organization (WTO). These factors have collectively resulted in commercial transfer of technology becoming an important element of the international business setting. Experience over the decades has shown that the technology transfer process can be problematic and transferees often lack the skills to manage it effectively. While the literature is rich in terms of the coverage of the areas of concern it is sparse when it comes to possible approaches that can be taken to remedy these problems.

Appropriate technology transfer is both vital and critical to drug discovery and development for novel medicinal products and is also essential to upgrade drug quality intended during research and development and to finishing product during manufacturing as well as to assure constant quality transferred. Successful growth and commercialization of innovative technologies is always apprehensive with difficulties, multifaceted endeavour, and a range of development tools exist to uphold this activity, by far the most popular approach to directly supporting successful innovation is through technology transfer. To develop appropriate clinical good manufacturing practice facilities, specify and design specialized process equipment, finalize process details, and correctly determine scale-up parameters requires the integrated efforts of a highly skilful technology transfer team. Successful technology transfer requires carefully studying conditions like careful evaluation of ultimate manufacturing requirements early in research and development and the consequent improvement of robust developments that endure large-scale operation, the assembly of a detailed technology transfer document that provides manufacturing with both "know how" and "know why," and will serve as the basis for facilities and equipment design as well as operator training and standard operating procedure generation in successful manufacturing.

**Keywords:** Technology transfer, drug discovery, development, scale-up, small and medium enterprises and commercialization

### Introduction

#### What is technology transfer???

- Transfer of technology is defined as a "logical procedure that controls the transfer of any process together with its documentation and professional expertise between developments or between manufacture sites."
- Technology transfer is both integral and critical to the drug discovery and development process for new medical products.
- Technology transfer is helpful to develop dosage forms in various ways as it provides efficiency in process, maintains quality of product, helps to achieve standardized process which facilitates cost effective production. It is the process by which by an original innovator of technology makes it technology available to commercial partner that will exploit the technology.
- In pharmaceutical industry, "Technology transfer "refers to the processes of successful progress from drug discovery to product development, clinical trials and ultimately full scale commercialization.
- Technology transfer is important for such researcher to materialize on a larger scale for commercialization especially in the case of developing product. Technology transfer includes not only patentable aspects of production but also includes the business processes such as knowledge and skills.

#### Facts of technology transfer

The transfer of technology could happen in following ways:-

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- Government labs to private sector firms
- Between private sector firms of same country
- Between private sector firms of different country
- From academia to private sector firms

**Guidelines /importance of Technology transfer**

- To elucidate necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D.
- Demonstration of necessary information to technology transfer from research and development to actual manufacturing.
- To elucidate necessary information to transfer technology of existing products between various manufacturing places.
- To exemplify specific procedures and points of concern for smooth technology transfer. For the smooth manufacturing of commercialized products.

**Reason for technology transfer**

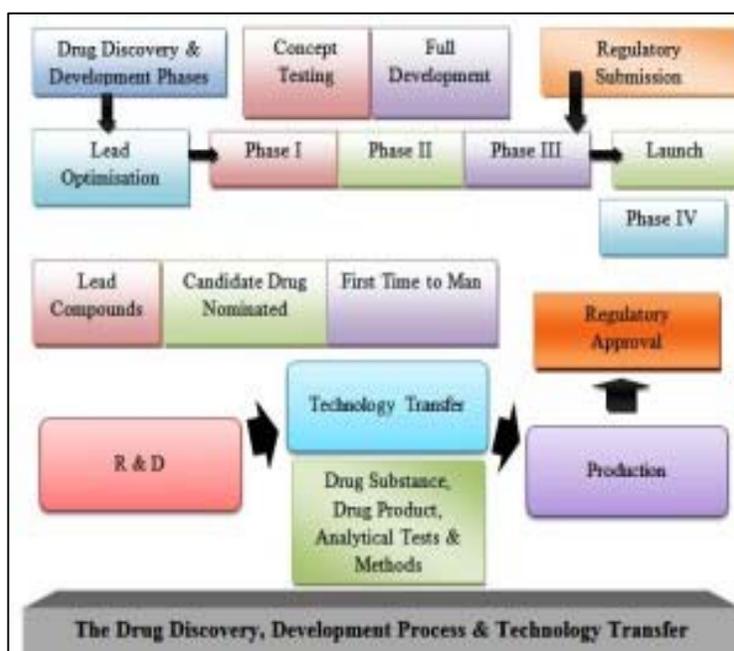
- Due to lack of manufacturing capacity:- The developer of technology may only have manufacturing equipment which is suitable for small scale operation, and must collaborate with another organization to do large scale manufacturing.
- Due to lack of marketing distribution and distribution capability

- Due to lack of resources to launch product commercially
- Forming alliances with partners
- Forming alliances with partners with marketing and distribution capability.
- Exploitation in a different field of application: - Each partner may have only half of the solution i.e. the developer of the technology might be capable of exploiting the technology itself in the field of diagnostic applications and may grant exploitation right to commercial partner for the exploitation of therapeutics application [36].

**Steps in Technology Transfer Process**

Technology Transfer is not a single way process. The development of new formulation goes through many stages. During development of a formulation, it is important to understand procedure of operations used, critical and noncritical 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 technology transfer 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 [9]. The processes are classified into the three categories:



**Fig.** Illustrates The Different Steps After The Drug Discovery, Different Phases Before Approval, And Different Kind Of Regulatory Approvals In The Launch Of New Medicinal Product In The Regulatory Country

- Research phase,
- Development Phase
- Production Phase.
- Research phase (Development of technology by R&D)

**1. Quality Design:** For drug products the quality design resembles to pharmaceuticals design to design properties and functions such as-

- Abolition of adverse reactions,

- Enhancement of efficacy,
- Assurance of stability during delivery and
- Data based on various data such as chemical and physical properties, efficacy, safety and stability obtained from preclinical studies.

For drug substance the quality design is to define starting materials and their reaction paths and basic specification of the drug.

## ➤ Development Phase

### 1. Research for factory production

For manufacturing drugs with qualities as designed, it is necessary to institute suitable quality control method and manufacturing method, after identifying unevenness factors to secure stability in the scale up (validation) that is executed to realize factory production of drug designed on the basis of result from small scale experiments.

### 2. Consistency between Quality and Specification

- When product specification is established on the basis of the quality of the product determined in the above, it is essential to validate that the specification adequately stipulates the product quality [12].
- Relations between upper and lower limits of manufacturing formula (composition and manufacturing methods) and upper and lower of control limits of the product specification should be fully understood, and the consistency between the product quality and specifications should be maintained.
- 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.

### 1. Assurance of consistency through development and manufacturing:

- For this purpose, the 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.
- For stable production of consistent products, it is fundamental to fully refer to information of similar products of the past maintained by the manufacturer when research for factory production is implemented.

### 2. Technology Transfer from R&D to Production:

R&D provides technology transfer dossier; TTD document to product development laboratory; PDL, which contains all information of formulation and drug product as given below:

- **Master formula card; MFC:** It includes product name along with its strength, generic name, MFC number, page number, effective date, shelf life and market.
- **Master packaging card:** It gives information about packaging type, material used for packaging, stability profile of packaging and shelf life of packaging.
- **Master formula:** It describes formulation order and manufacturing instructions. Formulation order and Manufacturing Instructions gives idea of process order, environment conditions required and manufacturing instructions for dosage form development.
- **Specifications and standard test procedure; STPs:** It helps to know active ingredients and excipients profile, in- process parameters and specifications, product release specification and finished product details.

## ➤ Production Phase

### 1. Validation & Production

- Production is implemented after various validation studies verify that it is able to stably product based on transferred manufacturing formula.

- While the manufacturing facility accepting technology is responsible for validation, the research and development department transferring technology should take responsibility for validation such as performance qualification; PQ, cleaning validation, and process validation; PV unique to subject drugs.

**Scale Up For Production:** Scale up involves the transfer of technology during small scale development of the product and processes. It is essential to consider the production environment and system during development of process<sup>10</sup>. Operators should concentrate on keeping these things in mind that their segment of the production process running smoothly if technology transfer is implemented thoughtfully. Effective technology transfer helps to provide process efficiency and maintain product quality.

### Feedback from Production and Technology Transfer of Marketed Product

- To accumulate technical information obtained from repeated production.
- The information of modify various standards.
- The improvement of process and products.
- The changes of specifications and methods.
- The technical information of reviewed and updated at regular intervals.
- Establish of adequate Feedback system.

**Exhibit Batches:** After taking scale up batches of the product, manufacturing of exhibit batches takes place. In case of exhibit, batch sizes are increased along with equipment's and their processes. This is done for filling purpose in regulatory agencies. The Purpose behind to run three consecutive batches are to shows process consistency, reproducibility and to demonstrate that the manufacturing process is under control throughout all the stages.

### Factors Influencing Technology Transfer

#### (A) Drivers for Technology Transfer [31, 32].

- **Good business and manufacturing practices:** The Company's success is primarily the result of its adoption of good business and manufacturing practices, particularly in the areas of product identification and formulation technology.
- **Potential for competitive pricing:** Balance cost to remain competitive by having higher private sector prices and very low public sector prices.
- **Strategic planning:** Create an enabling environment for vertical integration, with prospects for higher capacity utilization and eventual lowering of production costs.
- **Promising market scale and accessibility:** While it is not easy to define the market size or type that will make for viable economic production, it is generally the case that, the larger the country or geographic bloc, the greater the market potential and investment appeal.
- **Adherence to regulatory standards:** The pharmaceutical industry is one of the most heavily regulated, to ensure quality, safety and efficacy of its medicines and the well-being of patients. The ability to meet international regulatory standards, or at least those of the major markets, is a precondition for many technology transfer activities. Regulations and standards apply also in low- and middle-income countries. For example, governments require product registration and

data submissions to demonstrate quality, safety and efficacy.

- **Skilled workforce:** Human capital is an essential element of the technology transfer process. The successful absorption of technology or know-how in the recipient country and its translation into greater economic development hinges on the availability in the host country of an educated workforce with, for example, engineering and management skills.
- **Innovation- friendly environment with sound Intellectual Property Protection and Enforcement:** To successfully attract imported technology and to build the necessary preconditions for adapting imported technology, countries need a supportive environment that includes strong intellectual property protection and enforcement. Effective enforcement of any intellectual property laws and regulations already in force provides transparency and certainty for investors, licensees and customers. The level of intellectual property protection tends to be directly and positively linked to the rate of technology transfer.
- **Proper access to information or increased information exchange:** Where adequate intellectual property systems are in place, attention should be given to supporting access to information. This has a number of dimensions, from better documentation of available resources, to the longer-term issue of addressing the complexity of the global knowledge market. In the absence of effective systems for disseminating market-relevant information, technology-holders may find it difficult to identify precisely who is interested in purchasing their technology, while technology-demanders face a similar challenge in finding entities willing to transfer their technology.
- **Opportunities for contingency supply:** Multinational pharmaceutical companies are inclined to transfer technology to local manufacturers with the potential to receive when they foresee an inability to meet time scales and volume demand from large procurers.
- **Access to new machinery, training, know-how and business partnership:** This makes the prospect of technology transfer very desirable to local pharmaceutical manufacturers since the technology, equipment, etc. could be applied profitably beyond the initial purpose.

#### (B) Barriers of Technology Transfer <sup>[33, 34]</sup>.

- **Lack of awareness knowledge and efficiency:** Automation of manufacture processes to improve efficiency and lower costs.
- **Lack of government focus low market share:** Local producers face significant challenges in meeting International Quality Standards and capturing a critical market share. Greater market share would increase profitability
- **Web access and scientific publication:** Restricted access to scientific journals directed to massive complications for developing nation's scientists.
- **Cost of prequalification:** There is profit in meeting International Standards since it opens up the opportunity for trading across the entire world.
- **National security issues and restrictions on exports of particular technology:** International controls designed to protect national security and to prevent the proliferation of important technologies also restrict the flow of

technologies.

- **Inadequate funding in important areas and possible treaties:** There are areas of research of importance to the developing world that are being funded inadequately.
- **Labour issues:** The pharmaceutical sector demands relatively skilled labour. High labour turnover and absenteeism owing to unattractive conditions of service is negative contributor.

#### (C) Approaches to overcome barriers in technology transfer <sup>[35]</sup>

- **Commercializing publicly funded technologies:** The basic pattern envisioned is to give institutions receiving public research funds the right to obtain and exploit patents on inventions developed in the course of research.
- **Political stability and good transparent governance:** A country's relative political and economic stability will influence the rate of inward technology transfer and can be seen as a pre-condition for any technology transfer. Even when research-based pharmaceutical company technology transfers are benevolent in nature, they need to be sustainable in order to achieve their goals. Political leadership is critical to address global and local health challenges and, more importantly, healthcare system capacity strengthening.
- **Research tool patents and freedom to operate for the public sector:** Patents sometimes make it difficult for public researchers to carry out their research or to make the products of that research available. It is intensified by the tendency of some publicly funded research laboratories to avoid use of a patented technology without permission even in nations where no relevant patent is in force.
- **Appropriate Capital Markets:** For many governments seeking to expand technological capacity, attracting direct investment is very important, but there is also a question of making the most of the spill over benefits of investment. This can reveal a need for adequate capital markets. Governments can also promote inward investment through tax breaks and other forms of incentives designed to encourage technology transfer, in compliance with international trade rules.
- **Alignment with Economic Development Priorities:** The finite or limited resources available to governments imply that measures taken to promote technology transfer need to both be realistic and to fit with overall policy goals. A technology transfer policy dedicated to the creation of completely new types of economic activity and one which is as complex and as highly regulated as the pharmaceutical sector can present a much bigger challenge than building on a sector that already exist.
- **Co-operative research agreements:** Global support for public sector research might be encouraged is through co-operative research agreements designed to meet specific goals. It would seem more feasible to focus efforts on technologies of significant social benefit to the developing nations.
- **Possible treaty on scientific access:** There has also been a proposal for an international treaty on access to knowledge and technology negotiated on the basis of the type of reciprocity found in normal international trade negotiations. The concept is mean to be non- zero sums in the sense that, like free trade in goods, free trade in scientific ideas benefits all and such arrangements could

be made bilaterally as well as multilaterally.

### Success of Technology Transfer

The different "C" for successful technology transfer is: Communication, Certainty, Challenges, Capacity and Commitment [36].

- **Communication:** The technology transfer chain is often long, in terms of both distance and time. Effective communication is thus another essential ingredient in the recipe for successful technology transfer. Efficient and effective two way communication and corporation between key stakeholders will do much to remove barriers.
- **Certainty:** A lack of certainty, and the consequential high levels of risk, both real and perceived, are recognized a major impediments to the successful establishment and ongoing operation of functional markets. Removing barriers to technology transfer often translates into increased certainty, and decreased risk, for the key stakeholders such as developers, suppliers and recipients.
- **Challenges:** There are many barriers to successful technology transfer. All along the transfer path, from the supply side of technology to demand side, impediments occur at very node and, due to restrictions on movement of information and materials, for every linkage in technology transfer chain.
- **Capacity:** Enhancing the transfer of technologies that support sustainable development in largely about creating favourable circumstances for technology transfer-ensuring all stakeholders have the ability to fulfil their roles and meet their responsibilities, expeditiously. All key players and stakeholders must have the necessary knowledge and skills to perform the roles and tasks expected of them.
- **Commitment:** For a successful technology transfer there may be a good commitment to overcoming the challenges, providing technology users with the choice they deserve and desire, increase certainty, reducing risks, enhancing the communication between technology transfer stakeholders and building and strengthening the enabling environment and thus the capacity for technology transfer.

### Conclusion

- The transfer involves cost and expenditure that is negotiated and agreed upon by the transferee and transferor. The transfer may be said to be successful if the transferee can successfully utilise the technology for business gains and eventually assimilate it
- Appropriate efficiency in technology transfer from development to commercialization can be achieved through better communication and documentation by technology transfer team. A cooperative effort by team results in more successful initial and consistency runs leading to an earlier license, earlier launch and a greater market share.
- Use of enriched approaches like technology transfer to the development and start-up of new production systems will enable pharmaceutical organizations to fully benefit from the recent improvements in the new drug discovery and to complete more effectively in a rapidly changing marketplace.
- A dedicated technology transfer organization is set up to

facilitate and execute the process. Technology transfer can be considered successful if a receiving unit can routinely reproduce the transferred product, process or method against a predefined set of specifications is agreed with a sending unit and/or a development unit.

- Licensing is an imperative spectacle of technology transfer that has gained momentum in pharmaceutical industry by which pharmaceutical firms can contribute to research and development. Technology transfer is a complex issue and should be deal with using holistic approach.

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