

TECHNOLOGY TRANSFER IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

The objective of this review article is to study how technology is transferred in pharmaceutical industry. Technology Transfer is both integral and critical to drug discovery and drug development process for new medicinal products. This article highlights the process, reasons and different phases related to technology transfer with a brief description of methods associated with this process. Few cases of technology transfer being pursued in India are also discussed with a conclusion describing the importance of this process in upgrading research and commercialization in pharmaceutical field.

Keywords: Technology Transfer, Research and Development, Methods, Licensing.

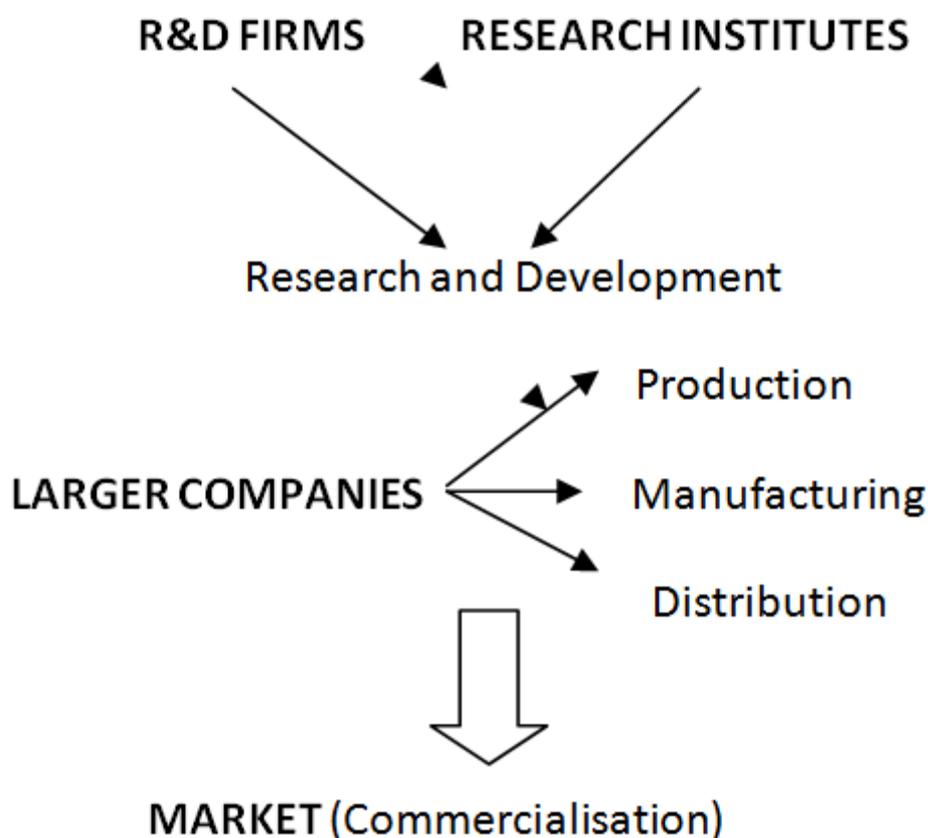
INTRODUCTION

Technology Transfer in Pharmaceutical Industry has been viewed from the perspective of Innovation and Research & Development. Since research is carried out in laboratories on small scale before it could be produced on commercial scale. Thus, Technology Transfer is important for such research to materialize on a larger scale for commercialization especially in case of developing and under developing countries. Technology Transfer is defined as "the process of taking an invention from its inception in a laboratory to product development phase and then to a commercial scale". Technology Transfer is an integral part of New Drug Discovery and development of

new medicinal products. Thus if Technology Transfer process to production site is carried out at an affordable cost, the cost of product development would not raise during pilot scale up[1].

For successful Technology Transfer of a product, the Departments responsible in a pharmaceutical industry are:- Research & Development; Production; Engineering; Quality Control and Quality Assurance.

Technology Transfer may be said to be successful if the receiving unit and the transferee can effectively utilize the technology for business gain.



WHY TECHNOLOGY TRANSFER ?? (Reasons)

1. **Lack of distribution and marketing channels:-** After fully developing the technology and getting necessary regulatory approvals to sell the product, the developer of the technology might

have to collaborate with other organizations with marketing and distribution capability.

2. **When developer has no commercial capability:-** In case, the developer of technology in a research institute that does not have

commercial capability. Thus, it has to collaborate with other organization to bring a pharmaceutical product to the market.

3. **Application in different field:-** With a view to create another source of income the developer may transfer the technology to another person for use in another field of application that is different from the field the technology is already applied.

4. **To launch the product commercially:-** If the developer of the technology does not have the capability to carry out the clinical and regulatory phases, he may collaborate to take it through these phases and then into the market[2].

STEPS IN TECHNOLOGY TRANSFER PROCESS IN PHARMACEUTICAL INDUSTRY

Technology Transfer process consist of 3 phases:

1. **Research Phase:** This process includes the design of procedure and selection of materials by research and development on the basis of innovator product characteristics. Thus quality of the product should meet the specifications and standards of innovators product.

2. **Development Phase:** R&D dept. must provide the necessary documents to the product development lab.that contains all the information of the formulation and drug product. These documents includes:

- **Master Formula Card (MFC):** This contains the information related to product i.e the product name, its strength, generic name, MFC number, shelf life etc.
- **Master Packing Card:** This provides information related to packaging type, materials used, stability profile and shelf life of packaging.
- **Master Formula:** This gives information about the formulation, manufacturing instructions etc.
- **Specifications & Standard Test Procedures(STP's):** These consist of active ingredient and excipients profile, in process parameters, product release specifications and finished product details.

3. **Production Phase:** This phase includes Validation Studies (performance qualification,operation qualification & process validation) and Scale Up for production that involves the transfer of technology during small scale development of product to larger scale.During all the phases of technology transfer, every step from R&D to production should be documented and it is the responsibility of Quality Assurance Department to check and approve the documentation of all the processes of Technology Transfer. The necessary documents to be prepared, maintained and inspected during the whole process are as follows:-

- The Research and Development Report that is a file which shows the basis for quality design of drug substance and its specifications and methods.
- Technology Transfer Plan that describes items and contents of technology to be transferred and detailed procedures of individual transfer, transfer schedules and establish judgement criteria for completion of transfer.
- Technology Transfer reports are maintained by both transferring and tranfered dept and are evaluated to confirm that the predetermined criteria are met.
- For filing purpose in regulatory agencies, exhibit batches are maintained. In this case batch sizes are increased along with their equipments and processes[3].

HOW Technology Transfer?? (METHODS)

Technology Transfer can be done in various ways such as contract Research and Development, establishment of joint ventures, setting up plants, licensing patents,designs etc. Licensing is however the most common method of technology transfer that grants the right to

use the technology in return for agreed payment. 2 main strategien of Licensing are:-

1. **LICENSING IN:** In this strategy, companies that are small and lack facilities to do basic research would wish to buy other's research. Also large scale and research based companies also might like to license in technology to expand its product line.

2. **LICENSING OUT:** In this, small scale companies that only have patents as their assets and cash in scarce would like to license out,whereas large companies license out technology if it is of very little knowledge for them[4,5].

(Ranbaxy,India's one of the leading pharmaceutical companies, is involved in both licensing in and licensing out opportunities for NDDS, Branded Generics and generics in developed and developing markets. On the other hand, Ranbaxy is looking for out licensing opportunities in therapeutic categories such as respiratory and anti infectives. [6]

EFFECTIVE FACTORS IN TECHNOLOGY TRANSFER

"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 as agreed with a Sending Unit and/or a Development Unit" [7].

Main factors that effect the process of technology transfer in pharmaceutical industry are as follows:

1. Investment in Research and Development.
2. Esablising relationship between production and research.
3. Traing of individual in relation of technology.
4. Information development in the field of technology transfer methods.
5. Organisational, Equipmental and Informational infrastructures.
6. Employment of International specialist in the field of technology and creation of appropriate relationship between recipient and sender technology.
7. Awareness of fundamental and important factors required for technology transfer.
8. Consideration of existing and old technologies.
9. Degree of development and improvement of technology on the basis of internal resources.



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

Govt. labs to private sectors

This type of Technology Transfer is advantageous as the Govt. labs can get good financial support and funds from the govt. for their research work and the technology developed by them reaches the private sector.

Between Private sectors of same country

This type of Technology Transfer generally occurs due to lack of appropriate financial resources or inadequate knowledge of

regulatory requirements, Thus the private sector that develops the technology is paid by other sector that absorbs the technology[8].

From Academics to private sectors

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

Between Academy, Private and Govt. sectors

In this type of Technology Transfer govt. provides necessary funds to the academic institutions in developing technology that can be transferred to the industry[9].

UNSUCCESSFUL TECHNOLOGY TRANSFER PROCESS may be due to following reasons:-

1. Unsuccessful or incomplete Process Validation.
2. High rates of batch rejections, excessive labour requirements, increased cost of product etc.
3. Incomplete Documentation.
4. Product does not show specifications as intended.
5. Delayed regulatory approval and/or product launch[10].

FEW CASES OF TECHNOLOGY TRANSFER

The process of Technology Transfer is actively being pursued in India through Government laboratories, Academic Institutions and Commercial entities.

1. *The Bhabha Atomic Research Centre (BARC)* has developed and transferred around 90 technologies in the areas such as environment and health; electronics; electrical and mechanical; chemical and metallurgy; radioisotope and applications.
2. *The National Chemical Laboratory (NCL) Pune*, has several linkages with universities and pharmaceutical industries to ensure successful scale up and implementation of technology[11].
3. *Department of Biotech (DBT)* has successfully transferred some techniques of forest trees through tissue culture.

4. *Eli Lilly has entered in technology transfer agreement with Shasun Chemicals and Drugs for the manufacturing of anti T.B drug CYCLOSERINE produced by Shasun to meet Eli Lilly global demand.*[12]

CONCLUSION

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. Licensing is an important phase of Technology Transfer that has gained momentum in pharmaceutical industry by which pharmaceutical companies can contribute to research and development. Technology Transfer provides an opportunity to reduce cost on drug discovery and development thus major pharmaceutical companies look for technology transfer opportunity as it reduces risk, cost and rate of failure.

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