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TECHNOLOGY TRANSFER IN PHARMA INDUSTRY: AN OVERVIEW

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ABSTRACT

Factors that have facilitated international technology transfer include globalization of business, liberalization 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). Appropriate technology transfer is vital and critical for the discovery and growth of drugs for new medicinal products and is also crucial for the improvement of the drug quality designed during research and development and the finishing of products during manufacturing, aswell as for ensuring the steady transfer of quality. Successful growth and marketing of innovative technologies is always apprehensive with problems, multifaceted efforts, and there are a variety of development instruments to support this activity, with technology transfer being by far most common strategy to directly promoting successful innovation. Successful technology transfer involves careful study of circumstances such as careful assessment of ultimate manufacturing demands early in research and development and the consequent enhancement of solid innovations that withstand large scale operation, through assembly. Technology transfer paper providing production with both"knowhow" and "knowhow" and serving as the basis for facilities and machinery design as well as operator training and normal working process generation in successful production.

KEYWORDS: Technology transfer, Drug discovery, Development, Scale-up, Technology transfer dossier, Process development laboratory.

INTRODUCTION

Technology transfer, also known as technology transfer, is the method of transferring abilities, expertise, techniques, manufacturing techniques, manufacturing samples and

equipment between sectors, governments or universities to make science and technological innovations available to a wider spectrum.[1]

There are two kinds of vertical and horizontal technology. Transferring vertical technology implies transferring technology respectively from basic research to growth & manufacturing. Transferring horizontal technology implies moving and applying it to another location in one location or context.

During the pilot scaleup, the cost of product development increases and the original manufacturing batch that is the critical path to achievement depends on completing the transfer of the technology to the manufacturing site at an inexpensive price.[3]

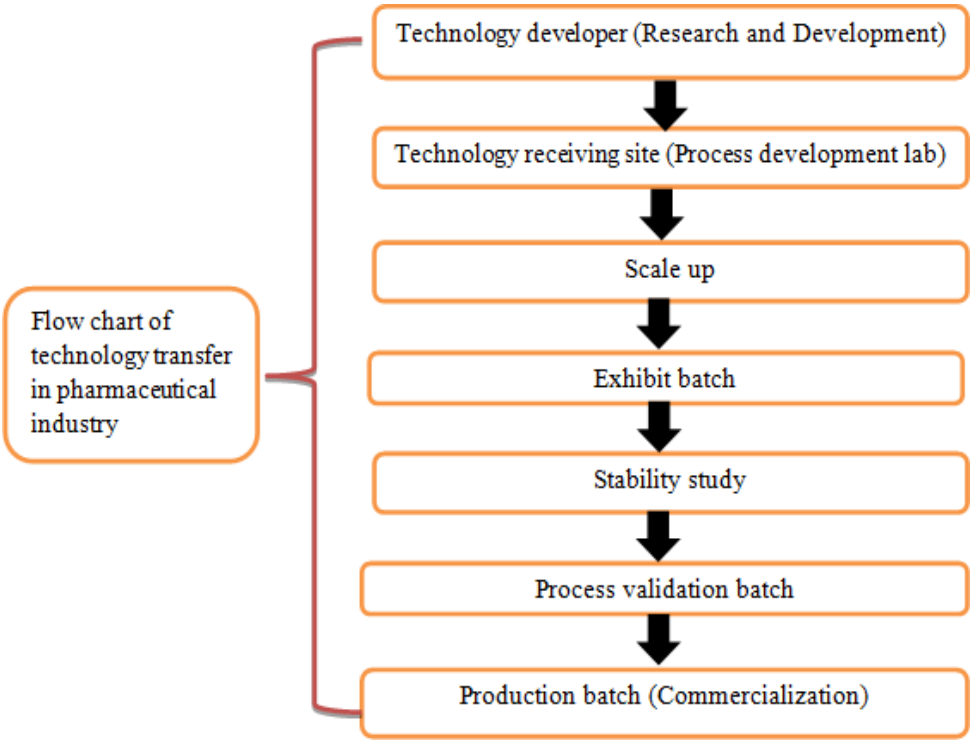

Fig. 1: Flow of stages involves after receiving the technology from R&D to PDL till commercialization of that technology in a pharmaceutical industry.

METHODS TECHNOLOGY TRANSFER

Technology transfer can be performed in different ways, such as contract research and development, joint venture establishment, plant set-up, licensing patents, designs etc.[12]

1. Licensing in

In this approach, business that are tiny and absence basic research equipment would like to purchase research from others.

2. Licensing out

In this, small scale business would like to license out only with patents as their assets and money in scarce.

2.1 Facets of technology transfer[24]

a) Govt. laboratories to private sector.
b) Between private sectors of same country.
c) From academics to private sectors.
d) Between academy, private and govt. sectors.

a. Govt. laboratories to private sector

Govt. laboratories can obtain axcellent economic assistance and govt funds. The private sector reaches for their study job and the technology they have created.

b. Between private sectors of same country

This sort of technology transfer usually happens owing to absence of adequate economic resources or insufficient understanding of legislative demands, so other industry that absorbs the technology pays for the private sector that develops the technology.

c. From academics to private sectors

It is made accessible to private companies by academic industries. Money can be saved through cooperation between private companies and institutions.

d. Between academy, private and govt. sectors

Govt. provides the required funding for the development of technology to educational organizations that can be transmitted to the sector.

2.2 List of Institutes in India assisting in Technology Transfer.[11]

1. Asia Pacific Centre for Transfer of Technology: C2, Qutab Institutional Area, New Delhi -110016. Phone no- 011 30973700
2. National Research & Development Corporation: 20-22, Zamroodhpur Community Center, Kailash colony, New Delhi-110048. Phone No-01126489037
3. Technology Bureau for Small Enterprises: Room no-123, Udyog Bhawan, Rafi marg, New Delhi-110011. Phone no- 011 23061431
4. Foundation for Innovation & technology transfer: Indian Institute of Technology Hauzkhas, New Delhi-110016. Phone no- +911126857762

ORGANIZATION OF TECHNOLOGY TRANSFER

Typical key Technology Transfer teams are likely to include people representing distinct company sections.

1) Project Manager

Coordination of general accountability and communication of advancement. Additional employees & accountability and delegated power may enhance his or her position as needed.

2) Regulatory Affairs

For coordination of the appropriate regulatory filings, advice on approval timing, content of the filing documentation and response to regulatory inquiries.

3) Engineering

To coordinate associated capital projects and direct and control construction, equipment acquisition, installation and qualification.

4) Material Management

This member (or members) will analyze and recommend the most favorable manufacturing strategy in consideration of internal capability, business partnership and tax advantages for the cooperation.

5) Manufacturing Operations

These representatives should have sufficient authority to commit the necessary personal and plant resource to accomplish the project within the defined cost and time limitations.

6) Research and Development

To support the technical issues and resolve problems. This group provides the process expertise and would be expected to train and direct the production trials at receiving site.

FUNCTION OF TECHNOLOGY TRANSFER TEAM[9]

1. Coordinate: Coordinating between technology users and developer between researcher and manufacturers is important element of technology transfer.

2. Nurture: A main ingredient for moving technology from a research laboratory to new business enterprises successfully in an environment that is supportive for entrepreneurship.

3. Link: Cataloging resources related to business enterprises and connecting would be entrepreneurship/researcher and other technology developers to outside group & organization which can help in the process of starting new product, companies etc. such linkage provide referrals for individual business counseling sources of financing.

STEPS IN TECHNOLOGY TRANSFER

During the development of a formulation, it is important to understand the procedure of the operations used, the critical and non critical parameters of each operation, the production environment, the equipment and the availability of excipients that should be taken into account during the early stages of the formulation development, so that a successful scale up can be achieved, Appropriate care during technology transfer is important to enhance the quality of drugs as developed in the final formulation by research and development as well as to ensure quality over a predetermined period of time.[28]

- Development of technology transfer by research and development (Research Phase)
- Technology transfer from research and development to production (Development Phase)
- Optimization and Production (Production Phase)

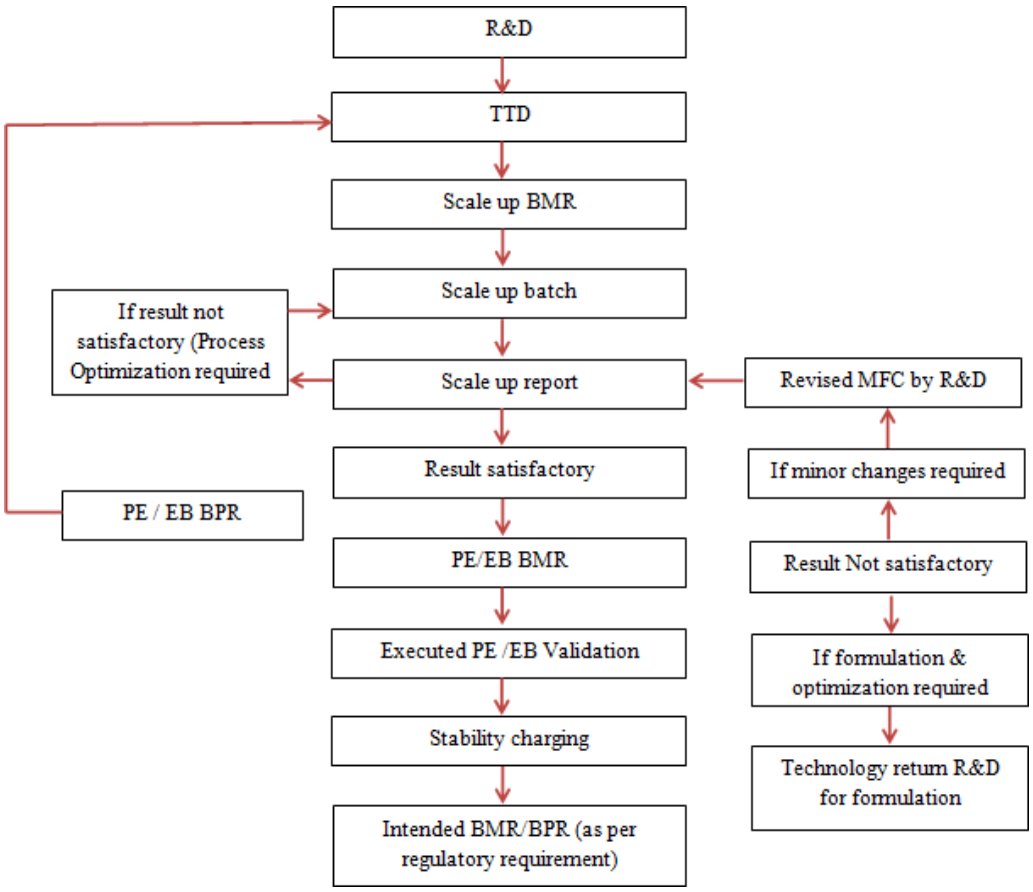

Fig. 2: Flow chart for technology transfer.

TTD: Technology Transfer Dossier, MFC: Master Formula Card, PE: Pre Exhibit, EB: Exhibit Batch, BPR: Batch Packaging Record, BMR: Batch Manufacturing Record.

1) Research Phase (Development of technology by research and development)

a. Quality Design

For drug products the quality design corresponds to pharmaceuticals design to design properties and functions suchas

- Elimination of adversereactions
- Improvement ofefficacy
- Assurance of stability duringdistribution

b. Data based on various data such as chemical and physical properties, efficacy, safety and stability obtained from preclinicalstudies

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

2) Development Phase

a. Research for factory production

In order to manufacture drugs with the designed qualities, it is necessary to establish the appropriate quality control method and manufacturing method after detecting variability factors in order to ensure stable quality in the scale up (validation) performed in order to produce factory designed on the basis of results from excipients on a small scale.

b. Consistency between Quality and Specification

When the product specification is determined on the basis of quality of the product as set out in the above, it is necessary to verify that specification specifies the quality of the product as set out in the above, it is necessary to verify that the specification pecifies the quality of the product as appropriate. Relations between upper and lower production foemula limits (composition and manufacturing methods) and upper and lower product specification control limits should be fully understood and the consistency between product quality and specification control limits should be fully understood and the consistency between product quality and specification 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.

c. Assurance of consistency through development and manufacturing

To this end, the development transfer pary should fully understand what kind of technical information is required by the transferred manufacturing party and should establish an

appropriate evaluation method to determine whether a drug to be manufactured meets the design quality.

d. Technology transfer from R&D to Production

R&D provides technology transfer dossier (TTD) document to process development laboratory, which contains all information of formulation and drug product as given below.[24]

- **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 procedures (STP):** It helps to know active ingredients and excipients profile, in-process parameters and specifications, product release specification and finished product details.

3) Production Phase

a. Validation and Production

Production is implemented after several validation studies verify that the product can be stable based on the manufacturing formula transferred. While validation is the responsibility of the manufacturing facility that accepts technology, the technology transfer department of research and development should be responsible for validation such as performance qualification, cleaning validation and process validation that is unique to the subject drugs.

b. Scale up for production

Scale up involves technology transfer during product and process development on a small scale. During process development, consideration of the product environment and system is essential. Operators should focus on keeping these things in mind as their production process segment runs smoothly if technology transfer is carefully implemented. Effective technology transfer contributes to the efficiency of processes and the quality of the product.

c. Considerations of different parameters for scale-up

We also regarded various parameters before beginning scale-up, which should be optimal for

effective technology transfer. Flexibility, price, reliability, innovation and quality of the product. It was essential to understand that excellent communication was critical to effective formulation and process transfer.

d. Selection of method

The batch manufacturing technique was chosen based on research and development information. Granulation, mixing, compression and coating were key technology parameters.

TECHNOLOGY TRANSFER DOCUMENTATION

Each step from research and development to manufacturing should be documented, job assignments and duties should be explained and criteria of recognition should be transferred to complete technology transfer related to individual technology.[18] It is the responsibility of the department of quality assurance to verify and approve the paperwork for all technology transfer procedures.

a. Development Reports

The report on Research and Development is a significant document that outlines the rationale for drug substance quality design and its requirements and test techniques. The development study is not a prerequisite for the authorization that can be used as a valid document for the quality design of new drug at the pre-approval inspection.[27] The report on growth includes-

1. Data of pharmaceutical development of new drug substances and drug products at stages from early development phases to final application of approval.
2. Information of raw material and components.
3. Design of manufacturing methods.
4. Change in histories of important process and control parameters.
5. Specification and test methods of drug substances.
6. Validity of specification range of important tests such as contents impurities and dissolution.
7. Verification of results.

b. Technology Transfer Plan

The Technology Transfer plan is designed to define technology products and contents to be transmitted and detailed processes for employee transfer and transfer schedule, create judgment requirements to complete the transfer. Before implementing the transfer, the transfer group should prepare the plan and reach an agreement with the transferred group on

its content.

c. Technology Transfer Report

Completion of technology transfer shall be done once information is collected in accordance with the technology plan and assessed to verify that the criteria of predetermined judgement are fulfilled. The report on technology transfer should be documented by both transferring and transmitted sides.

Exhibit batches

After the item has been scaleup batches, display batches are produced. Batch sizes are improved in the event of display along with equipment and procedures. This is performed in regulatory organizations for the purpose of filling. The aim behind running three successive lots is to show process consistency reproducibility and show that all phases of the manufacturing process are under control.

FEW CASES OF TECHNOLOGY TRANSFER[14,22]

The process of technology transfer is actively being pursued in india through Government laboratories, Academics Institutions and Commercial entities.

1. **The Bhabha Atomic Research Center (BARC)**has developed and transferred around 90 technologies in the area such as environment and health, electronics, electrical and mechanical, chemical and metallurgy, radioisotope and applications.
2. **The National Chemical Laboratory (NCL)** has several linkages with Universities and pharmaceutical industries to ensure successful scale up and implementation of technology.

   Department of Biotech(DBT) has successfully transferred some techniques of forest trees through tissue culture.
3. **Eli Lily** has entered in technology transfer agreement with Shasun Chemicals and Drugs for the manufacturing of anti- Tuberculosis drug Cycloserine produced by Shasun to meet Eli Lily global demand.

   Other pharmaceutical companies likew Wockhardt Ltd., Cipla Ltd., Torrent Pharmaceutical Ltd., Dr. Reddy's Laboratories Ltd., USV Ltd have already signed in-licensing agreements with foreign drug makers.
4. **Central Drug Research Institute (CDRI)**has developed technologies in the areas such as Malaria and other parasitic diseases, CNS-CVS related disorder, reproductive health, diabetes and energy metabolism, cancer biology and related areas, safety and clinical

development.

5. **Tata Institute of Fundamental Research**has successfully transferred some techniques of mathematics, natural sciences, computer sciences, biological sciences.

CONCLUSION

Appropriate technology transfer is essential in order to upgrade the design quality to be the product quality and to guarantee that the product is stable and of high quality. The key to the achievement of technology transfer and growth is good communication between distinct nations and distinct organizations.

Technology Transfer offers an chance to decrease drug discovery and development costs, so significant pharmaceutical companies are looking for opportunities for technology transfer as it decrease risk, price and failure rate. The plan, the individual concerned, and the method are the three main factors to be discussed during an efficicent technology transfer. Licensing is an significant technology transfer phenomenon that has gained momentum in the pharmaceutical industry through which pharmaceutical companies can add to R&D. Technology transfer is a complex issue and should be deal with using holistic approach.

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