IJCRR
Section: Healthcare
Sci. Journal Impact
Factor: 6.1 (2018)
ICV: 90.90 (2018)

Copyright@IJCRR

Technology Transfer: An Overview of Process Transfer From Development to Commercialization

Kanak Pandey¹, Himanshu Joshi¹, Sonia Paliwal¹, Shikha Pawar¹, Navin Kumar²

¹College of Pharmacy, Graphic Era Hill University, Sattal Road Nainital- 263156 Uttarakhand, India; ²Department of Biotechnology, Graphic Era Deemed to be University, Dehradun, Uttarakhand, India.

ABSTRACT

Objective: The journey of a brand-new compound from a quest laboratory followed by pilot plant production then proportion batches whereas below going through validation to a commercial product is explained under this text. A definitive objective for fruitful innovation move is to have archived proof that the fabricating measures for drug substances and medication item, individually, are hearty and successful in creating the medication substances what's more, drug item agreeing to the enlisted particulars and Good Manufacturing Practice necessities. This critical review attempts to clarify regarding the assorted problems associated with Technology Transfer and also the completely different side of Technology transfer within the field of Pharmacy. This text will discuss regarding the requirement, importance and factors moving method also the steps concerned within the process of Technology Transfer.

Conclusion: This article explains a significant choice centres around where the thought or cycle is progressed from a pharma research-situated program focuses on commercialization.

Key Words: Drug Discovery, Drug Development, Pharmaceutical Commercialization, Scale Up, Need of Technology Transfer, Technology Transfer Process

INTRODUCTION

The term “Technology Transfer” in Pharmaceutical sector refers to the process of progress from drug discovery to development, clinical trials and ultimately full-scale commercialization. It's an essential step that forms a bridge between drug discovery and also the development of a brand new medicative product. In keeping with World Health Organization, Transfer of technology is outlined as “a logical procedure that controls the transfer of any method in conjunction with its documentation and skilled experience between development and manufacture or between manufacture sites”. It may be outlined because the flow of technology from transferrer or developer to the transferee to induce an advert profit when undergoing upon mutual affection.^{1,2} It conjointly involves the application of transferring scientific findings from one organization to a different for additional development of existing merchandise or transfer of technology between the two producing units.

Process of technology transfer

Figure 1: Flow Chart of Technology Transfer in the Pharmaceutical Industry.

Corresponding Author:

Dr. Himanshu Joshi, College of Pharmacy, Graphic Era Hill University Sattal Road Nainital, Uttarakhand 263136, India.
Contact: +91 8217548866, +91 9482043369; Email: 2hjoshi@gmail.com.

ISSN: 2231-2196 (Print)

ISSN: 0975-5241 (Online)

Received: 19.07.2020

Revised: 22.08.2020

Accepted: 26.09.2020

Published: 06.10.2020

For achieving success associated stability in market place innovations area unit needed and transfer of those discoveries from work to the commercial batches is one in every of the essential and an integral half for a pharmaceutical business. It needs a team of skilled experience in conjunction with correct documentation of the accountable departments like analysis and development, QA, QC, Production and Engineering (**Figure 1**). The various phases of the technology transfer will be concisely mentioned as follows³:

- a) **Analysis and Development:** To switch the planning and properties of the pre-existing drug or a method a quest is being conducted in laboratories which may end up in betterment in physical, chemical properties of drug besides as rising its safety efficaciousness and stability. it should conjointly embody discovery of a brand-new moiety with some specific property or which can have some helpful property within the field of Pharmacy⁴
- b) **Method of development:** To manufacture the drug as per the planning and establishing the link between the higher and lower producing limits that quality specification ought to be ready. So, the standard product will be factory-made meeting the pre-set specification and satisfying the standard style. The producing method should conjointly commit providing a high-quality product on consistent production too. During the transfer from analysis and development to produce the right documentation of the detail of the merchandise and method is two-handed over to the assembly department by the analysis and development department within the type of written record. It includes:
  - i) **Technology Transfer Dossier (TTD):** Technology Transfer is written record (TTD) analysis and development provide technology transfer written record (TTD) document to development laboratory that contains all info of formulation and drug product.
  - ii) **Master Formula Card (MFC):** Shaping the producing directions, status needed, generic name, strength, master formulation record no. master packaging record no. SPS no, STP no.
  - iii) **Master Formulation Record (MFR):** It provides an elaborated description of status needed for producing at the site and the steps concerned in production.
  - iv) **Master Packaging Record (MPR):** It provides info relating to the kind of packaging material to be used, the steadiness and also the shelf life of packaging material.
  - v) **Specifications (SPS):** These area units the standard side establishing the link between higher and lower producing limit.
  - vi) **Standard Test Procedures (STP):** These area units the quality procedures either taken from any of the aggregation or were set in-house.
- c) **Scale-up:** Scale-up refers to the rise within the batch size of a product. for instance, if a drug gets thriving results, then it should scale-up or its batch size may increase to satisfy growing demand. because the drug or drug substance has been taken into the assembly from the pilot batch (Pilot Batch is that the tiny scale volume of the merchandise that is created as a result of the operation of the method (but not under cGMP)).⁵ It's the degree ample for method development, stability testing and connected quality testing moderately needed by the event Program, mistreatment excipients moderately anticipated to be clinically safe and created on the market in containers appropriate for the aim below the event program, however, this batch doesn't ought to go with cGMP or cGLP). It's essential to think about the assembly atmosphere and system throughout the development of the method. Completely different operations concerned within the producing method of the actual dose kind like just in case of pill formulations steps concerned square measure dispensing, sifting, blending, compaction/dry granulation/wet granulation, compression, the coating is employed. Numerous parameters like flexibility, cost, responsibility, innovation and products quality also are thought of throughout the dimensions up method. It was necessary to appreciate that smart communication was important for the formulation and method transfer.^{6,7}
- d) **Exhibit Batches:** Exhibit batch is created during a production plant or maybe during a pilot plant but it should have similar equipment like that in the production plant. The batch size should be in and of itself so the steadiness study is conducted in each accelerated and long-term conditions. the most aim of exhibit batch is to get stability information as per the ICH guideline to submit for an ANDA (Abbreviated New Drug Application) application⁸ and to induce the restrictive regulatory approval.
- e) **Stability Study:** Stability studies of the drug or drug substance is conducted of three consecutive batches. within which an ample quantity of drug or drug substances is being collected and square measure unbroken for accelerated and long-term stability studies, that were then tested at pre-defined time intervals. A report generated by such studies is needed for filing to restrictive agencies.
- f) **Production Batches:** Production is enforced when numerous validation studies, stability studies substantiating that the transferred producing formula is in a position to supply the consistent product. While the producing facility acceptive technology the standard department is liable for conducting all style of validation, like performance qualification (PQ), cleaning validation, and method validation.
- g) **Validation batches:** To go in administrative unit three validation batches with enlarged batch at the side of enlarged instrumentation square measure taken. Fil-

ing of the drug product in several restrictive markets or countries for approval through an efficient technology transfer results in an increase in productivity and profit. The aim behind running three consecutive batches square measure to shows method consistency, dependableness and to demonstrate that the producing method is in restraint throughout all the stages.

The process of technology development and exploitation takes place over three broad phases-: the event of the latest science, the conversion of science to technology and also the conversion of technology to product.⁹

NEED OF TECHNOLOGY TRANSFER:¹⁰

There are several reasons why the technology developer considers making its technology be on the market for an additional person. To diminish the gap between and to make a bridge between the educational institute and establishment with the business mission or to transfer technology from one company to a different a skill full technology transfer is needed. Company toughened and effective technology transfer skilled perceive the variations between the educational culture which can involve correct communication and negotiation between the two parties.^{11,12} Several which might be as follows:

- The developer should not be financially sound to require the discovered drug through the whole method of drug development because it includes many steps and wishes to travel through the restrictive part. In such cases, the collaboration of developer with a corporation is needed so the invention could reach to the market.
- It's going to additionally doable that the developer is financially sound to launch its product to the market however if the demand rises, the producing facilities weren't ample to fulfil the need at that point additionally collaboration will come about between the developer and also the producing units to induce reciprocally benefitted.
- Technology transfer may occur from analysis labs to the producing companies, which might be the drug discovered within the educational institutes or the drug discovered within the analysis and development units. In such quite technology transfer a mutual collaboration will result in generating the required fund for the analysis labs and may additionally lead the producing companies to induce monetarily benefitted.

TECHNOLOGY TRANSFER TEAM:¹³

Whenever a replacement technology or formulation is formed and also the management decides to transfer it from the laboratory to the producing unit the team of delicate personnel's is being trained so they should become acquainted of the method and must work with the constant goal because the management goes with to realize the simplest doable ac-

tion and the success of technology transfer depends upon the workforce concerned within the method from the invention at analysis level to its transfer to producing unit followed by its availableness to the market.

The various persons involved in the process of technology transfer are:

Researchers: These are the person concerned within the method of analysis and development moreover as getting ready the general information associated with the formulation within the kind of a written account known as dossier.

QA Personnel's: These are the key persons in the whole process of technology transfer their main function is to make a bridge between the research technologist and the manufacturing unit. Their work includes reviewing the documents received by the research lab, to understand it and to opt for the best possible process to implement it with no productivity loss. It is also the responsibility of the QA personnel's to be prepared for the regulatory requirement which may include preparing validation protocols, designing new SOPs if required, preparing master document such as manufacturing records personnel: Engineering department, change control, market complaint.

Engineering Personnel: Engineering is responsible for controlling the temperature and pressure of a particular area. Along with the production team, it is also responsible to check and verify the calibration status of machines and equipment.

Production Personnel: First of all, they cross verify the instruction provides to them by the QA Personnel's to confirm the capacity and capability of the manufacturing unit. It may include verifying the SOP's Master manufacturing records. Providing training to the operators and other manufacturing personnel.

Quality Control personnel: Quality Control department deals with setting up the testing procedures and testing specifications as well as the conducting the validating the analytical methods along with QA personnel, also are responsible to update the equipment status to QA and to perform the quality testing of the formulation prior and post-manufacturing.

QA personnel: Perform final review including equipment qualification, testing procedures, maintaining the area for manufacturing, conducting validation and stability studies and finally releasing the particular formulation for commercialization.

As this is the teamwork training to each person in their respective field must be provided by QA with the help of management before starting manufacturing of the transferred technology to the manufacturing unit. So that productive result must be achieved.

IMPORTANCE OF TECHNOLOGY TRANSFER:^{14,15}

- It leads to the economic expansion of the pharmaceutical industry influencing the economic performance of the nation.
- It leads to the collaboration of science and business which may result in the introduction of a new drug or health tool to the market.
- It is a critical process which results in transferring the scientific finding of the research labs to be available to the commercial units.¹⁶

FACTORS AFFECTING THE PROCESS OF TECHNOLOGY TRANSFER:

- **No compromise with regulatory standards:** Pharmaceutical industry is the heavily supervised industry by the regulatory bodies, as in the medicines assurance of quality, safety and efficacy is the basic requirement which should not be compromised in any condition.
- **Cost-effectiveness:** The transferred technology must remain beneficial for the manufactures while should be able to reach in a lower possible value to the common public.
- **Fair practices:** This includes the fair professional ethics which must be followed by the organization to achieve success it also covers the GLP, GDP practices must be followed by the manufacturing without leaving any loophole.
- **Establishing strategic goal:** The organization must set some priorities keeping the strength, resources in mind also must influence the employees to work towards a common goal which will increase production benefit with low investment.
- **Basic training and knowledge:** Whenever there is an introduction of new formulation or anew equipment is required in the manufacturing process proper training must be provided to the employees so the technology can be used in a better way. The employees must also be skilled so that they can also contribute to high productivity.

BARRIERS OF TECHNOLOGY TRANSFER:^{17,18}

The basic challenges faced by the organisation while transferring the technology can broadly be defined as:

i. Economic Factors

- Poor business administration and lack of business agreement.
- Lack of pre-risk management for the assessment, control and review of risks to the quality of the pharmaceutical product throughout the product life-cycle.

ii. Technical Factors

- The difference in the infrastructure of the research lab and the manufacturing unit may give rise to the technical issue.
- Improper transfer and lack of cooperation between the Research and development unit and the manu-

facturing units may also create hurdle in the process of technology transfer.

- In the case of discovery sometimes it takes too long in the process of testing and demonstration due to which the formulation takes competitively long to reach the market and compete with the pre-existing formulations.

iii. Miscellaneous Factors:

- **Inadequate funding** in important areas and possible treaties: Some time due to inadequate fund available at the research centres leads to incompetent results.
- **Labour issues:** In the pharma sector highly skilled and experienced labour is required lack in their number may result in low production.

FACTORS INFLUENCING THE SUCCESS OF TECHNOLOGY TRANSFER:^{19, 20}

The success of technology transfer will depend upon how frequently the barriers must be overcome; some of such factors are given as follows:

- The government should provide the organisations and research institutions with an easy funding process so that the new technology can be easily made available to the market.
- Research agreements must be fair and transparent between the research units and the manufacturing units.
- A process of technology transfer deals with introducing a new formulation for gaining an economic benefit but it must be quite challenging as it has to compete with the pre-existing formulation in the market which is a risk-taking job but can lead economic growth of the industry as well as the country.

The above-mentioned factors²¹ can be summarized as indicated in **Table1**.

S. No.	Basic Factors	Explanation
1.0	Restrictions at the Innovation site	Limited Resources, administrative and arranging aptitudes in associations.
2.0	Restrictions at Manufacturing Site	Hierarchical foundation; Equip mental framework; Informational foundation; also, Human framework. Capacity in the assimilation of bringing in innovation; Establishing the connection between creation and examination; Training of individual comparative with innovation.
3.0	Global Factors	Interaction with various global focuses on innovation participation zones. Employment of global master in the field of innovation; and Creation of proper connection between the beneficiary and sender innovation. Workforce preparing in worldwide legitimate organizations;

4.o	Administrative Factors	Level of accomplishing innovation; Degree of moved innovation value; Degree of straightforwardness and complicity of the innovation; and Degree of improvement and improvement of innovation based on interior prerequisites.

CONCLUSION

To achieve a successful technology, transfer the most important points to be considered is teamwork with good understanding and communication between the sending unit and the receiving unit. Building up a strong and constantly improved cycle related to Drug Quality Systems guarantees meeting or to surpass GMP necessities. It will also depend upon the documentation which includes dossier given by the research unit as well as the overall documentation in which QA is involved which is a community-oriented exertion with Research and Development, Manufacturing Specialized Operations, Quality, Manufacturing and so on that is expected to guarantee a fruitful innovation move and a robust last made item. Such a small initiative may lead to getting regulatory approvals in a short duration as well as the formulation will be ready to compete the already existing marketed product in a very short period. If the process of technology transfer takes place in a proper way it may contribute to enhancing the productivity and economic growth of an organization without making sacrifices with the quality of the formulation.

ACKNOWLEDGEMENT

We gratefully thank Graphic Era Hill University for all support and encouragement for writing this review.

Conflict of interest: The authors declare that there are no conflicts of interest.

Financial funding: None.

REFERENCES

1. Steenhuis HJ, De Boer SJ. Differentiating Between Types of Technology Transfer: The Technology Building; *International Journal of Technology Transfer and Commercialization*; 2002.1(1/2): 187-200
2. Popat B., Mohite, Sangle Sachin V., Technology Transfer in Pharmaceutical Industry: A Review; *International Journal of Adv. in Pharm*; 2017.6(1): 1-7.
3. Patel D.S., Nadia. Technology Transfer an Overview of Pharmaceutical Industry; *Int. Biopharm Association*; 2009.2(4): 2-8.
4. C. Manu, Gupta Vishal N., Review on Technology Transfer in the Pharmaceutical industry. *Int. J. Pharma. Q. A*; 2016.79(10):7-14.
5. Gibson M., *Pharmaceutical Preformulation and Formulation: A Practical Guide From Candidate Drug Selection to Commercial Dosage Form*; A division of Taylor and Francis Books; Interpharm /CRC Press; 2001.
6. Anuj A., Bhuvnesh K.S., Importance of Technology Transfer in the Pharmaceutical Industry: A Review. *International Journal of Pharmaceutical Research.*; 2016.1(4):141-142.
7. Biruk A., Biruk Abate. Technology transfer in pharmaceutical industries through product development and scale-up approaches Challenges and opportunities for developing countries. *International Journal of Emerging Technology and Advanced Engineering*; 2016.6(7): 232-243.
8. Tiwari, Process Scale up of Ibuprofen tablet. *J. Pharm. Sci. Res.*; 2011.1525-1529.
9. Anuj A, Bhuvnesh KS. A Review on Importance of Technology Transfer in the Pharmaceutical Industry: An International Journal of Pharmaceutical Research; 2016.1(4):141-142.
10. Patil R.P., Technology Transfer in Pharmaceutical Industry, Objective, Issues and Policy Approaches: *International Journal. Pharma. Research & Development*; 2010.2(10): 43-48.
11. *Pharmaceutical Quality System: ICH Q10*; European Medicines Agency; ICH; 214732; 2007.
12. Singh A., Aggarwal G., Technology Transfer in Pharmaceutical Industry: A Discussion. *International. Journal. Pharma. Biosci*; 2009.1(3): 1-5.
13. Madu C.N., Transferring Technology to Developing Countries- Critical Factors for Success. *Long-Range Planning*; 1989.22(4): 115-124.
14. Gupta. Technology Transfer in the pharmaceutical industry: An overview; *Novel Science International Journal of Pharmaceutical Science*; 2012. 1(7): 430-434.
15. Al Ali S., Developing Countries and Technology Transfer. *International Journal. Tec. Man*; 1995.10 (7/8): 704-713.
16. Green S., Warren P., *Technology Transfer in Practice*: Sue Horwood Publishing Limited, Storrington; 2002.
17. Souder W.E., Nashar A.S., Padmanathan V. A.: Guide to The Best Technology Transfer Practices: *Journal of Technology Transfer*; 1990.15: 1-2.
18. Reamer A, Iceman L, Youtie J.: Technology Transfer and Commercialization: Their Role in Economic Development; 2003.10-16.
19. Donald. Transfer of Process from Development to Manufacturing. *Drug Information J.*; 1998.32: 19-26.
20. Akhavan A. Technology Transfer to Developing Countries: The Iranian Experience, University of Bradford UK; 1995.
21. Alam MS., Ahmad J., *Pharmaceutical Technology Transfer: An Overview*; *International Journal of Pharmaceutical Science & Research*; 2013.1(1/2): 187-200.