International Journal of Pharma and Bio Sciences

TECHNOLOGY TRANSFER IN PHARMACEUTICAL INDUSTRY: A DISCUSSION

AMANJEET SINGH* AND GEETA AGGARWAL

Rayat Institute of Pharmacy, Railmajra, District S.B.S. Nagar, Punjab,India.

*Corresponding Author amanjeetnarang13@gmail.com

ABSTRACT

Technology transfer is both integral and critical to drug discovery and development process for new medicinal products. A major decision focuses on that point where the idea or process is advanced from a research- oriented program to targeted toward commercialization. Generally the cost of product development rises dramatically during the pilot scale-up and initial production batch efforts. In other words, the critical path for success is dependent on completion of the technology transfer to the production site at an affordable cost. The success of any program is highly dependent on the effectiveness of the communication preceding its implementation. The ultimate goal for successful technology transfer is to have documented evidence that the manufacturing processes for drug substances and drug product, respectively, are robust and effective in producing the drug substances and drug product complying with the registered specifications and Good Manufacturing Practice requirements.

KEY WORDS

Technology transfer, Technology transfer dossier, Scale up, Exhibit batch

INTRODUCTION

Technology transfer is the practice of transferring scientific findings from one organization to another for further development, So that new products such as medicines, educational tool, electronic devices, safety equipment and health services can become available to the public. Technology transfer is the intersection between business, science, engineering, law and government[1-2]. Technology transfer is both integral and critical to the drug discovery and development process for new medicinal product. This process is important for to elucidate necessary information for technology transfer from R & D (Research & Development) to PDL (product development laboratory) and for development of existing products to the production for commercialization. Technology Transfer is helpful to develop dosage forms in various ways like it provides efficiency in process, helps to maintain quality of product, helps to achieve standardized process, which in turn facilitates timely & cost effective production[3-4].

Why technology transfer in pharmaceutical industry

In the pharmaceutical industry technology transfer refers to the processes that are needed for successful progress from drug discovery to

product development, to clinical trials to full scale commercialization or it is the process by which a developer of technology makes its technology available to commercial partner that will exploit technology. In pharmaceutical industry preparation of dosage form needs scale up in/at several stages, such as small scale laboratory development from 0.5-2kg batch can be scaled up to 5-10 kg and then to 20-100 kg on a pilot scale. Production scale can typically range from 200 kg to greater than 1000 kg. Technology transfer involves manufacturing drug product with increasing batch sizes on larger equipment or using continous processing on pilot scale equipment. Generally scale up involves the transfer of technology and the transfer of knowledge that has been accumulated during the small scale development of product and processes. It is important to realize that good communication is critical for formulation and process transfer to be successful. It is essential for a researcher or developer of technology to make available this technology to another person's to exploit for the progress of development of technology and for exploitation of a technology in different fields of applications and to make is use with another organization that may have better manufacturing capability, marketing capability and commercial capability. In the pharmaceutical industry, technology transfer by collaborating with other departments and other organizations to commercialize a pharmaceutical product is a common process[5-7].

Steps in technology transfer

Technology Transfer is not a single way process. Whether a tablet, a transdermal patch, a topical ointment, or an injectable, the transformation of a pharmaceutical prototype into a successful product requires the cooperation of many individuals. The classic view of a flow from basic to applied technology is a great oversimplification-sometimes, e.g. problems or insights arising at the production level give rise to new ideas that contribute to fundamental basic advance. At least in some sectors, close links between the basic researchers and manufacturing experts, and even marketing personnel contribute to competitiveness and advancement[2, 6-7]. The development of new formulation goes through many stages as shown in figure. 1

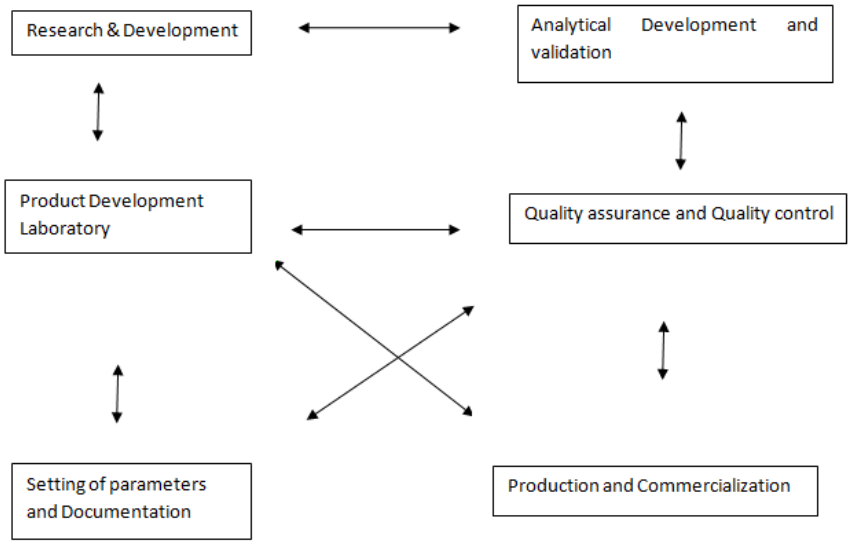

Figure 1 Representation of Process of Technology Transfer

During development of a formulation, it is important to understand procedure of operations 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 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. The various steps involved in technology transfer are given below:

1. Development of technology by R & D

a. **Design of procedure and selection of excipients by R & D:** Selection of materials and design of procedures is developed by R & D on the basis of innovator product characteristics. For this different tests and compatibility studies are done.

b. **Identification of specification and quality by R & D:** Generally it should be considered by R & D that quality of product should meet the specifications of an innovator product. For this different stability studies are carried out for innovator product and for product which is to be manufactured.

2. 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 and drug product as given below:

a. **Master formula card (MFC) includes** product name along with its strength, generic name, MFC number, page number, effective date, shelf life and market.

b. **Master packaging card** gives information about packaging type, material used for packaging, stability profile of packaging and shelf life of packaging.

c. **Master formula** 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.

d. **Specifications and standard test procedure (STPs)** helps to know active ingredients and Excipients profile, in-process parameters and specifications, product release specification and finished product details.

3. Optimization and Production:

a. **Validation studies:** Production is implemented after validation studies that can verify that process is able to stabilize the product based on transferred manufacturing formula. While the manufacturing department accepting technology is responsible for validation, the research and development department transferring technology should take responsibility for validation such as performance qualification, cleaning validation, and process validation which are unique to subject drugs.

b. **Scale up for production:** Scale up involves the transfer of technology during the small scale development of the product and processes. It is essential to consider the production environment and system during development of process. Different operations e.g. dispensing, sifting, blending, compaction/dry granulation/wet granulation, compression, coating are used in the formulation of solid dosage form. From blending to film coating, each process is easy for pharmaceutical professionals to be absorbed in the particular part of the manufacturing process for which they are directly responsible. Operators concentrate on keeping their segment of the production process running smoothly. But the whole manufacturing line can be improved, even before production

begins, if technology transfer is implemented thoughtfully. Effective technology transfer helps to provide process efficiency and control and maintain product quality[4,6].

4. **Technology transfer documentation:** Technology transfer documentation is generally interpreted as document indicating contents of technology transfer for transferring and transferred parties. Each step from R & D to production should be documented, task assignments and responsibilities should be clarified and acceptance criteria for completion of technology transfer concerning individual technology to be transferred. It is duty of quality assurance department to check and approve the documentation for all processes of technology transfer.

   a. **Development report:** The ultimate goal for successful technology transfer is to have documented evidences. The R & D report is a file of technical development, and the research and development department is in charge of its documentation. This report is an important file to indicate rationale for the quality design of drug substances and drug specifications and test methods. The development report before the approval inspection. Although the development report is not prerequisite for the application for approval, it can be used at the preapproval an inspection as valid document for quality design of new drug. In addition, this report can be used as raw data in case of post-marketing technology transfer. The development report contains data of pharmaceutical development of new drug substances and drug products at stages from early development phase to final application of approval, information of raw materials and components, rational for dosage form & formula designs and design of manufacturing methods, change in histories of important processes and control parameters, stability profile, specifications and test methods of drug substances, intermediates, drug products, raw materials, and components, which also includes validity of specification range of important tests such as contents impurities and dissolution, rational for selection of test methods, reagents and, columns, and traceability of raw data of those information.

   b. **Technology transfer plan:** The technology transfer plan is to describe items and contents of technology to be transferred and detailed procedures of individual transfer and transfer schedule, and to establish judgment criteria for the completion of the transfer. The transferring party should prepare the plan before the implementation of the transfer and reach an agreement on its contents with the transferred party.

   c. **Report:** Report completion of technology transfer is to be made once data are taken accordingly to the technology plan and are evaluated to confirm that the predetermined judgment criteria are met. Both transferring and transferred parties can document the technology transfer report; however, they should reach an agreement on its contents[8-9].

5. **Exhibit**: After taking scale up batches of the product, manufacturing of exhibit batches take place. In case of exhibit, batch sizes are increased along with equipments and their processes involved. They are done for filing purposes in different regulatory agencies[10-11.]

CONCLUSION

In pharmaceutical industry, technology transfer means action to transfer of information and technologies necessary to realize quality of design of drugs during manufacturing. The three primary considerations to be addressed during an effective technology transfer are the plan, the persons involved, and the process. A plan must be devised to organize the personnel and the process steps. Once prepared, the plan must be communicated to the involved parties

in research, at the corporate level and at the production site. The technology transfer does not mean one-time actions taken by the transferring party toward the transferred party, but means continuous information exchange between both the parties to maintain the product manufacturing[1,5]. To assure the drug quality, it is desire to make sure that is what, when, and why information should be transferred to where and by whom and how to transfer, then share knowledge and information of the technology transfer each other between stake holders related to drug manufacturing[1, 10-11].

REFERENCES

1. E. Domb. Using TRIZ to Accelerate Technology Transfer in the Pharmaceutical Industry, PQR Group and The TRIZ Journal 3-5 (2004) Cited 2009 October 07. Available from: URL: http://www.trizjournal.com/archives/2004/12/02.pdf.
2. Notes on technology transfer, Cited 2009 October 07. Available from: URL:http://www.research.cornell.edu/cotaba.html
3. A. Reamer, L Icerman and J. Youtie. Technology Transfer and Commercialization: Their Role in Economic Development, 2003. cited 2010 january31. Available from: URL: http://www.eda.gov/ImageCache/EDAPublic/documents/pdfdocs/eda_5fttc_2epdf/v1/eda_5fttc.pdf
4. D.S. Patel. An overview for pharmaceutical industry, Int Biopharm Association publication 1-10. Cited 2010 march 18. Available from: URL: http://cleanroomsfaq.blogspot.com/2007/08/technology-transfer.html
5. M.S. Janodia, D. Sreedhar, V.S. Ligade, A. Pise, N. Udupa. Facts of Technology transfer: A perspective of Pharmaceutical industry, J. Intellectual property rights 13: 28-34 (Jan. 2008).
6. C.E. Ruegger, A.E. Royce, M.J. Mollan, R.F. Wagner, S.J. Valazza and M.R. Mecadon. Scale up of Solid Dosage Forms. 2006. Cited 2009 October 08. Available from: URL: http://www.informaworld.com/smpp/content~db=all~content=a758580018
7. P. Mendes . Licensing and Technology Transfer in the Pharmaceutical Industry, cited 2010 February23. Available from: URL: http://www.wipo.int/sme/en/documents/pharma_licensing.html
8. H.R. Pyle and L.J. Silvestri. Good Development Practices, Cited on : 2010 March 8. Available from: URL: http://www.regulatory.com/forum/article/gdps.html
9. Technology Transfer from R & D to production, Cited 2010 February 6. Available from URL: http://www.bioqc.org/workshopdata/1Technology.pdf
10. M. Gibson. Technology Transfer Introduction and Objectives, 1-11. Cited on : 2010 february 02. Available from: URL: https://store.pda.org/bookstore/TableOfContents/Tech_Transfer_Ch01.pdf
11. Guideline for Technology Transfer (Draft), Cited 2009 December 12. Available from: URL: http://www.nihs.go.jp/drug/GMP/04BDH0149-1post.pdf