Review Article

TECHNOLOGY TRANSFER FROM R & D TO PRODUCTION AND ITS DOCUMENTATION IN PHARMACEUTICAL INDUSTRY: A REVIEW

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ABSTRACT

Technology transfer plays a milestone in the pharmaceutical industry during the citation of drug discovery to drug product development. Technology transfer technique transferred from Research & Development (R&D) department to production department through the process of the research phase, development phase, and production phase for further product commercialization. This study was an attempt to discuss the reasons and importance of technology transfer, processing steps for technology transfer, and its documentation report. Establishing confirmation technique for all kinds of documentation and will be inspected and accepted by quality assurance department before the technologies reaches the production department. Hence, the proposed transferring technique will help to develop the product through the processes mentioned in the documentation report.

Keywords: Technology Transfer, R&D, Production, Documentation.

INTRODUCTION

Technology transfer is a rational system that guidance the exchange of any design alongside its documentation and knowledge between the event and producing site. Inside the pharmaceutical industry, transfer of technology applies to the activities of no-hit programs from drug discovery and development, clinical investigations, and at last huge scope commercialization. These transfer techniques are useful to develop dose kind in varied process since it gives potency in method, prolong the product standard, to attain systemized method that enables cost-efficient creation. The no-hit transfer of technology from research and development (R&D), the transferring site, the receiving site, may be an important method within the development and initiate a new branded drug. It may be very expensive to all organization if transferred techniques are wrong throughout the transferred report ^{1,2}.

REASONS FOR TECHNOLOGY TRANSFER

Due to absence of producing capability

The designer of the technology might solely possess to produce instrumentality that appropriates for laboratory and produce little things, then they should try to produce the product for huge scope by help of another organizations ^{2,3}.

Due to absence of sources to initiate the new brand promotion

The initial discoverer of technology might solely possess sources to conduct initial stage of analysis for clinical investigation.

Due to absence of selling administering and capability

The discoverer of technology might solely possess totally designed technology and even possess obtained regulatory approvals and product registrations; however, it's going to not

possess the selling and administering channels and they should combine with other organizations for administering the product.

Construct the association with associates

It conjointly involves producing and administering capabilities for progress the event of technology to be require ⁴.

IMPORTANCE OF TECHNOLOGY TRANSFER

- To explicate predetermined guidance for technology transfer from R&D to definite producing by checking out numerous details acquired throughout R&D.
- Demonstration of the predetermined guidance for technology transfer of live product, connecting the numerous producing sites ^{5,6}.
- To illustrate specified procedures and points of study of sleek technology transfer for the graceful production of commercialized products.
- This can be pertinent to the transferring technique through R&D to production and associated with post-marketing changes in producing sites.
- The last word objective for made technology transfer is own documented proof that the producing method for drug substances and drug product square measure sturdy and virtual in manufacturing drug product yielding with the prescribed specifications and sensible producing practices demand ⁷.

TECHNOLOGY TRANSFER PROCESS

Technology transfer is integral, then important to the drug discovery and development method to initiate a new branded drug. The choice of transfer product connecting the producing site often pilot by administering. Pivotal stages of the method embrace information assortment, information analysis, regulatory

influence with explicit stress on any amendment compliance, pilot or complete method analysis, analytical validation, and stability of the product. The process of technology transfer illustrated in Figure No. 1. In the technology transfer process; new technologies are made by R & D department like formulation development, analytical development, and packing development. These technologies transferred to respective departments like manufacturing, quality control and packing after the documented technology report was accepted by quality assurance department⁸.

Figure 1: Technology Transfer

Steps in Technology Transfer Process

Throughout the event of a dosage form, and it's essential to grasp the techniques of operations used, crucial and incidental parameters of equipment, excipients, process, and production setting accessibility might be taken into the account throughout the development of formulation for first phases in order that successful production will be meted out⁹. Adequate consideration all through technology transfer is vital to support drug quality as developed by R&D inside the final formulation similarly on guarantee quality for an arranged time frame. The processes square measure classified into three classes¹⁰.

- Development of Technology by R&D (Research Phase)
- Technology Transfer from R&D to Production (Development Phase)
- Optimization and Production (Production Phase)

DEVELOPMENT OF TECHNOLOGY BY R&D (RESEARCH PHASE)

The goal of research phase is to design the drug product under standardized conditions which corresponds to potential drugs and its properties, functions like discharge of drug- drug interaction, adverse reactions, drug efficiency, stability, throughout the administering and their supported knowledge like physical and chemical properties, safety, efficacy, and stability acquired from diagnosing studies^{11,12}.

TECHNOLOGY TRANSFER FROM R&D TO PRODUCTION (DEVELOPMENT PHASE)

Production plant research

The development phase should need to determine the acceptable control for manufacturing techniques to produce with quality and designed specifications of developing product. The factors variability to secure stable quality within the validation studies that performed to production plant for developing product in small-scale experiments^{11,12}.

Product quality and its specifications

After the establishment of product specifications, development phase needed to determine the products are within the standardized specification adequately describes quality of the product. Understood the relationship between higher and lower limits for producing formula like composition of product and producing method ought to be their quality and specifications. Then needed to confirm the products are within the quality and specifications that the standard design of quality is assured. Because the product satisfies with quality, safety under the standard design of the product.

Development and manufacturing assurance

For this intention, development site assures which type of technical guidance needed by transferred party who is in charge of producing site and transferring party should understand their technical guidance and exhibit appropriate method to identify the product under the respective design with quality¹³.

Technology Transfer from R&D to Production

Technology Transfer Dossier (TTD) is given by R&D. It is a type document that holds all technical guidance of design and product quality follows,

- **Master Formula Card (MFC):** This MFC encompass name of the product in concurrence with their dosage, mater formula card number, date, and product shelf-life.
- **Master Packaging Card (MPC):** This MPC encompass the guidance concerning packaging materials and their stability, and duration of packaging time frame.
- **Master Formula:** This narrates order of product design and producing directions. Order of product design and producing directions propose a method of order, required atmosphere conditions, and producing directions for indefinite quantity kind of design and development.
- **Standard Test Procedures (STPs) and their Specifications:** This specification assist to understand excipient and active ingredient profile, requirements for in-process parameters and their specifications, and product attributes.

OPTIMIZATION AND PRODUCTION (PRODUCTION PHASE)

Validation & Production

After varied studies of validation report substantiate that able to produce the product supported under transferred technical formula. Whereas production facility is too responsible for studies of validation, and development phase of transferring technology also ought to take responsibility for such things of validation studies like performance qualification, validation improvement, and validation method; distinctive to analysing of drugs¹⁴.

TECHNOLOGY TRANSFER DOCUMENTATION

This documentation is mostly taken as documents specifies the contents of both transferring and transferred parties' technologies. Document information ought to be complied and ready consequently and it will be invariably traceable and accessible. For 'no-hit' technology transfer, their assignments, and responsibilities ought to be refined and integration criteria for the technology transfer completion regarding transfer of individual technology. Establishing confirmation technique for all kinds of documentation and will be inspected and accepted by quality assurance department. This document accommodates each knowing 'how and why' for no-hit technology transfer¹⁵. The team of technology transfer possess a lot of information

regards antecedent and peripheral, and will higher measure choice and might discriminate the important from the incident reports. This document is to produce each and every applicable guidance in order that the technology transfer travels simply and will occurred changes is created fully acknowledge, why this system and products are in its latest array. Therefore, the documentation clearly understood the reasons for the choice of specific equipment and their conditions, and working operation ¹⁶.

Firms for Technology Transfer

The foremost vital components for efficient transfer of technology could be reporting with both transferring and transferred parties. Hence, the firms should establish a number of parties and their responsibilities and should be an undertaking of data to be assured fascinating that this firm complies with the standard of Good Manufacturing Practice (GMP).

Report of R&D

The report of R&D is a systematic technological file for development and their other departments are administering for this documentation report. These report possess historical information of pharmaceutical development of latest design of drug substances and drug products and stages of technologies from preliminary development to final requisition of drug approval, types of dosage and master formula style, raw material, synthetic route, quality parameters of scale-up batches, stability guidance and their specifications of raw materials, drug substances, intermediates, drug products, and their validation specifications like dissolution, bioavailability, and their full of quality target product profile. Hence, the above information and such things of validation specifications should be reported in the documentation released by R&D ¹⁷.

Description of product report

The necessary guidance for the preliminary process and prolongation of producing a product and their quality assurance, environmental report for producing product, prices, operational safety assurance while production and other necessary guidance of the product should be mentioned in the description report.

Plan of Technology Transfer

Narrate the things and technologies for the latest design of the product to be transferred. Express the elaborated technologies of discrete transfer and their scheme. Transferring parties ought to work out the arrangement of technologies before the execution of developed technologies associated with their contents of technologies to be transferred. Exhibit perception criteria for the execution of the technologies ¹⁸.

Technology Transfer Report

Report the information once technology transfer in line with the technology set up. Assessment of the guidance and pre-set perception criteria for all technologies. The technology transfer report should document by both transferring and transferred parties, but those parties ought to compass associate with the content of technologies ¹⁹.

CONCLUSION

Through documentation and higher conversation by the technology transfer team, possess pertinent potency in the transfer of technology accomplished from the development phase to the production phase. Technology transfer thought of as 'no-hit' if the production phase will habitually stimulate the transferred products and its method or methodology suitable for the current design of the products specifications united with the development phase. Hence, the proposed transferring technique will help to

develop the product through the processes mentioned in the documentation report given by quality assurance department.

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