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A Review on Technology Transfer: A Significant Facet in Pharmaceutical Industry

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Abstract

Technology transfer (TT) plays a pivotal role inproduct development,right from drug discovery to full-scale product commercialization, and it is indispensable to ensure the appropriate and seamless transfer of technology in the realm of drug discovery as well as development for novel products. Additionally, it is vital for enhancing drug quality from development phase to final manufacturing process, thereby ensuring consistent and superior quality. The successful growth and commercialization of innovative technologies in the pharmaceutical industry are inherently challenging endeavors, necessitating the utilization of various development tools. Among these tools, technology transfer emerges as the most popular approach to foster successful innovation. This article aims to delve into the process of technology transfer, outline the steps involved, elucidate the reasons for its adoption, highlight its significance, and address the pertinent issues related to transfer of technology in pharma sector.

Keywords: Technology Transfer, Modes, Procedure, Barriers, Approaches, Success.

1. Introduction

Proper technology transfer (TT) holds immense significance in the realm of drug discovery as well as development for novel medicinal products, and it plays a crucial role in upgrading drug quality from the research and development phase to the final manufacturing process while ensuring the seamless transfer of stable quality [1]. World Health Organization (WHO) defines technology transfer as logical procedure encompassing transfer of processes, documentationand professional expertise between research and development departments and manufacturing sites [2].TT is systematic procedure employed to transfer documented knowledge and experience toresponsible and authorized party,which is gained during development and commercialization, and additionally it involves transfer of both documentation and the demonstrated proficiency of the receiving unit (RU) in effectively executing the critical aspects of TT, satisfying all stakeholders and relevant regulatory bodies. In pharmaceutical context, TT refers to transfer of the manufacturing process for a new pharmaceutical Drug Substance (DS) as well as Drug Product (DP) from the research and development site to the receiving or designated commercial manufacturing site. This encompasses all the requisite knowledge, information, and skills necessary for DS and DP manufacturing at the receiving site. Technology transfer can be categorized into vertical and horizontal processes. Vertical technology transfer entails the transfer of data from basic research to development and production stages, while horizontal TT involves the application of technology in diverse contexts or locations [3].Commercial TT is a mutually agreed and goal-oriented process, hinging upon a comprehensive understanding of the methods or the ability to accurately predict the long-term performance of a process, and also is integral and critical to drug discovery and development for new medical products. It aids in dosage formdevelopment through process efficiency, product quality maintenance, and the establishment of standardized processes, which facilitate cost-effective production [4]. In pharmaceutical industry, TT encompasses the successful progression from drug discovery to product development, clinical trials and full-scale commercialization, wherein it encompasses not only patentable aspects of production but also the business processes, knowledge and skills required. It comprises transfer of formulation and analytical strategies from the research and development department to the production department, scaling up drug product from the laboratory to the production scale [6].A proper TT is vital to drug discovery and development of

new medicinal products, ensuring the planned upgrade of drug quality from research to manufacturing stages, and the seamless transfer of stable quality. Therefore, three criteria must be met: First, knowledge must be systematic, organized in a manner that provides solutions to problems. Second, knowledge must exist in tangible forms, whether in individuals' expertise or documented resources, and must be transferrable from one person to another. Third, knowledge must be purpose-oriented, capable of being utilized for practical purposes in industries, agriculture, and commercial fields [7].

2. Need of TT in Pharmaceutical Industry

In pharmaceutical industry, TTis the process that includes necessary processes for the successful transition from drug discovery to product development, clinical trials, and ultimately, full-scale commercialization. Itis the process through which technology developer enables a commercial partner to utilize and exploit the technology. In the context of pharmaceuticals, the preparation of dosage forms requires scaling up at various stages. For instance, laboratory development on a small scale, typically ranging from 0.5-2 kg batches, can be escalated to small batches up to 10 kg, and then further to large batches up to 100 kg on pilot scale, and ultimately, production scale can range from 200 kg to well over 1000 kg.TT entails the manufacturing of drug products using larger equipment or implementing continuous processing techniques on pilot scale equipment. The scale-up process involves not only transfer of technology but also transfer of accumulated knowledge acquired during the development of products and processes at small-scale [7-9].

3. Objectives of TT

In order to facilitate the transfer of processing information from the research and development (R&D) stage to production site, it is essential to compile and document the relevant information gathered during R&D. This includes data on the formulation, analytical methods, process parameters, equipment specifications, and any other details in relation with development of the drug product.When transferring technology for an existing drug product to different locations, it is crucial to effectively communicate the processing information. This involves sharing comprehensive documentation that encompasses the formulation details, manufacturing procedures, quality control measures, and any specific considerations or modifications required for the new location.Smooth technology transfer can be achieved by following specific procedures and considering key points for both types of technology transfer. This includes creating a well-defined transfer plan, thus establishing clear communication channels between

sending and receiving sites, conducting thorough risk assessments, ensuring compatibility of equipment and facilities, validating analytical methods, and addressing any regulatory requirements that may arise during the transfer process.The gathered knowledge serves as the foundation for developing a manufacturing control strategy. It involves using the acquired information to design a robust process, determine critical process parameters, and establish appropriate acceptance criteria. This knowledge is also utilized for process qualification, ensuring that the manufacturing process consistently produces products of the desired quality.Furthermore, continuous improvement efforts are based on the gathered knowledge to optimize the process and enhance product quality over time.Continuous monitoring is essential to track the transition of product/process/analytical method knowledge between the development and manufacturing sites. This involves closely monitoring the transfer process, conducting regular reviews and assessments, and addressing any discrepancies that may arise during the knowledge transfer, and to ensure that the process and parameter variability is controlled and sufficient for the demands of commercial production, rigorous measures must be in place. This includes implementing robust process controls, conducting comprehensive process validation, performing regular process monitoring, and implementing appropriate quality control measures to mitigate any potential variability.Verification of parameters established during development is crucial for ensuring they remain within the determined design space when scaling up the process, and it involves conducting thorough evaluation and assessmentof the process at the new scale, verifying that the established parameters are still effective and appropriate, and making any necessary adjustments or optimizations to ensure the process remains robust and meets the desired quality standards.

4. Modes ofTT

Licensing stands as the most prevalent method of technology transfer, encompassing two main strategies: licensing in and licensing out. Under the licensing-in strategy, small companies lacking research facilities seek to acquire research capabilities by purchasing them from other entities. Conversely, in the licensing-out strategy, a company grants the rights to its technology to another party [4].

4.1. TT from government labs to the private sector

This form of TT holds several advantages. Government labs can receive substantial financial support and funding from the government for their research endeavors, while the technology developed by these labs can be effectively transferred to the private sector [10].

4.2. TT between private sector firms within the same country

This type of TT often arises due to financial constraints or lack of comprehensive knowledge regarding regulatory requirements, wherein a private sector firm that has developed a particular technology can be compensated by another sector that intends to utilize the technology [8].

4.3. TT from academia to private firms

Academic institutions actively engaged in research play crucial role in developing technology and subsequently making it available to private firms. Collaborative efforts between private firms and academic institutions can lead to cost savings and a more efficient transfer of knowledge and technology [11].

4.4. Collaborations among academia, government, and industry

In this form of TT, the government provides necessary funding to academic institutions to develop technology that can subsequently be transferred to the industry. Such collaborations foster innovation and facilitate the translation of research into practical applications within the industrial sector [12].

5. Responsibilities of Different Departmentsin TT

5.1. Research and development department (R&D)

The TT of products and associated documentation should be initiated by R&Ddepartment, as it plays crucial role in this process by conducting a comprehensive review of product development report, which encompasses essential aspects such as storage conditions, shelf life, equipment requirements based on available facilities, relevant tests with method validation, analytical methods, regulatory requirements, safety considerations, and label claims. This thorough review ensures that each critical control point is identified and addressed effectively. The aim is to facilitate a seamless and successful transfer of technology from R&D to the subsequent stages of production and commercialization while adhering to regulatory standards and ensuring product quality and safety.

5.2. Quality assurance department

The responsible party should thoroughly review the documents to ensure their adequacy and compliance with the required standards, and are also tasked with preparing the necessary process

validation documents. Additionally, it is important to conduct a comprehensive review of the analytical validation methods in collaboration with the quality control team to ensure proper regulation and adherence to quality standards. This careful review and validation process play a critical role in maintaining the integrity and reliability of the technology transfer, ensuring that all necessary procedures and documentation meet the required criteria.

5.3. Production department

The assigned individual is responsible for evaluating the suitability of manufacturing and packaging processes, as well as the equipment and facilities involved, and their role includes assessing whether the processes and equipment align with the requirements and standards set forth. Furthermore, they must ensure the availability of necessary resources to effectively execute the manufacturing process. This evaluation process aims to guarantee that the manufacturing and packaging operations are conducted in a suitable environment and with the appropriate resources, ultimately contributing to the successful technology transfer and ensuring the desired quality and efficiency in the production phase.

5.4. Quality control department

The individual responsible conducts a thorough review of the analytical method requirements and assesses the availability of suitable instruments for their execution. They are also in charge of organizing the analytical method transfer for both the drug substance and the drug product, which involves coordinating the transfer process for ensuring successful transfer of analytical methods from one location to another, while maintaining their accuracy and reliability. The aim is to ensure seamless continuity and consistency in the analytical testing procedures, thereby supporting the overall TT and contributing to quality control of drug substance as well as drug product [13].

6. World Health Organization (WHO) Guidelines for TT

The WHO guidelines for technology transfer (TT) serve as a flexible framework, offering guiding principles to prioritize the quality aspects of pharmaceutical products according toWHO's mandate, and this transfer process follows a sequence that encompasses development, scale-up, manufacturing, production, launch, and approval phases [13].These guidelines provide fundamental guidance and general recommendations for conducting a successful intra or inter site transfer of technology. The aim is to address the essential considerations that satisfy regulatory authorities overseeing the transfer process, and it is significant to note that each TT

project is unique and the WHO document does not provide an exhaustive set of guidelines. Additionally, guidelines do not cover legal, financial, or commercial aspects related with TT projects [13].

7. TT Protocol

TT process involves two key units, SU (sending unit) and RU (receiving unit), and in certain cases, additional unit may be involved to oversee and approve the transfer. Formal agreement is established between the parties, outlining their respective responsibilities before, during, and after the transfer. Effective management is essential for successful TT, with proper execution and documentation, and project management plan is developed to identify and control all necessary activities from the beginning. The transfer protocol outlines the sequential stages.SU is responsible for providing validation documentation for the process, and prior to the transfer, SU or third party should assess the RU's readiness, including premises, equipment, and support services.Both SU and RU must verify the availability of satisfactorily completed validation protocols, including installation qualification and operational qualification data at RU site.

8. Phases of TT

The successful transformation of prototype into marketable product relies on the collaborative efforts of multiple individuals. During the formulation development stage, it is crucial to thoroughly understand the operational procedures, critical and non-critical parameters, production environment, instrumentation, and convenience of excipients. These factors must be considered early on to ensure a seamless scale-up process [14]. The technology transfer process encompasses several steps [15, 16] as described below.

8.1. Technology development by R&D (research phase)

R&D selects materials and designs procedures based on characteristics of the innovator product, wherein various tests and compatibility studies are conducted to ensure that the quality of the product meets the innovator's specifications, and also stability studies are performed for both the innovator product and the product under development.

8.2. TT from R&D to production (development phase)

R&D provides a TT dossier containing essential information about the formulation and drug product to product development laboratory.

8.3. Optimization and production

Validation studies are conducted to ensure that manufacturing process can consistently produce a stable product based on the transferred manufacturing formula, and production is implemented once validation studies have been completed. The manufacturing department assumes responsibility for technology acceptance and validation. The R&D department, which is transferring the technology, should also be responsible for validation processes such as performance qualification, cleaning and method validation, and scale-up involves transfer of technology accumulated during small-scale product development. It is crucial to consider production environment and system during the method development stage, as effective TT plays a vital role in achieving process efficiency and maintaining product quality. By following these steps and ensuring a smooth technology transfer, pharmaceutical companies can enhance process efficiency, uphold product quality, and ultimately bring successful products to market.

9. TT Documentation

Typically, TT document serves as a comprehensive record outlining the contents and procedures involved in transfer process between the transferring and transferred parties, and each step, from R&D to production, should be thoroughly documented and clearly defining task assignments, responsibilities and acceptance criteria for completion of each transferred technology. The QA department assumes the responsibility of reviewing and approving the documentation related to all aspects of technology transfer [17, 18].

9.1. Development report

The development report, compiled by the R&D department, serves as a technical document capturing the progression of drug substance as well as product development, and this report plays a vital role in substantiating the rationale behind the quality design of the drug, including its specifications and test methods.

9.2. TT plan

TT plan outlines the items, contents, detailed procedures, and transfer schedule for each individual technology being transferred, and the transferring party prepares the plan before initiating the transfer and reaches an agreement on its contents with transferred party [19].

9.3. Report

Upon completion of TT, a comprehensive report is generated. This report confirms that the data have been collected in accordance with the technology plan and evaluated to ensure compliance with the predetermined acceptance criteria.

9.4. Exhibit

Following the scale-up batch of product, exhibit batches are manufactured. These batches involve increased batch sizes and the utilization of specific equipment and processes. Exhibit batches are created primarily for filing purposes with different regulatory agencies [20].By adhering to meticulous documentation and reporting practices throughout the technology transfer process, pharmaceutical companies can ensure transparency, compliance, and successful TT between parties.

10. TT Procedure

10.1. Manufacturing and packaging procedure

After3 validation or commercial batches are completed, R&D is responsible for preparing TT dossier (TTD), which is then undergoes review by the Heads of Production, QC, and Engineering, and is ultimately approved by the Head of QA. Following the successful TT for the manufacturing process, the production department assumes responsibility for the manufacturing of the respective product. In the event of any issues, QA conducts an investigation and submits an investigation report to R&D through an Inter-Office Communication (IOC). Any process deviations are supported by applicable deviation/change control forms. For third-party products, the respective organization provides TTD to QA[21, 22].

10.2. Analytical method transfer procedure

The analytical department initiates the transfer of analytical methods for all validated methods, wherein analysts from the analytical department, along with QC analysts, perform analyses. A comprehensive report is prepared, summarizing the results and conclusions, and it undergoes review by the Head of QA and the Head of QC before being approved by the Head of QA. This analytical method transfer process is considered complete upon certification by the analytical department, QA and QC that the method meets the acceptance criteria. Finally, an analytical method transfer report is prepared [23-25].By following these meticulous procedures for manufacturing and packaging, and analytical method transfer, organizations ensure the smooth transfer of technology, maintain product quality, and comply with regulatory requirements.

11. Barriers of TT

The implementation of automated manufacturing processes is aimed at enhancing efficiency and reducing costs. Local manufacturers in developing nations encounter significant obstacles in meeting global quality standards and securing substantial market share. Expanding their market

presence would enhance profitability. However, limited access to scientific journals poses challenges for scientists in developing nations, hindering their progress. Complying with international standards not only ensures profitability but also facilitates global trade opportunities. Nevertheless, international regulations focused on safeguarding national security and controlling the dissemination of critical technologies also impose restrictions on technology transfer. Insufficient funding for research areas crucial to developing world remains a prevalent issue. Pharma industry necessitates a skilled workforce, but the sector suffers from high labor turnover and absenteeism due to unfavorable working conditions, which negatively impact productivity [26-28].

By embracing automation in manufacturing processes, companies can improve operational efficiency and cost-effectiveness. Local producers in developing countries face notable hurdles in meeting global quality standards and gaining a substantial market share, however, capturing a larger market share is crucial for their profitability. Restricted access to scientific literature poses a significant challenge for scientists in developing nations, impeding their progress in research and innovation. Nonetheless, international controls aimed at protecting national security and preventing the proliferation of sensitive technologies also impose constraints on technology transfer, and furthermore, insufficient funding for research areas vital to the developing world remains a pressing concern. [26-28].

12. Approaches to Overcome TT Barriers

12.1. Facilitating the commercialization of publicly funded technologies

A proposed approach involves granting institutions that receive public research funding, the right to obtain and exploit patents for inventions, resulting from their research endeavors.

12.2. Political stability and transparent governance

The level of political and economic stability within a country plays crucial role in attracting TT and ensuring its sustainability, wherein effective political leadership is essential for addressing global and local health challenges and strengthening healthcare systems.

12.3. Research tool patents and public sector freedom to operate

Patents can sometimes hinder public researchers from conducting their research or making their research outputs accessible, and this issue is further complicated by the tendency of publicly funded research laboratories to avoid utilizing patented technologies without permission, even in countries where relevant patents are not enforced.

12.4. Adequate capital markets

Governments seeking to enhance their technological capabilities often prioritize attracting direct investments and maximizing the spillover benefits of such investments, and to achieve this, well-functioning capital markets are necessary.

12.5. Alignment with economic development priorities

Given the limited resources available to governments, TT initiatives should be realistic and aligned with policy goals, and implementing TT policy poses greater challenges compared to building upon existing sectors.

12.6. Collaborative research agreements

Encouraging global support for public sector research can be achieved through cooperative research agreements that target specific objectives, and it is more feasible to focus efforts on technologies that hold significant social benefits for developing nations.

12.7. Potential treaty on scientific access

A proposal for an international treaty on knowledge and technology access, based on reciprocity principles similar to those in international trade negotiations, has emerged. The concept aims to create non-zero-sum arrangements where the free exchange of scientific ideas benefits all parties involved. Such agreements could be established bilaterally or multilaterally [29-31].

13. Success of TT

The success of TTis attributed to several key factors, often referred to as "Five Cs": Communication, Certainty, Challenges, Capacity, and Commitment.

13.1. Communication

Effective communication plays crucial role in successful technology transfer, especially considering the long distances and timeframes involved in the process. Open and collaborative communication between key stakeholders helps overcome barriers and facilitates smooth transfer.

13.2. Certainty

A lack of certainty and high levels of risk pose significant obstacles to establishing and operating functional markets. By addressing these uncertainties and reducing risks, technology transfer can thrive. Providing clarity and certainty for developers, suppliers, and recipients enhances the transfer process.

13.3. Challenges

Technology transfer encounters various barriers and challenges throughout the entire transfer chain, from the supply side to the demand side. These barriers can arise at every node and are exacerbated by restrictions on the movement of information and materials. Identifying and addressing these challenges is important for successful technology transfer.

13.4. Capacity

Creating favorable conditions for TT involves building the necessary capacity among all stakeholders to fulfill their roles and responsibilities effectively and efficiently. This requires equipping key players with the knowledge and skills required to contribute to transfer process.

13.5. Commitment

Commitment is vital for successful TT, and It involves a dedicated effort to overcome challenges, provide technology users with desired choices, enhance communication among stakeholders, reduce risks, and strengthen the enabling environment. Strong commitment ensures a robust foundation for technology transfer.

By emphasizing effective communication, providing certainty, addressing challenges, building capacity, and fostering commitment, TT can be successfully facilitated [34-36].

14. Conclusion

In pharma sector, TT refers to the process of transferring information and technologies essential for ensuring the quality of drug manufacturing, and it also involves the exchange of knowledge between different departments within a company and between companies, spanning from small-scale to large-scale production. The key to successful TT lies in establishing a strong relationship between the transferring and receiving parties, and it should be noted that TT is not a one-time occurrence, but rather entails ongoing information exchange to support continuous product manufacturing.

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