

TECHNOLOGY TRANSFER IN PHARMACEUTICAL INDUSTRY: AN OVERVIEW

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ABSTRACT

Technology transfer refers to the process of transferring scientific ideas and innovations from one unit to other. Technology Transfer involves the transferring of details about the formulation and analytical techniques from one department to another such as from R&D to Manufacturing unit and from laboratory scale to Pilot plant scale. Technology transfer is beneficial to the development of dosage forms in a variety of different ways, including improving process output, maintaining product quality, and establishing a consistent process that allows for cost-effective manufacturing. The intend of this article is to address the technology transfer process, various aspects of technology transfer, stages involved in technology transfer, the reasons for using technology transfer in the pharmaceutical industry.

KEYWORDS: Technology Transfer, Stages in technology transfer, Barriers, Scale-up, Product Commercialization.

1 INTRODUCTION^[1,2,3]

Technology transfer is also known as Transfer of Technology (TOT) is the process of moving knowledge, experience, techniques, manufacturing operations, samples, other details, and Capabilities between corporations, governments, and academic institutions to assure that scientific and technical advances are open to many consumers who can then further adapt and exploit the technology into new goods, processes, software, materials, or services.^[1,3] Technology transfer can benefit dosage form manufacturing in several ways, including

improving effectiveness over time, ensuring product quality, and establishing a comprehensive plan for cost-effective manufacturing.

The technology innovator enables his or her technology available to business partners who can use it. “Technology transfer” is a term used in the pharmaceutical industry to describe the processes of ultimately progressing from drug discovery to manufacturing process, clinical studies, and finally full-scale commercialization.^[2]

2 VARIOUS ASPECTS OF TECHNOLOGY TRANSFER^[4,5,6,7,8]

Any of the following techniques could be used to migrate technology:

- Government laboratories to the private industry.
- Between organizations in the same country's private sector
- From universities to the Private sector, there's a lot to learn.
- Between academia, government, and industry^[5,6]

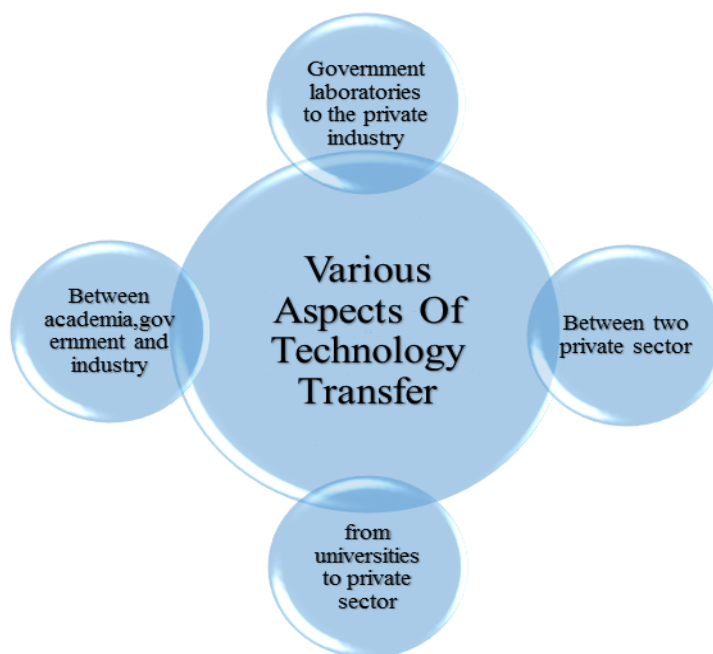


Fig 1. Various aspects of Technology Transfer.

A Government laboratory to the Private industry

This kind of technology transfer is useful as government laboratories will receive financial assistance and funds from the government.

They conduct research and develop technology that is used in the private market.

B Between organizations in the same country's private sector

This kind of technology transfer occurs due to a major lack of financial assets or a lack of understanding of regulatory requirements. As a result, the private sector that develops the technology is paid by the private sector that utilizes it.

C Universities to the private sector

Academic institutions that engage in active research build technology and forward it to private companies. By working together, Money can be saved by partnering private businesses with institutions.

D Between the academies, the private sector, and government

The government contributes funds to research universities to help them develop innovative ideas that can be used in this type of technology transfer.^[4,7,8]

3 STAGES INVOLVED IN TECHNOLOGY TRANSFER^[5,9]

The process of drug discovery and development for new pharmaceutical products highly depends on technology transfer. The decision to move products from one production facility to another the economics of a site is often the driving force behind it. Data collection, data analysis, and regulatory effect are all important stages of the process, with any change approvals being especially important.

The transfer of technology is crucial to understand the procedure of operations used critical and non-critical parameters of each operation, output during the creation of a formulation.

Environmental conditions, facilities, and excipient availability should all be considered during the early stages of formulation production to ensure a good scale-up.^[9]

A The Development of Technology by R&D (Research Phase)

- R&D is in charge of procedure design and excipient selection. Based on the innovator product, R&D establishes material selection and procedure design.
- R&D identifies requirements and quality – Product quality should follow the specifications of an innovator product

B Transfer of Technology from R&D to Production (Development Phase)

The R&D department sends a technology transfer dossier (TTD) document to the product development lab, which includes the following details and drug product.

- THE MASTER FORMULA CARD (MFC) – The master formula card is an important document that contains the product name, strength, generic name, MFC number, Page number, Effective date, shelf life, and market details for a pharmaceutical product.
- THE MASTER PACKING CARD (MPC) – Provides information on the packaging style and material used, as well as the packaging's stability profile and shelf life.
- THE MASTER FORMULA – It specifies the order of formulation and production orders, as well as the procedure and environmental conditions.
- The Standard Test Procedures (STP) and Specifications – It aids in the recognition of committed individuals.

In-process requirements, product release criteria, and finished product specifics for ingredients and excipients.

C. The Optimization and Production (Production Phase)

The validation studies – After validation studies, product manufacturing is applied to ensure that the process will stabilise the product using transferred manufacturing techniques.

Scale up for production – entails the transition of technology during small-scale product and process growth. It is critical to understand the production environment and system during process development, and operators should focus on this.^[9]

On ensuring that their part of the manufacturing process runs smoothly.



Fig 2: Flow chart of Process of Technology transfer.^[5,9]

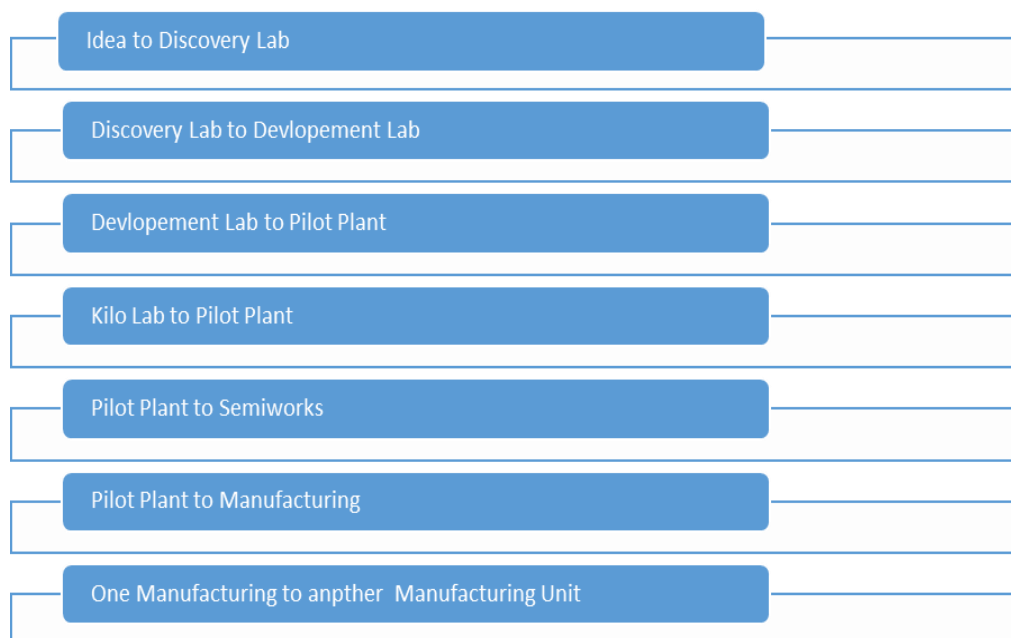


Fig. 3: Flow chart of Technology Transfer in Pharmaceutical Industry.

4 REASONS OF TECHNOLOGY TRANSFER^[(10,11,12,13,14)]

There are many reasons why a company would choose to share its technology with others.

a Due to lack of assets

Making collaborations with partners who can help to accelerate the technology development and bring it to market will help to use maximum resources of another firm which will help in the development of pharmaceutical dosage to meet quality standards.

b Due to a lack of money to commercialize the product

Many small scales pharmaceutical industries face the problem of scarcity of funds. technology transfer could help to meet regulatory requirements & to commercialize products to these organizations.

c Due to lack of marketing distribution ability and distribution resources

Associating with a company that has a broad market distribution capacity will help increase a product's market value.^[(10,11,12,13,14)]

5 CONCLUSION

Technology transfer is the process of forwarding technical ideas and innovations from one unit to another. It entails moving formulation and analytical techniques from one department to another, such as from R&D to manufacturing and from lab scale to pilot plant scale. It's the procedure by which a technology's original inventor makes his or her technology available to

a business partner who would use it. Moving technology from research to larger-scale production is important. Technology transfer encompasses not only patentable elements of manufacturing but also market processes such as technology and skills. Communication between teammates, direct communication between technical participants, and effective and timely communication with the regulatory team are all critical to the success of technology transfer. To ensure the effectiveness of technology transfer, both the sending and receiving units must participate equally in the process.

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