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## AN OVERVIEW ON TECHNOLOGY TRANSFER OF PHARMACEUTICAL INDUSTRY

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**ABSTRACT:** The purpose of this review article is to discuss in detail about technology transfer in the pharmaceutical industry. The article highlights the objective, reasons for undergoing technology transfer, factors which affect technology transfer, steps involved in technology transfer process. Clearly explains the technology transfer documentation part this is an attempt to understand the aspects related to technology transfer. The transfer may be said to be successful if the receiving unit and the transferee can effectively utilize the technology for business gain. The success of any particular technology transfer depends upon process understanding or the ability to predict accurately the future performance of a process. Three primary considerations to be addressed during an effective technology transfer are the plan, the persons involved and the process. 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.

**INTRODUCTION:** Technology transfer is transferring of details of concerning formulation and analytical strategies from one area to another area that's from R&D to Production department and succeeding drug product from the laboratory scale to the production scale<sup>1</sup>. In Pharmaceutical Industry, "Technology Transfer" refers to a method of victorious steps forward from drug discovery to product development, clinical trials and at last to full-scale commercialization<sup>2</sup>. Researcher of technology creates his technology existing to a commercial collaborator which will make use of the technology.

It's an organized procedure that's followed to pass the documented information and know-how knowledge gained throughout development<sup>3</sup>. According to WHO outlined as a logical procedure that controls the transfer of any method alongside its documentation and professional expertise between development and manufacture or b/w manufacturer site<sup>4</sup>. It is useful to build up dosage form in various ways because it provides efficiency in development, maintains quality of product, helps to realize a standardized process that facilitates price-effective production<sup>5</sup>. There are 3 standards in the definition of technology:

- First, knowledge must be systematic. This means that it must be organized in terms of providing solutions to problems.
- Second, knowledge must exist in certain places like in someone's head or documents and must be able to be presented, so no matter

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what it means it must be able to be transferred from one person to another.

- Third, it must have purpose-orientation, so that it can be utilized for useful purposes in industry, farming, and commercial fields<sup>6</sup>.

There are two sorts of technology transfer processes<sup>7</sup>:

- ✓ Vertical
- ✓ Horizontal

Vertical technology transfer refers to the transfer of data from basic study to development and production respectively. Horizontal technology transfer refers to the movement and application of technology is to be used in one place or context to a different place. Commercial technology transfer is mutually agreed, and goal destined. The achievement of any specific technology transfer depends upon method understanding or the flexibility to predict exactly the long term performance of a process<sup>1</sup>.

Designing drug product → Developing → drug product → Technology transfer → manufacturing site

**1.1 Goals of Technology Transfer:** It is to transfer product and process knowledge between and manufacturing and within or between manufacturing sites to achieve product realization. This knowledge forms the basis for the manufacturing process, control strategy process validation approach and ongoing continual improvement<sup>9</sup>.

### 1.2 Objective of Technology Transfer:

- To explain the processing information to transfer technology from R&D to production site by listing out information gathered during R&D.
- To explain the processing information to transfer technology of already existing drug product between various places.
- To illustrate specific procedures and points to be considered for the above two types of technology transfer to contribute smooth technology transfer<sup>10</sup>.

**1.3 Methods for Technology Transfer:** Licensing is the most common method of technology transfer. There are two strategies for licensing one is licensing in and licensing out. In licensing - in strategy, small companies and lack facilities to do basic research and these facilities want to buy other research. In case of licensing - out strategy, the company right is given to another party<sup>1</sup>.

**1.4 Facets of Technology Transfer:** The technology transfer could happen any of these following ways:

- Government labs to the private sector
- Between the private sector firms of the same country
- From academia to private sector firms
- Academia, government, and industry collaborations<sup>1</sup>.

**1.4.1 Government Labs to Private Sector:** This type of technology transfer is advantageous as the government labs can get good financial support and funds from the govt. for their research work, and the technology developed by them reaches the private sector.

**1.4.2 Between the Private Sector Firms of the Same Country:** This type of technology transfer generally occurs due to lack of appropriate financial resources or inadequate knowledge of regulatory requirements thus, the private sector that develops the technology is paid by another sector that absorbs the technology

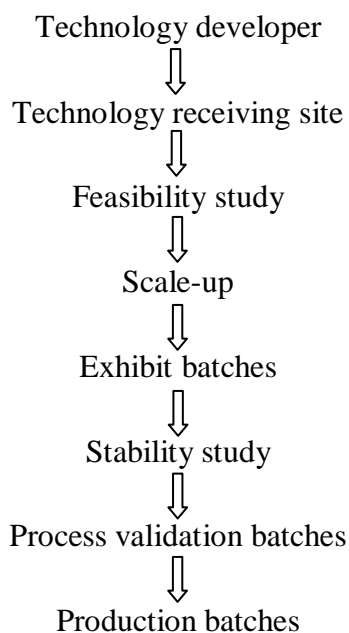
**1.4.3 From Academia to Private Sector:** Academic sectors that are actively involved in research develop the technology and make it available to private firms. By collaboration of private firms with the institutions, money can be saved.

**1.4.4 Between Academy, Private and Government Sectors:** In this type of technology transfer government provides necessary funds to the academic institutions in developing technology that can be transferred to the industry.

**1.5 Importance of Technology Transfer:** Technology transfer shows important in extended benefits of R&D to the society. In the pharmaceutical industry, designing of dosage form

needs scale up at several stages, such as pilot-scale from 0.5 - 2 kg batch can be scaled up to 5/10 kgs then to 20/100 kg. Production scale typically ranges from 200 kg to 1000 kg. It involves manufacturing of drug product with increasing their batch sizes with the help of larger equipment. Generally scale-up involves transfer of technology and transfer of knowledge that has been accumulated during small scale development of product and process. Usually research has been carried out on a small scale before it produced for large scale commercial batch. Technology transfer is important for research activities to materialize on a large scale for commercialization especially in case of developing a drug product<sup>13</sup>.

### 1.6 Flow Chart of Technology Transfer in the Pharmaceutical Industry:



### 1.7 Reason for Technology Transfer<sup>15</sup>:

- **Lack of Manufacturing Capacity:** the developer of the technology could solely have to produce instrumentation that appropriates for lab and small scale operations and should partner with another organization to try to do massive scale manufacturing.
- **Lack of Resources to Launch Product Commercially:** The original inventor of technology may only have resources to conduct early stages research and phase - I and II clinical trials.

- **Lack of Marketing Distribution and Distribution Capability:** The developer of the technology could have absolutely developed technology and even have obtained regulative approvals and product registration, but it may not have the marketing and distribution channels and should collaborate within another organization that has the capability.

### 1.8 Factors that Affect the Process if Technology Transfer in the Pharmaceutical Industry:

- Investment in R&D.
- Establishing the link between production and research.
- Data development within the field of technology transfer methods.
- Organizational, equipmental and informational infrastructures.
- Awareness of basic and necessary factor need for technology transfer.
- Consideration of existing and old technologies<sup>16</sup>.

### 2. Steps Involved in Technology Transfer:

Transformation of Pharmaceutical prototype into a successful product needs the cooperation of many people. During development of a formulation, it is vital to understand procedure of operations used, critical and non-critical parameters of every operation, production environment, instrumentation, and excipient convenience, that ought to be taken into consideration throughout the first phases of development of formulation, so that successful scale-up can be carried out<sup>17</sup>.

### Various Steps Concerned in Technology Transfer as Follows:<sup>16, 17, 18</sup>

#### 2.1 Research Phase (Development of Technology by R&D):

- Design and Choice of Excipients by R&D:** choice of materials and design of procedures are carried out by R&D on the premise of innovator product characteristics. For this completely different tests and compatibility, studies are performed.

**b) Identification of Specifications and Quality by R&D:** Quality of product ought to meet the specifications of an innovator product. For

this stability, studies are carried out for innovator product and for product that is to be manufactured.

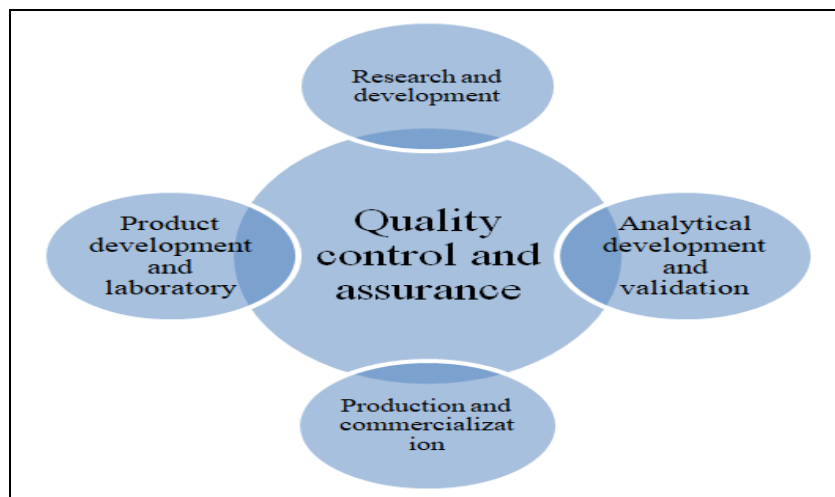


FIG. 1: REPRESENTATION OF TECHNOLOGY TRANSFER

## 2.2 Technology Transfer from R & D to Production (Development Phase):

R&D provides technology transfer dossier (TTD) document to a product development laboratory that contains all data of formulation and drug product as given below:

- a) **Master Formula Card (MFC):** It includes product name along with its strength,
- b) The generic name, MFC number, page number, effective date, shelf life, and market.
- c) **Master Packaging Card:** It provides data regarding packaging sort, the material used for packaging, stability profile of packaging and shelf life of packaging.
- d) **Master Formula:** It describes formulation order and manufacturing instructions. Formulation order and Manufacturing Instructions offer the plan of process order, surroundings conditions needed and manufacturing instructions for the development of dosage form.
- e) **Specifications and Standard Test Procedures (STPs):** These help to know active ingredients and excipients profile, in-process parameters and specifications, product release specifications and finished product details.

## 2.3 Optimization and Production (Production Phase):

- a) **Validation Studies:** Validation studies verify that the method will stabilize the product based on transferred manufacturing formula and production is enforced once validation studies. The manufacturing department is accepting technology and liable for validation. The research and development department transferring technology ought to take responsibility for validation like performance qualification, cleaning and method validation.
- b) **Scale Up for Production:** Scale up involves the transfer of technology throughout small scale development of the product and processes. It's essential to contemplate the production surroundings and system throughout the development of the method. Operators ought to target keeping in mind that the production process can run smoothly if technology transfer is enforced thoughtfully. Effective technology transfer helps to provide process efficiency and maintain product quality.

**3. Technology Transfer Team:** As the team concept is always the best approach to achieve successful technology transfer projects. The core technology transfer team must be commissioned immediately following the decisions of the



executive management to pursue the drug candidate to commercialization. A typical technology transfer core team will likely be comprised of individual's representatives of the different segments of the

business<sup>19</sup>. The technology transfer team consists of the following members, and their responsibilities are given below:<sup>20</sup>

**TABLE 1: TECHNOLOGY TRANSFER TEAM MEMBERS AND THEIR RESPONSIBILITIES**

TECHNOLOGY transfer team members	RESPONSIBILITIES
Process Technologist	a) Central focus for transfer activities. b) Collates documentation from the donor site c) Performs initial assessment of the transferred project for Feasibility, Compatibility with site capabilities and Establishes resource needs.
QA Representative	d) Reviews documentation to work out compliance with marketing authorization (MA) e) Reviews analytical strategies with QC to work out capability, instrumentation training requirements. f) Initiates conversion of donor site documentation into local systems or format. g) Initiates or confirms regulatory needs, e.g., an amendment to manufacturing license; variations to MA if method changes needed, etc.
Production Representative	h) Reviews process instructions (with process technologist) to verify capacity and capability. i) Considers any safety implications, e.g., solvents; toxic; sanitizing materials. j) Considers the impact on local standard operating procedures (SOPs). k) Considers the training requirements of supervisors or operators.
Engineering Representative	l) Reviews (with production representative) instrumentation requirement. m) Initiates required engineering modifications, change or part purchase. n) Reviews preventative maintenance and calibration impact, e.g., use of a lot of aggressive ingredients; more temperature-sensitive method, and modifies consequently.
QC Representative	o) Reviews analytical requirement. p) Availability with instruments. q) Responsible for analytical technique transfer for drug substance and drug product.

#### 4. Technology Transfer Documentation:

Technology transfer document demonstrates the contents of technology transfer from transferring and transferred parties. Each step from research and development to production should be documented, task assignments and responsibilities ought to be processed and acceptance criteria for completion of technology transfer regarding individual technology to be transferred. Its duty of the Quality Assurance department to examine and approve the documentation for all processes of technology transfer<sup>21-22</sup>.

a) **Development Report:** It is used at the pre-approval examination as a valid document for quality design of new drug. The ultimate goal for successful technology transfer is to possess documented evidence. The R&D report may be a file of technical development, and also the research and development department is accountable for its documentation. This report is a crucial file to point rationale for the quality design of drug

substances and drug specifications and test methods. Additionally, this report can be used as raw data just in case of post-marketing technology transfer.

The development report contains the following:

- Data of pharmaceutical development of new drug substances and drug products at stages from the early development phase to final application of approval.
- Data for raw materials and components
- Rational for the dosage form and formula designs and design of manufacturing ways. modification in histories of vital processes and control parameters
- Stability profile, specifications and test methods of drug substances, intermediates, drug products, raw materials, and components, which also include the validity of specification range of important tests such as contents impurities and dissolution.

- Rational for selection of test methods, reagents and columns Verification of results.

**b) Technology Transfer Plan:** The technology transfer plan describes the things and contents of technology to be transferred and elaborate procedures of individual transfer and transfer schedule, and to determine judgment criteria for the completion of the transfer. The transferring party ought to 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 created once information is taken consequently to the plan and are evaluated to substantiate that the planned judgment criteria are met. Both transferring and transferred parties will document the technology transfer report; but, they must reach an agreement on its contents.

**d) Exhibit:** After taking a scale-up batch of the product, manufacturing of exhibit batches take place. In case of exhibit, batch sizes are increased along with equipment, and their process is involved. They are done for filing purposes in different regulatory agencies.

### 5. Implementation of Technology Transfer:

- Avoids the technology transfer only by handing over the technology transfer documentation<sup>23</sup>.
- Both parties should cooperate in implementing technology education training and validation at facilities where the transferred technology is actually used.

**6. Verification of Result of Technology Transfer:** After the completion of technology transfer and before the start of manufacturing of the product, the transferring party should verify with appropriate methods such as product testing and audit that the product manufactured after the technology transfer meets the predetermined quality and should maintain records of the results<sup>23</sup>.

**CONCLUSION:** In pharmaceutical trade, technology transfer suggests that action to transfer

of data and technologies necessary to realize quality of design of drugs throughout manufacturing. The technology transfer does not mean one-time actions taken by the transferring party toward the transferred party however, suggest that continuous information exchange between both the parties to maintain the product manufacturing. Technology transfer is a complex issue and should be deal with using holistic approach.

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