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# An Overview: Technology Transfer & It's Process

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ABSTRACT

The term "Technology Transfer" in the field of Medicine refers to the process of progress from drug discovery to development, clinical trials and finally full sales. It is an important step in building a bridge between drug discovery and the development of a new drug product. Creating appropriate clinical practice structures, defining and designing special process equipment, completing process details, and accurately determining measurement parameters requires the concerted efforts of a highly skilled technical transfer team. Successful technology transfer requires careful study as a careful examination of the final production requirements at the beginning of research and development and subsequent development of high-performance development, a comprehensive technology transfer document that provides production both "how to" and "know why," and will serve as a basis for resources and equipment and equipment. of processors and the process of normalizing the process of effective production.

**Keyword :** Technology Transfer Process , Scale Up , Pharmaceutical Commercialization. etc.

## Introduction:

Transfer of technology is defined as "a logical process that controls the transfer of any process
by associating with its writings and its expertise during development or in the middle
create sites. "

- Transfer of technology is integrated and very important in the acquisition and implementation of the drug process with new medical products. [1]
- Technology transfer helps to improve scale forms in a variety of ways as it provides better performance while in operation, the quality of the product is maintained, helping to achieve a standard process that makes it easier it costs effective production. It is a process performed by the first developer of technology makes the technology available to business partners who will use the technology.
- In the field of medicine, "Technology transfer" means the processes of effective progress from drug discovery to product development, clinical trials and full dosage at the end trading. [1]
- The transfer of technology is essential for the researcher to act on a large scale in order to
- trading especially in the case of a developing product. Technology transfer is not involvedonly patentable aspects of production but also includes the business processes such as knowledge and skills.[2]

## WHO guidelines for Technology Transfer (TT) :

1.During the development, scale-up, manufacture, production, and launch phases of a product's life cycle, as well as the post-approval phase, most operations are relocated to an alternate site.

2. A logical procedure that oversees the transfer of any process, including its documentation and professional experience, from development to manufacture or across manufacturing sites is defined as technology transfer. It's a way of communicating documented information and experience gained throughout development and/or commercialization to the appropriate, responsible, and authorised party.

3. Literature searches turned up little material from national or regional regulatory bodies on the subject. Guidelines for intra-company transfers were published by the International Society for Pharmaceutical Engineering (ISPE).

4. Pharmaceutical companies' ever-changing business strategies increasingly include intra- and intercompany technology transfers for reasons such as increased capacity, relocation of activities, or consolidations and mergers. As a result, in its 42nd report, the WHO Expert Committee on Pharmaceutical Preparation Specifications recommended that WHO address the issue by producing WHO recommendations on the subject.

5. Technology transfer necessitates a well-documented, well-planned strategy with skilled and knowledgeable employees operating inside a quality system, with data documentation covering all stages of development, production, and quality control. A transmitting unit (SU), a receiving unit (RU), and a unit overseeing the process (which may or may not be a separate entity) are usually present.

6. If there is documented evidence that the RU can routinely duplicate the transferred product, process, or method against a predefined set of requirements agreed upon with the SU, the technology transfer is considered successful.

7. If the RU notices any problems with the process throughout the transfer, the RU should report them to the SU to ensure that knowledge management is maintained.

8. Technology transfer programmes, especially those involving multiple enterprises, have legal and financial repercussions. If such issues, which could include intellectual property rights, royalties, pricing, conflicts of interest, and secrecy, are expected to have any impact on open communication of technical matters, they should be addressed before and during the transfer planning and execution. Any lack of transparency may result in poor technology transfer.

9. Some of the responsibilities outlined in this document for the SU may also be considered to be part of the management unit responsibilities. The guidelines address the following areas

- Transfer of development and production (processing, packaging and cleaning).
- Transfer of analytical methods for quality assurance and quality control.
- Skills assessment and training.
- Organization and management of the transfer.
- Assessment of premises and equipment.
- Documentation; and qualification and validation. [1]

**Facts of technology transfer :[3]**

The transfer of technology could happen in following ways :

- Government labs to private sector firms.
- Between private sector firms of same country.
- Between private sector firms of different country.
- From academia to private sector firms.

## Process of technology transfer:

**Analysis & Development**

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**Method of Development**

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**Scale -Up**

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**Exhibit Batches**

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**Stability Study**

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**Production Batches**

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**Validation Batches**

I. **Analysis and Development :** Changing the formulation and properties of an existing drug or method of research conducted in laboratories that can end up physically, chemically chemically dehydrated without increasing its durability and safety. must include the acquisition of a brand new organization and certain assets or potential assets in the Pharmacy sector. [5]

II. **Method of development:** Designing medicine as planning and establishing links between the upper and lower production limits that quality specification should be appropriate. Therefore, the standard product will be made into a factory assembly with pre-set details and satisfy the standard style. The production process must be committed to providing a high quality product in consistent production. During the transfer from analysis and development to produce relevant documentation of the meeting details and method is provided twice in the meeting department by the department of analysis and development within the form of a written record. [3]

It includes:

i) Technology Transfer Dossier (TTD): Technology Transfer is written record (TTD) analysis and development provide technology transfer written record (TTD) document to development laboratory that contains all info of formulation and drug product.

ii) Master Formula Card (MFC): Shaping the producing directions, status needed, generic name, strength, master formulation record no. master packaging record no. SPS no, STP no.

iii) Master Formulation Record (MFR): It provides an elaborated description of status needed for producing at the site and the steps concerned in production.

iv) Master Packaging Record (MPR): It provides info relating to the kind of packaging material to be used, the steadiness and also the shelf life of packaging material.

v) Specifications (SPS): These area units the standard side establishing the link between higher and lower producing limit.

vi) Standard Test Procedures (STP): These area units the quality procedures either taken from
any of the aggregation or were set in-house.[3]

III. **Scale-up:** Rate increases in product group size. for example, if a drug gets good results, then it should increase or its batch size may increase to meet the growing demand. because drug or drug prescription is included in the meeting from the driving vehicle (Pilot Batch that is the minimum

volume of sales made due to the operation of the system (but not under cGMP). badly they are expected to be clinically protected and created in the market in vessels suitable for the purpose under the event plan, however, this bulk is not suitable to go with cGMP or cGLP). It is important to think about the meeting and the program in all the development of the method. Completely different activities involved within the production method of the actual volume type such as in the case of pill formulation affected measures of square measurement, filtration, mixing, congestion / dry granulation / wet granulation, compression, coating are employed. Many parameters such as flexibility, cost, responsibility, new quality and products are also considered throughout the size. It was necessary to understand that intelligent communication was essential to the construction and transmission of the road.

IV. **Exhibit Batches:** Exhibit batch is made during production or perhaps during driver installation but must have the same equipment as in the production facility. The batch size should be internal and self-contained so that the stiffness study is conducted in certain fast and long-term conditions. The main purpose of showing the masses is to obtain information on sustainability such as the ICH's directive to apply for the ANDA (Summary of New Drug Application) and to impose restricted regulatory approvals. [6]

V. **Stability Study:** Drug or drug stability research is conducted in three consecutive groups. within which a sufficient amount of drugs or drugs and the constant square measure of rapid and sustained long-term studies, which were assessed at a predetermined time, were collected. The report created by that study is required for filing with limited agencies.

VI. **Production Batches:** Production is enforced when multiple validation studies, stability studies ensure that the transmitted production formula is in a position to deliver a consistent product. While the accepted technology of the manufacturing facility the general department is responsible for performing all the certification style, such as performance qualifications (PQ), cleaning verification, and method verification. [6]

VII. **Validation Batches:**Go to the unit of handling three sets of verification batches with a magnified batch next to the square measurement of the magnified instrumentation. The completeness of product marketing in a number of restricted markets or countries for approval through transfer technology results in increased productivity and profitability. The purpose after using three consecutive sets of square measure is to show the consistency of the method, the reliability and to show that the production method is held in all stages. [6]

**Technology Transfer Team:[1]**

The various persons involved in the process of technology transfer are:

i. **Researchers:** These are the people involved within the analysis and development process in addition to the preparation of general information related to the construction within the type of written account known as the dossier.

ii. **QA Personnel's:** These are the people who are important in the whole process of technology transfer their main job is to make a bridge between technical research and the production unit. Their work includes reviewing documents obtained by the research, understanding and selection lab the best way to use it without losing product. It is the responsibility of QA staff to prepare for regulatory requirements which may include adjusting the verification criteria, designing new SOPs if necessary, preparing the main document such as production Personnel records: Department of engineering, change management, market complaint.

iii. **Engineering Personnel:** Engineering is responsible for controlling the temperature and pressure of a particular area. Along with the production team, it is also considered to evaluate and verify the balance of equipment and machinery.

iv. **Production Personnel:**First, they strive to ensure that the instructions given by QA Personnel's ensure the strength and power of the production unit. It may involve verifying the production records of SOP's Master. Provide training for staff in other productive areas as well staff.

v. **Quality Control personnel:** The Quality Management Department is responsible for setting up inspection procedures and test descriptions and for making assurance methods and QA staff, and is responsible for updating the equipment in QA and conducting quality inspections before and after production.

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