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Review on Technology Transfer in Pharmaceutical Manufacturing

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ABSTRACT:
The goal of this review article is to go through technology transfer in the pharmaceutical business in depth. The goal, reasons for experiencing technology transfer, factors that affect technology transfer, and procedures involved in the technology transfer process are all discussed in this article. This is an attempt to grasp the aspects of technology transfer by clearly explaining the technology transfer paperwork part. If the receiving unit and the transferee can efficiently use the technology for business gain, the transfer is considered successful. Process comprehension or the ability to effectively predict the future performance of a process is critical to the success of any technology transfer. The plan, the people involved, and the procedure are three major factors to consider during a successful technology transfer. Technology transfer does not imply one-time activities by the transferring party toward the transferred party, but rather a constant interchange of information between the two parties in order to maintain product manufacture.

Keywords: Technology Transfer, Transferee, Transferor.

I. INTRODUCTION:

Technology transfer is the process of moving specifics about formulation and analytical strategies from one department to another, such as from R&D to Production, and then from the laboratory size to the production scale. "Technology Transfer" in the pharmaceutical industry refers to a way of taking successful steps forward from medication discovery through product development, clinical trials, and finally full-scale commercialization. A technology researcher develops his technology and then sells it to a commercial collaborator who will use it. It's a method for passing down the documented information and know-how obtained throughout development. According to the World Health Organization, a logical procedure that governs the transfer of any method, along with its documentation and professional competence, from development to manufacture or across manufacturer sites. It is advantageous to construct dosage forms in various ways since it improves development efficiency, preserves product quality, and aids in the realisation of a standardised process that promotes cost-effective production. In the definition of technology, there are three standards:

- To begin, knowledge must be organised. This implies that it must be structured to provide solutions to problems.
- Secondly, knowledge must exist in particular places, such as in someone's head or in documents, and it must be able to also be presented, therefore it must be transferable from one person to another, whatever that implies.
- Third, it must be purpose-oriented so that it may be used for practical reasons in industry, agriculture, and business.

The success of "Technology Transfer" in pharmaceutical manufacturing starts with drug discovery and continues through product expansion and full-scale commercialization. Both the transferor as well as the transferee should take into account the regulatory requirements of their respective nations in every step of the technology transfer process. For an effective technology transfer project to generate results within the predetermined set of standards, documented evidence is required. If there are any problems with the transfer procedure, the transferee should notify the transferor and the problem should be documented. (WHO)

Two types of technology transfer processes are:

- Vertical
- Horizontal

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Fig 1: Technology Transfer Representation.

The movement of data from fundamental research to development and production is referred to as vertical technology transfer. Horizontal technology transfer is defined as the movement and use of technology from one location or context to another. Commercial technology transfer is jointly agreed upon and directed toward a specific aim. Any specific technology transfer is contingent on procedure understanding or the ability to accurately estimate a process' long-term performance.
Creating a drug product-→ Development-→ drug product -→Technology transfer -→ manufacturing site.

Causes of Technology Transfer-

Shortage of production space: The product maker is responsible for the equipment used in small-scale production and for collaborating with contract manufacturing businesses in large-scale production.
Scarcity of outlets for bringing manufactured items to market: The Developer has the ability to do preliminary research such as animal examinations and toxicity studies, but not the ability to display the results.
Insufficient marketing and supply capacity: Although a manufacturer may possess advanced technologies and have gained regulatory licences and product registrations, it may lack marketing and supply passage.The technology process is divided into categories:

Research Phase-

The selection of the New Chemical Entity (NCE), its shape, and formulation is the first step in the manufacturing process. It should include discovery, scale-up of the preliminary development phase, and manufacture.

- Molecule Selection; Improve systems to upgrade.
- Formulation design and form selection
- Process improvement and development.
- Controlling the process.
- Technology transfer and scaling up
- Validate the process.
- Continuous process improvement and monitoring
- These figures show how regulatory bodies are exposed to less risk.

Development Phase-

F&D begin designing the product during this period. Raw Critical Quality is a novel material property. Chemical, Physical, Biological, and Environmental Attributes (CQA) This can be defined, measured, and quantified microbiologically. The final product outputs are constantly monitored. Critical Process must stay within acceptable quality standards. In pharmaceutical manufacture, parameters (CPP) are crucial. variables that influence the manufacturing process. CPPs are qualities that are monitored to detect deviations from standardised production operations and product output quality, as well as changes in CQA and critical equipment. Develop standard test procedures and requirements to validate analytical methods for raw materials, excipients, and packaging materials. Following completion of the developmental phase, a small scale from 0.5 to 2 kilogramme batch can be scaled up to 5-10kg and three validation batches must fulfil preset quality criteria before moving to a pilot scale of 20-100kg.

Technology transfer members	Responsibilites
Process Technologist	a. The focal point for all transfer activities. a. Gathers information from the donor site c. Assesses the feasibility of the transferred project, as well as its compatibility to site capabilities and resource requirements.
QA Representative	a. Examines documentation to ensure that it complies with marketing permission (MA). b. Discusses analytical methodologies with QC to assess capability

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	and training requirements for equipment. b. Starts the process of converting donor site documentation to local systems or formats. d. Starts or confirms regulatory requirements, such as a change in manufacturing licence, MA modifications if process adjustments are required, and so on.
Production Representative	a. Confirms capacity and competence of process instructions (with process technologist). b. Takes into account any safety considerations, such as solvents, poisonous compounds, and sanitising materials. b. Takes into account the effect on local standard operating procedures (SOPs). d. Considers supervisory or operator training requirements.
Engineering Representative	a. Examines equipment requirements with a production representative. b. Initiates necessary engineering changes, changes, or part purchases. c. Evaluates the impact of preventative maintenance and calibration, such as the use of more aggressive ingredients or a more temperature-sensitive procedure, and makes changes as needed.
QC Representative	a. Examines the analytical necessity b. Instrument availability. c. In charge of transferring analytical methods for drug substances.

Technology Transfer from R&D to Production:

It is upscaled to production of 200kg to higher than 1000kg after verification of three pilot scale validation batches. Before going into commercial production, R&D should transmit supporting data to the Quality Assurance department for assessment. The following are the supporting data:

Master Formula Record-It includes information such as the product name, MFR number, Mfg. licence number, batch size, shelf life, effective date, general dos and don'ts, CCP's equipment list, and predicted, theoretical, and percentage yield range, among other things.

Data on batch stability in the lab and on the pilot scale-Stability report of at least 6 months Real time study (30°C and 70% RH/30°C and 75% RH/30°C and 65% RH and 25°C and 60% RH), accelerated study (40°C 2°C/75 percent 5% RH), Photo stability, Freezer condition (2°C to 8°C).

Specification and STP's-Specifications for raw materials, bulk materials, and finished goods Product, packaging, and labelling specifications Standard Test Procedure must be followed.

Production Phase (Validation and Production):

R&D must develop a protocol for cleaning validation of manufacturing equipment and certify that the current cleaning procedure is appropriate. Equipment and processes should be tested against standard methodology before initiating production manufacturing facilities. Quality Assurance should jointly review the supporting documents with production, Quality control and other relevant departments for the adequacy of all documents prior to the technology transfer and Quality Assurance should share the observations with R&D. R&D's response to observation and amended documents will be reviewed by Quality Assurance. Process validation protocol, Batch manufacturing

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formula, and batch packaging record should be prepared in commercial production facilities accordance with the approved Master formula record by Quality Assurance.

Technology Transfer Documentation:

A technology transfer summary report, which should present an outline of the extent of transfer, should be prepared and described by documenting the data in every phase of transmission that can be regarded successful.

Potential deviation should be recorded and appropriate decisions made; sorting them before/during the procedure is recommended. From the beginning to the end of the procedure, data is recorded. These are the documents:

- Critical quality attributes
- Critical process parameters.
- Standard operating procedure (SOP).
- Stability data of Lab scale validation batches.(at least 6 months real time study)
- Lab Batch Manufacturing Record (BMR)
- Batch packaging record.
- Pilot Batch Manufacturing Record (BMR
- Drug Master File (DMF).
- Analysis of excipients
- Raw Material Certificate of analysis.
- Analytical method validation.
- Cleaning Validation report.
- Process validation report.
- Standard test procedure.
- Facilities & Equipment validation report
- Specifications.
- Change control form.
- Complaints
- Deviation reports.
- Technology Transfer summary report.
- Training Documentation
- Product Specification (Product Specification File:

The purpose of the product specification is to collect data that permits the product to be manufactured, as well as to specify the product's specification, production, and quality assessment techniques, and the transferring party is responsible for documenting the file. The new product development report can be included in the product specification file. At regular intervals, the product specification file should be checked, incorporating diverse information gained after the product's commencement of production, and reassessed as necessary. The following should be included in the product specification file:

- To begin the production of the product.
- The product's quality assurance
- To guarantee the operation's security.
- Environmental impact assessment.
- Price instructions
- Other details about the product.

Technology Transfer Plan:

To depict the components and contents of the technology to be transmitted, as well as a detailed plan for individual transfers and transfer programmes, and to manage the transfer's conclusion. Before executing the transfer, the transferor should establish the plan and reach an agreement with the transferred party on its contents.

Technology Transfer Report.:

Is to report the achievement of technology transfer once the process has been completed according to the technology plan and the data has been preserved according to the pre-agreed judgement criteria. The technology transfer report can be documented by both the transferor and the transferee; however, they must agree on its contents.

Check and Approval by Quality Assurance Department:

It is recommended that the quality assurance department commence a confirmation procedure for all forms of technology transfer documentation, and then examine and approve the documentation with production as part of the Batch Manufacturing Process.

Enforcement of Technology Transfer:

Documentation alone will not suffice to implement the technology transfer procedure. Both parties should work together to ensure technical education, training, and validations at sites where the transferred technology is actually employed, according to the proposal.

Confirmation of Technology Transfer Conclusions:

Before and during the technology transfer process, the transferring party should confirm that the appropriate mechanism for evaluating whether the manufactured goods meet the pre-agreed quality limits is in place and documented.

Examine Technology Transfer After Marketing:

During normal inspections, we may discover that some marketed items lack a progressive report; these products are reported as raw data, requiring fresh documentation as a reference file.

Execution:

Following the successful execution at the lab and pilot scale, the commercial scale was

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implemented with larger batch sizes, equipment, and processes.

#Case Study-Process Validation Issues with Blend Uniformity

Condition:

Blending is a well-known unit operation in the manufacturing process; problems did not arise during the risk assessment, and even though the drug load was not high, it caused a delay, so the blending process was revalidated to determine the root cause of the blend uniformity issues during material transfer.

Output:

By maximising the blending capacity and material drop heights from the blender to the receiver. By grasping the downstream impact on material separation. It was necessary to recognise potential issues during the technology transfer. Equipment and material management should be considered during the process or formulation risk assessment.

II. CONCLUSION:

Technology transfer in the pharmaceutical industry refers to the action of transferring data and technologies required to ensure the quality of medication design across the manufacturing process. The term "technology transfer" does not refer to one-time activities made by the transferring party toward the transferred party, but rather to the ongoing interchange of information between the two parties in order to maintain product manufacture.

Technology transfer is a complicated topic that requires a comprehensive approach.

Conflict Of Interest: None.

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