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A COMPREHENSIVE REVIEW ON TECHNOLOGY TRANSFER

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➢ ABSTRACT:

The purpose of this review article is to discuss in detail technology transfer in the pharmaceutical industry, legal issues in the pharmaceutical industry. Technology transfer requires a documented, designed progress using skilled and knowledgeable personnel working inside a quality system, with documentation of data casing all aspects of development, production, and quality control. This article 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.

➢ *KEYWORDS:*

Technology Transfer, Documentation, Team Members, Facets, Manufacturing.

➢ INTRODUCTION:

A proper technology transfer (TT) is both essential and important to drug discovery and development for new medicinal products. Which is also required to upgrade drug quality planned during research development and to finalize the product during manufacturing as well as to guarantee that stable quality is transferred.

According to WHO, transfer of technology is defined as “A logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites". It is a systematic procedure that is followed to pass the documented knowledge and experience gained during the development and or commercialization to an appropriate, responsible, and authorized party. Technology transfer involves both the transfer of documentation and the demonstrated ability of the receiving unit (RU) to effectively perform the critical elements of the transferred technology, to the satisfaction of all parties and any applicable regulatory bodies. Technology transfer (TT) is defined as “the transfer of the manufacturing process for a new pharmaceutical Drug Substance (DS) and Drug Product (DP), respectively, from the transferring site (in this case R&D) to the receiving site or designated commercial manufacturing site. This includes all the associated knowledge, information, and skills to be able to manufacture the DS and DP at the receiving site. The development and transfer of knowledge and technology have been and will continue to be critical to success in the pharmaceutical industry. The transfer of technology is considered both fundamental and significant to the

drug discovery and development process for any new medicinal entity. This process is important to elucidate necessary information for technology transfer from R & D (Research &Development) to PDL (product development laboratory). [1]

In today's business setting, interest in the profitable firm's technological assets, through technology transfer, has been clarified. Factors that promote international technology transfer include the globalization of business, liberalization of the economic sections of many countries, and the momentum given to the protection of intellectual property after the formation of the World Trade Organization (WTO). These factors have collectively resulted in a commercial transfer of technology becoming an important element of the international business setting. The importance of technology and management is increasingly being recognized as an important strategic consideration by organizations. The technology used by organizations should enable them to be competitive in the global market. Hence organizations should manage technology and the aspects surrounding technology properly. One of the important aspects to be considered in the management of technology is the transfer of the most appropriate technology to the organization. This necessitates the transfer of the technology from a development environment to a user environment. Knowledge of the technologies used by an organization, the technologies available to organizations as well as the technologies used by their competitors, may assist decision-makers in selecting the most appropriate technology. Technology resides in three key areas, namely those of skill, equipment, and knowledge. [2]

However, the importance of technology transfer from a development perspective is nothing new. More than three decades back, Mansfield (1975) pointed out that, "One of the fundamental processes that influence the economic performance of nations and firms is technology transfer.

Technology transfer is transferring of details concerning the 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. In Pharmaceutical Industry, "Technology Transfer" refers to a method of various steps forward from drug discovery to product development, clinical trials, and at last to full-scale commercialization. A 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. According to WHO TT is a logical procedure that controls the transfer of any method alongside its documentation and professional expertise between development and manufacture or between manufacturer sites. It is useful to build up dosage form in various ways because it provides efficiency in development, maintains the quality of product, helps to realize a standardized process that facilitates price-effective production.

IMPORTANCE OF TECHNOLOGY TRANSFER IN THE PHARMACEUTICAL INDUSTRY:

- To elucidate necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D.
- To elucidate necessary information to transfer technology of existing products between various manufacturing places.
- To exemplify specific procedures and points of concern for the two types of technology transfer in the above to contribute to smooth technology transfer. This applies to the technology transfer through R&D and production of drug substances or drug products and the technology transfer related to post-marketing changes in manufacturing places. [3,4]

➢ CLASSIFICATION OF TECHNOLOGY TRANSFER:

Technology transfer is classified into two types by Mansfield they are:

- Vertical transfer begins with preliminary research ending with clinical research to the manufacturing of new drug products.
- Horizontal transfer means the development and the application of technology utilized in one area, context, or institution to a different area, context, or institution. [5]

According to Sounder's (1990) classification, vertical technology transfer is the progress of moving technology from one phase to another phase. vertical technology transfer is otherwise called internal technology transfer. Horizontal technology transfer is possible to transfer technology at any stage of the lifecycle. Horizontal technology transfer is otherwise called external technology transfer. Steenhuis (2002) categorized technology transfer into Material transfer, Capacity transfer, and Design transfer. [6]

- The transfer of new material or products is denoted as a material transfer.
- Various types of instructions or guidelines are transferred to meet the numerous requirements of the product is called a Capacity transfer.
- For improving the manufacturing of the product various designs and blueprints are transferred this is denoted as design transfer. [7]

➢ METHODS OF 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 the case of an out-licensing - out strategy, the company right is given to another party. [8]

➢ GOALS OF TT:

According to ICH Q10 guidelines,

1) To transfer product and process knowledge between and within manufacturing sites to achieve product realization. This knowledge forms the basis for the manufacturing process, control strategy process, validation approach, and ongoing continual improvement.
2) TT is a valuable step in the developmental life cycle leading to successful commercial manufacturing. To take all the gathered knowledge and use it as the basis for the manufacturing control strategy, the approach to process qualification, and ongoing continuous improvement.
3) The transition of the product/process/analytical method knowledge between development and manufacturing sites.
4) To ensure variability of process and parameters are controlled and sufficient in the face of the rigors of a commercial production environment.

5) To verify parameters established during development are still within the determined design space and adjusted at scale-up. [9]

➢ OBJECTIVES:

- 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 to smooth technology transfer. [10]

➢ IMPORTANCE OF TECHNOLOGY TRANSFER:

Technology transfer has importance in extended benefits of R&D to the society.

1) In the pharmaceutical industry, designing of dosage form needs to scale up at several stages, such as pilot-scale from 0.5 - 2 kg batch can be scaled up to 5/10 kg than to 20/100 kg. Production scale typically ranges from 200 kg to 1000 kg. It involves the manufacturing of drug products with increasing their batch sizes with the help of larger equipment.
2) Scale-up involves the transfer of technology and the transfer of knowledge that has been accumulated during the small-scale development of products and processes. Usually, research has been carried out on a small scale before it is produced for a large-scale commercial batch. Technology transfer is important for research activities to materialize on a large scale for commercialization especially in the case of developing a drug product. [11]
3) To elucidate necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D; To elucidate necessary information to transfer technology of existing products between various manufacturing places.
4) Commercialization of university-discovered technologies is a driver of economic growth and universities have played a major role in bringing innovative ideas and inventions to market. Technology transfer can potentially generate revenues for universities, create research connections between academics and industry, and enhance regional economic growth and development. So the development and transfer of knowledge and technology has been and will continue to be critical to success in all types of industries. [12] In recent years, there is a growing awareness that an appropriate transfer of manufacturing technologies (technology transfer) is important to upgrade drug quality as designed during R&D to be a final product during manufacture as well as assure stable quality transferred for many reasons between the contract giver and contract acceptor during manufacture. [13]

➢ HOW TECHNOLOGY TRANSFER IS HELPFUL? :

Academics and research institutes engaged in technology transfer for a variety of reasons such as,

1. 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.
2. 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.
3. 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.
4. Exploitation in a different field of application: Each partner may have only half of the solution i.e. the developer of the technology might be capable of exploiting the technology itself in the field of diagnostic applications and may grant exploitation right to commercial partner for the exploitation of therapeutics application.
5. Forming alliances with partners: That can progress the development of the technology to take it to market.
6. Forming alliances with partners with manufacturing capability.
7. Local economic development.
8. The attraction of corporate research support. [14,15]

➢ FACETS / ASPECT OF TECHNOLOGY TRANSFER:

a. Government labs to private sectors: This type of Technology Transfer is advantageous as the government labs can get good financial support and funds from the government for their research work and the technology developed by them reaches the private sector.
b. Between Private sectors 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 other sectors that absorb the technology.
c. From Academics to private sectors: Academic sectors that are actively involved in research develop the technology and make it available to private firms. By the collaboration of private firms with the institutions, money can be saved.
d. 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. [16]

➢ WHEN DOES TECHNOLOGY TRANSFER OCCUR?

1. The idea to Discovery Lab
2. Discovery Lab to Development Lab
3. Development Lab to Kilo Lab
4. Kilo Lab to Pilot Plant
5. Pilot Plant to Semi-works (another pilot plant)
6. Pilot Plant/ Semi-works to Manufacturing
7. Manufacturing to Exhibit.

➢ FACTORS INFLUENCING TECHNOLOGY TRANSFER IN THE PHARMACEUTICAL INDUSTRY:

1. Investment in R&D.
2. Establishing the link between production and research.
3. Data development within the field of technology transfer methods.
4. Organizational and Informational infrastructures.
5. Awareness of basic and necessary factors need for technology transfer.
6. Consideration of existing and old technologies.
7. Good business and manufacturing practices: The company's success is primarily the result of its adoption of good business and manufacturing practices, particularly in the area of product identification and formulation technology.
8. Potential for competitive pricing: Balance cost to remain competitive by having higher private sector prices and very low public sector prices.
9. Strategic planning: Create an enabling environment for vertical integration, with the prospect for higher capacity utilization and eventual lowering of production cost.
10. Strong economy and environment: For Technology transfer to be successful their needs to be a supportive business and scientific environment in the recipient country, and that environment should include skilled workers, Economic and political stability, supportive regulatory environment, market size, and potential.
11. Transparent rent and efficient regulations: Pharmaceuticals is necessarily a highly regulated industry, the regulatory function must be efficient and transparent for technology transfer to be economically viable.
12. Opportunities for contingency supply: Multinational pharmaceutical companies are inclined to transfer technology to local manufactures with the potential to receive when they foresee an inability to meet time scale and volume demand from large procurers.
13. Access to new machinery, training, know-how, and business partnership: These makes the prospect of technology transfer very desirable to local pharmaceutical manufactures since the technology, equipment, etc. [17]

➢ ORGANIZATION OF TECHNOLOGY TRANSFER:

Since a team concept is always the best approach to accomplishing a successful technology transfer project. The core technology transfer team should be commissioned immediately following the decision of executive management to pursue the drug candidate to commercialization. Typical technology transfer core team will likely be comprised f individuals representative of different segments of the business.

1. Project Manager- For overall responsibility, coordination, and progress communication to management. His or her role may be enhanced as necessary by additional staff & responsibility & authority delegated as appropriate.
2. Regulatory Affairs- For coordination of the appropriate regulatory filings, advice on approval timing, the content of the filing documentation & response to regulatory inquiries.
3. Engineering- To coordinate associated capital projects & direct & control construction, equipment acquisition, installation & qualification.
4. Material management- To include those units responsible for pure chasing, Strategic planning, resource allocation & supply chain activities. This member (or members) will analyze & recommend the most favorable manufacturing strategy in consideration of internal capability, business partnership & tax advantages for the corporation.
5. Manufacturing operations- To represent the originating site and receiving location production activities. These representatives should have sufficient authority to commit the necessary personal & plant resource to accomplish the project within the defined cost & time limitations.
6. Research and Development- To support the technical issues and resolve problems. This group provides the process expertise and would be expected to train and direct the production trials at receiving site. [18]

➢ STEPS INVOLVED IN THE TECHNOLOGY TRANSFER PROCESS:

During the development of a formulation, it is important to understand the procedure of operations used, critical and non-critical parameters of each operation, production environment, equipment, and excipient availability should be taken into account during the early phases of development of formulation.

(A) Development of technology by R&D. (Research Phase) -

(a) Design of procedure and selection of excipients by R&D – Selection of materials and design of procedures is developed by R&D based on innovator product characteristics.

(b) Identification of specifications and quality by R&D – Quality of product should meet the specifications of an innovator product.

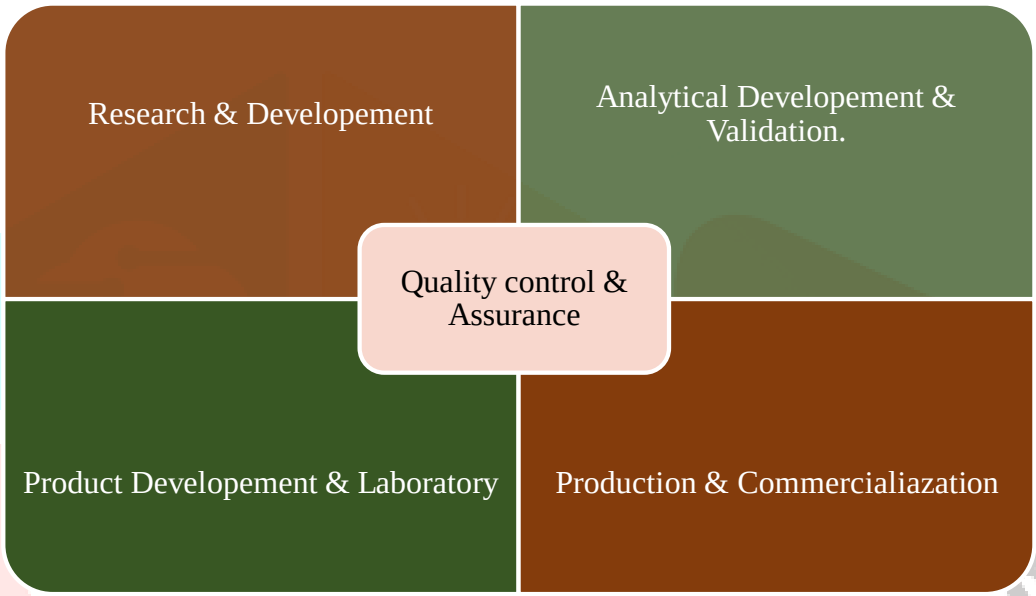


FIG.1: STEPS INVOLVED IN TECHNOLOGY TRANSFER.

(B) Technology transfer from R&D to production (Development Phase) -

R&D provides technology transfer dossier (TTD) document to product development laboratory, which contains all information of formulation and drug product as follows –

(a) Master Formula Card (MFC) – Includes product name along with its strength, generic name, MFC number, page number, effective date, shelf life, and market.

(b) Master Packing Card – Gives information about packaging type, the material used for packaging, stability profile, and shelf life of packaging.

(c) Master Formula – Describes formulation order and manufacturing instructions. (Process order and environment conditions.)

(d) Specifications and Standard Test Procedures (STP) – Helps to know active ingredients and excipients profile, in-process parameters, product release specifications, and finished product details.

(C) Optimization and Production. (Production Phase) -

(a) Validation Studies – Production is implemented after validation studies that can verify that process can stabilize the product based on transferred manufacturing formula. The manufacturing department accepting technology is responsible for validation and the R&D department transferring technology should take responsibility for validation such as performance qualification, cleaning, and process validation.

(b) Scale-up for production – Involves the transfer of technology during small-scale development of the product and processes. It is essential to consider the production environment and system during the development of a process. Operators should concentrate on keeping their segment of the production process running smoothly.

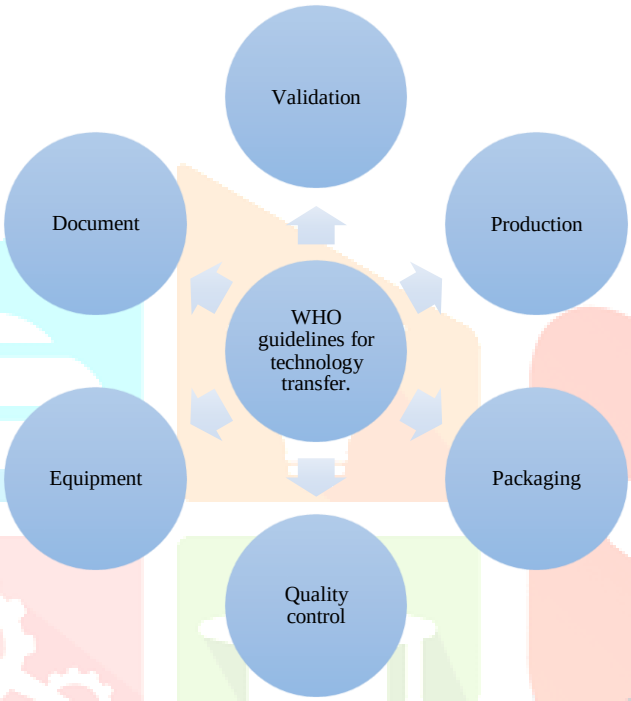


FIG.2: WHO GUIDELINES FOR TECHNOLOGY TRANSFER.

(D) Technology Transfer Documentation –

Generally interpreted as document indicating contents of technology transfer for transferring and transferred parties. Each step from R&D to production should be documented, task assignments and responsibilities should be clarified, and acceptance criteria for completion of technology transfer concerning individual technology to be transferred. The Quality Assurance department has to check and approve the documentation for all processes of technology transfer.

(a) Development Report – The R&D report is a file of technical development, and the R&D department is in charge of its documentation. This report is an important file to indicate the rationale for the quality design of drug substances and its specifications and test methods. The development report is not a prerequisite for the application for approval; it can be used at the pre-approval and inspection as a valid document for the quality design of the new drug. The development report contains –

(1) Data of pharmaceutical development of new drug substances and drug products at stages from the early development phase to final application of approval.

(2) Information of raw materials and components.

(3) Design of manufacturing methods.

(4) Change in histories of important processes and control parameters.

(5) Specifications and test methods of drug substances.

(6) Validity of specification range of important tests such as contents impurities and dissolution.

(7) Verifications of results.

(b) Technology Transfer Plan – The technology transfer plan is to describe items and contents of technology to be transferred and detailed procedures of individual transfer and transfer schedule, establish judgment criteria for the completion of the transfer. The transferring party should prepare the plan before the implementation of the transfer and reach an agreement on its contents with the transferred party.

(c) Report – Completion of technology transfer is to be made once data are taken according to the technology plan and are evaluated to confirm that the predetermined judgment criteria are met. Both transferring and transferred parties should document the technology transfer report.

(E) Exhibit –

After taking scale-up batches of the product, manufacturing of exhibit batches takes place. In the case of an exhibit, batch sizes are increased along with equipment and their processes. This is done for filling purposes in regulatory agencies. [19]

➢ TECHNOLOGY TRANSFER FLOW CHART:

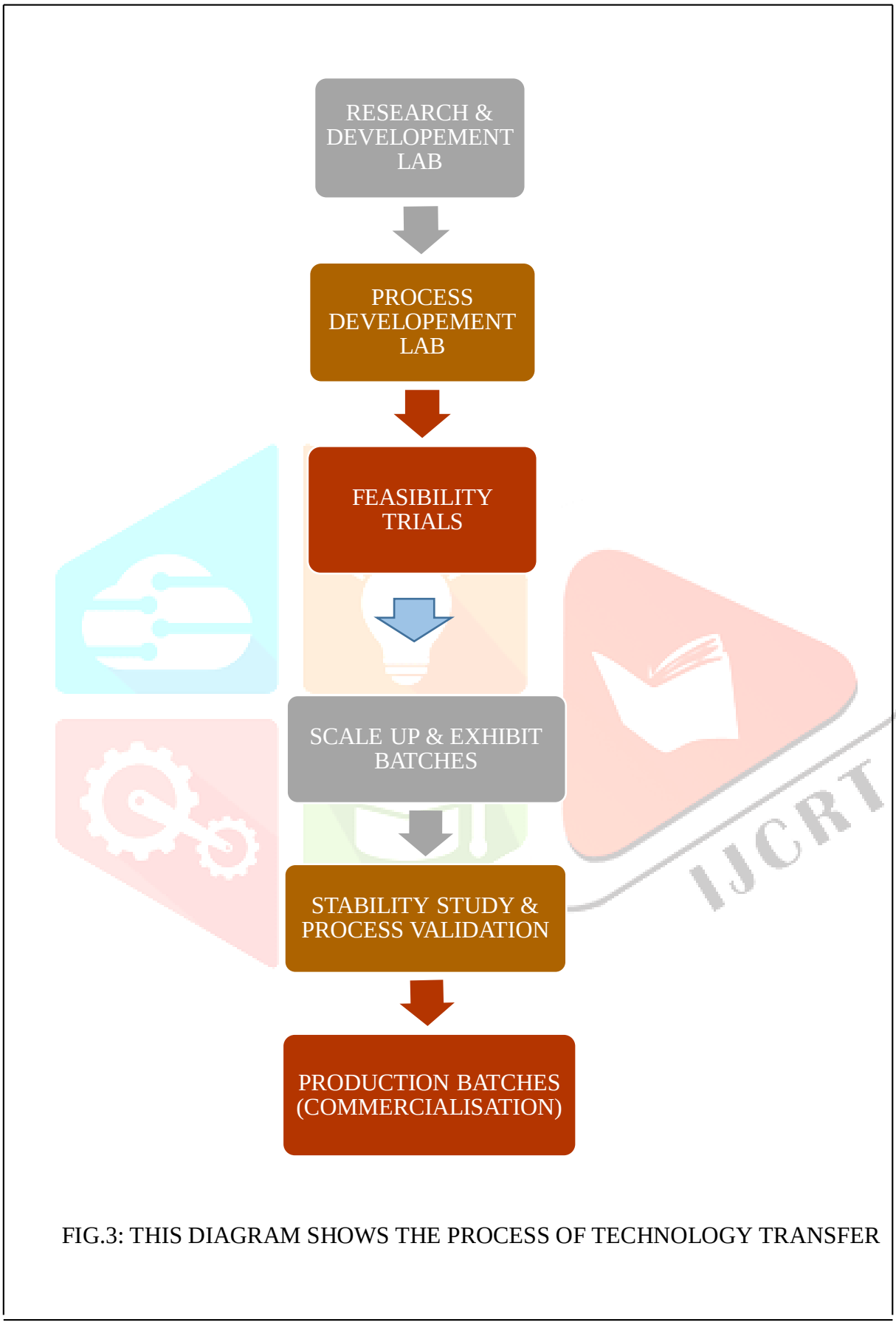
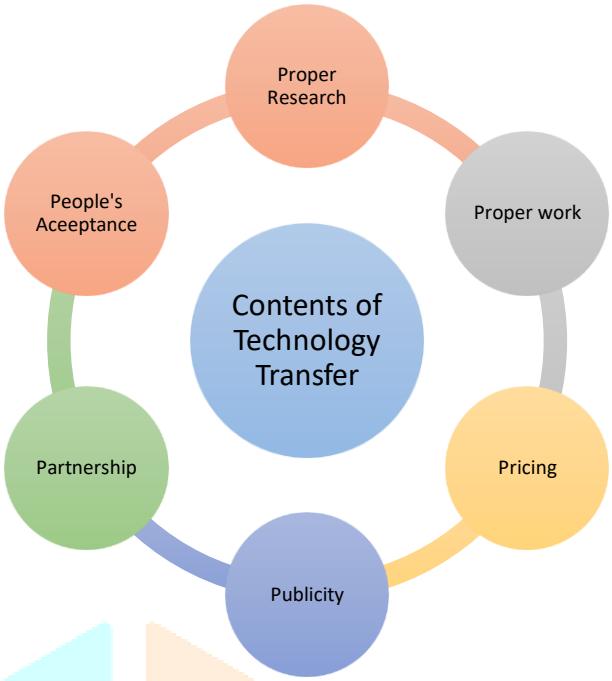


FIG.3: THIS DIAGRAM SHOWS THE PROCESS OF TECHNOLOGY TRANSFER

➢ CONTENTS OF TECHNOLOGY TRANSFER:



1. Proper Research – By proper research we mean firstly that in which the result is reproducible and issues such as scale-up, stability, etc, and other practices now have been addressed, also that in which problems were taken up in first place.
2. Proper work- This refers to institutional and guidelines regarding IP Protection licensing modalities etc. which must be in place beforehand. In the absence of these, the decision gets delayed, lack of fairness in decision e.g. case of X institute, which came up with good technology but since no guidance was there, kept running around for two years and then gave up.
3. Pricing – most difficult and critical area of Transfer of technology. - Too high a price can put off buyers, leaving the technology unsold. - Too price a result in revenue loss. - There are two models regarding pricing Price charged for technology should depend upon market force i.e. impact of the technology irrespective of the amount spent on developing it. The price charged should include all expenses involved in developing it.
4. Publicity – It is important to identify and then approach the buyer i.e. adopt targeted Publicity and not blanket publicity. Specific journal, website, letters to the manufacturer, personal selective visit, etc. are some common approach which helps in locating a buyer.
5. Partnership – this means working along with the industry. Industry takes it up, manufacturer and makes it available to society. Partnerships are important to ensure your technology is successfully adopted simply conveying the details may not be sufficient.
6. People's Acceptance – It is no use trying to develop a technology which people will not accept e.g. due to religious reasons/social concern etc. genetically modified food, irradiated vegetables processed beef in India, the improved capsule made of non-vegetarian material. [19]

➢ BARRIERS OF TT:

a. Lack of market share: Local producers face significant challenges in meeting international quality standards and capturing a critical market share. Greater market share would increase profitability.
b. Cost of pre-qualification: There is a benefit in meeting international standards since it opens up the opportunity for trading across the entire world.
c. Labor issues: The pharmaceutical sector demands relatively skilled labor. High labor turns over and absenteeism owing to unattractive conditions of service is a negative contributor.
d. Unsuccessful or incomplete Process Validation.
e. High rates of batch rejections, excessive labor requirements, increased cost of a product, etc.
f. Incomplete Documentation.
g. The product does not show specifications as intended.
h. Delayed regulatory approval and/or product launch. [20]

➢ TECHNOLOGY TRANSFER TEAM MEMBERS AND THEIR RESPONSIBILITIES: [21]

Technology transfer team members	**RESPONSIBILITIES**
Process Technologist	1. Central focus for transfer activities. 2. Collates documentation from the donor site 3. Performs initial assessment of the transferred project for Feasibleness, Compatibility with site capabilities, and Establishes resource needs.
QA Representative	4. Reviews documentation to work out compliance with marketing authorization (MA) 5. Reviews analytical strategies with QC to work out capability, instrumentation training requirements. 6. Initiates conversion of donor site documentation into local systems or format. 7. Initiates or confirms regulatory needs, *e.g.*, an amendment to manufacturing license; variations to MA if method changes needed, etc.
Production Representative	8. Reviews process instructions (with process technologist) to verify capacity and capability. 9. Considers any safety implications, *e.g.*, solvents; toxic; sanitizing materials. 10. Considers the impact on local standard operating procedures (SOPs). 11. Considers the training requirements of supervisors or operators.
Engineering Representative	12. Reviews (with production representative) instrumentation requirement. 13. Initiates required engineering modifications, change, or part purchase. 14. Reviews preventative maintenance and calibration impact, *e.g.*, use of a lot of aggressive ingredients; more temperature-sensitive method, and modifies consequently.
QC Representative	15. Reviews analytical requirements. 16. Availability with instruments. 17. Responsible for analytical technique transfer for drug substance and drug product.

➢ FUNCTIONS OF TECHNOLOGY TRANSFER:

1. CO-ORDINATE- Coordinating between technology users and developers, between researchers and manufacturers is an important element of technology transfer.
2. LINK- Catalogue resources related to business enterprises & connecting would be entrepreneurship/researcher and other technology developers to outside group & organization which can help in the process of starting a new product, companies, etc. such linkage provide referrals for individual business counseling, sources of financing.
3. NURTURE- The main ingredient for moving technology from a research laboratory to business enterprises successfully in an environment that is supportive of entrepreneurship. [19]

➢ FEW CASES OF TECHNOLOGY TRANSFER:

The process of Technology Transfer is actively being pursued in India through Government laboratories, Academics Institutions, and Commercial entities.

1. The Bhabha Atomic Research Centre (BARC) has developed and transferred around 90 technologies in the areas such as environment and health; electronics; electrical and mechanical; chemical and metallurgy; radioisotope, and applications.
2. The National Chemical Laboratory (NCL) Pune, has several linkages with universities and pharmaceutical industries to ensure successful scale-up and implementation of technology.
3. Department of Biotech (DBT) has successfully transferred some techniques of forest trees through tissue culture.
4. Eli Lily has entered into a technology transfer agreement with Shasun Chemicals and Drugs for the manufacturing of anti T.B drug CYCLOSERINE produced by Shasun to meet Eli Lily's global demand. [22]

➢ IMPLEMENTATION OF TECHNOLOGY TRANSFER:

1. Avoids the technology transfer only by handing over the technology transfer documentation.
2. Both parties should cooperate in implementing technology education training and validation at facilities where the transferred technology is used. [23]

➢ CONCLUSION:

Appropriate technology transfer is important to upgrade the quality of manufacturing products and ensure stable and high quality of the product. 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 parties to maintain the product manufacturing.

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